CROSSTREE

Clinical Trial PATIENT ACCESS ORGANIZATIONS

An Emerging Ecosystem

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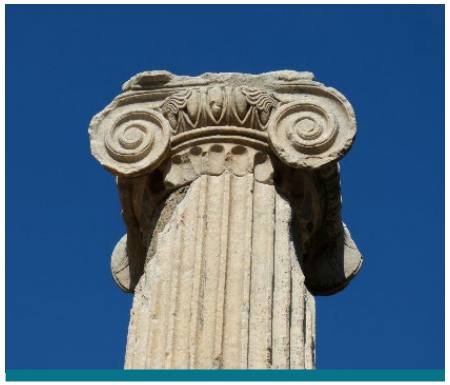
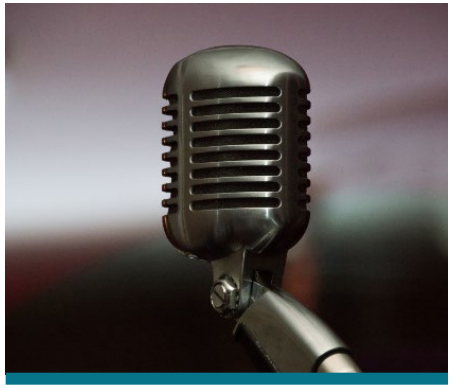




* Based on the number of announced global transactions

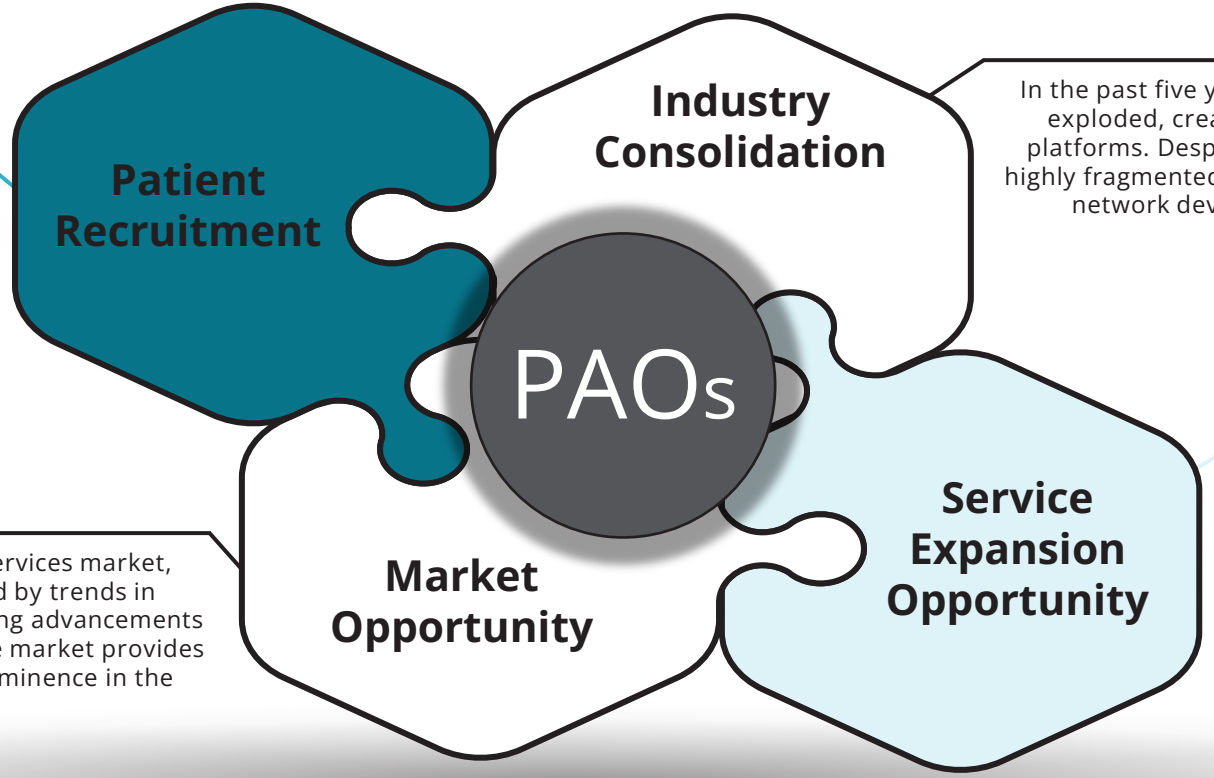
OVERVIEW: CORNERSTONE OF THE TRIAL EXECUTION JOURNEY

Executive Summary

CROSSTREE

Independent clinical research sites are an increasingly critical component of clinical research, as traditional research sites undergo a groundbreaking transformation into Patient Access Organizations (PAOs) with expanded networks of principal investigators, innovative solutions to patient recruitment and extensive histories of clinical trial execution. PAOs have evolved into more formidable outsourced clinical service providers and have significantly scaled their operations by securing substantial financial backing to unlock a wave of expansion possibilities, both geographically and functionally. PAOs standardize SOPs for efficient start-up and trial execution, seamlessly integrate pharma technology from site feasibility to billing and patient payments and generally bring a more patient—centric approach to trial recruitment and business development by leveraging greater access to patient data and community-based care relationships. As the PAO evolution gathers momentum, compelling questions emerge: Will partnerships among complementary platforms emerge? Will CROs resort to M&A to manage this evolving market? Or will PAOs establish a new, sustainable niche, challenging their CRO counterparts for leadership in the outsourced pharma services market? Regardless of the outcome, the unfolding dynamics promise to disrupt the current clinical trial service industry landscape for years to come.

PAOs distinguish themselves through a patient-centric approach, strategically enhancing patient recruitment, improving enrollment rates and establishing a foundation for more effective and inclusive clinical trials.



In the past five years, clinical research site consolidation has exploded, creating new opportunities for emerging PAO platforms. Despite rapid consolidation, the market remains highly fragmented, offering significant potential for further site network development and subsequent PAO growth.

PAOs address a major pain point in the pharma services market, patient recruitment, which has been exacerbated by trends in precision medicine, rising trial complexity and ongoing advancements in drug development and regulations. This expansive market provides PAOs with a runway for sustained growth and prominence in the clinical research landscape.

Beyond their core functions, PAOs stand to expand their revenue by acquiring adjacent clinical trial services from site feasibility to payment processing. Emerging solutions across the trial execution journey act as a ladder, positioning PAOs to evolve into holistic services providers in much the same way their CRO cousins evolved over the last 20+ years.

Evolution of Patient Access Organizations (PAOs)

Prior to 1990

EMERGENCE OF SITES

- Pharmaceutical sponsors have historically conducted clinical research primarily through academic medical centers (AMCs) and other large hospital systems[1]
- Between the 1980s and 1990s, the cost of clinical trials increased by a multiple of 5x in comparison to pre-clinical costs; by 2003, drug development costs increased to an estimated $802 million on average to bring a drug to market, causing sponsors to evaluate strategies to lower costs[2]

1990-2019

SHIFT TOWARDS INDEPENDENT SITES

- Independent commercial research sites initially emerged as physician-owned, standalone clinics or sites embedded in physician practices
- These private sites appealed to sponsors due to their efficiency of onboarding trials, direct collaboration with the institutional review boards (IRBs) and effective recruitment of a wider cohort of participants – all of which lower trial costs[1]
- A highly fragmented market emerged, making it difficult for sponsors and CROs to manage large-scale clinical trials across multiple, independent investigator-owned sites

2020-2023

SITES AS PLATFORMS

- The COVID-19 pandemic highlighted the fragmentation and recession-resilience of the clinical research site sector[3]
- Private equity has taken interest in clinical research sites and SMOs, recognizing the opportunity for significant growth and consolidation[3]
- Financial backing affords independent sites the means to create operational efficiencies for a new level of operational sophistication
- A recent survey found that SMOs are increasingly popular among sponsors and CROs, with the number of respondents expecting to use SMOs in larger phase two and three studies doubling from 2021 to 2023[4]

2024+

EVOLUTION INTO PAOS

- As independent sites evolve into larger PAOs with centralized operations and resources, they are naturally taking more active roles in patient recruitment, data capture and trial management
- New operating models continue to arise as clinical research technology develops and market adoption of decentralized clinical trials and integrated research increases
- Already the liaison between sponsors and patients, PAOs will continue to evolve into larger, more integrated organizations, further entrenching these relationships

PATIENT ACCESS SOLUTIONS

- **Pre-screening Processes**
- **Proprietary Patient Databases**
- **Standardized SOPs Across Multiple Sites / Locations**
- **Local Community Outreach**
- **Single Point of Contracting for Multiple Sites / PIs**
- **Expanding Site Networks**
- **DCT & Hybrid Trial Capabilities**
- **Clinical Research as a Care Option (CRAAC)**

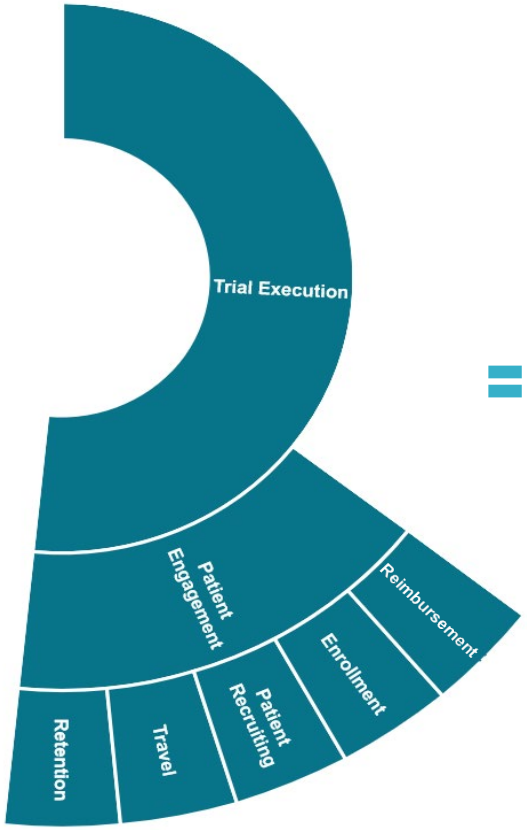
[1]ClinicalResearch.io; [2]Collier (2009); [3]Middle Market Growth; [4]LEK Consulting

Expansion Opportunities For PAOs

Current Core Capability
Expansionary Capability
Peripheral Clinical Studies Capabilities

Current State PAO

Capability Expansion



PAO 2.0

Patient Access Funnel

PATIENTS

Healthcare Providers

Primary Care Provider | Specialist | Academic Medical Center
Clinical Care Provider | Hospital | Integrated Health System

Healthcare providers have traditionally acted as gatekeepers to access patients to volunteer for clinical trials. Patients are sourced from a variety of provider channels.

Patient Access Organization

Site Management Organization | Virtual Sites | Integrated Research Organization | Dedicated Research Sites | Mobile Sites

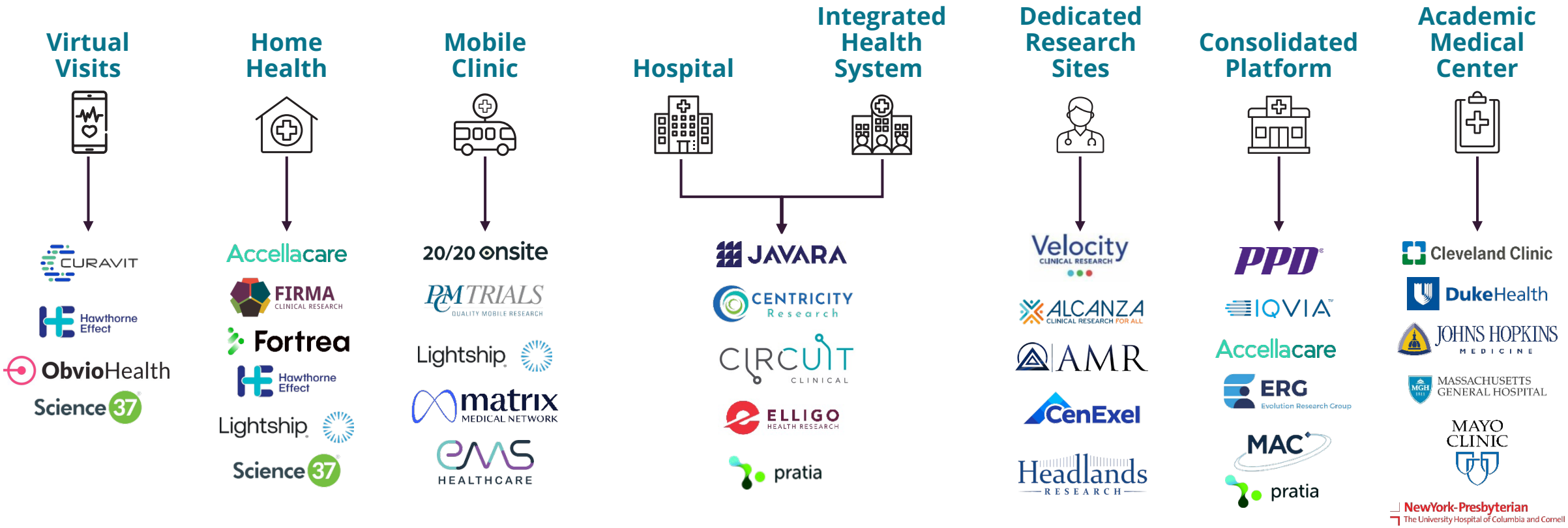
Once a cottage industry of fragmented clinical trial "sites" and loosely organized "Site Management Organizations" (SMOs), Patient Access Organizations have emerged as sophisticated, well-financed companies that have begun to consolidate and professionalize the commercial research site market. At the same time, channels for accessing patients have become significantly more diversified.

Patient Recruiting & Engagement

Patient recruiting remains the most significant, unresolved pain point in clinical trials, upon which millions of reports and market studies are written. As the industry advances towards precision medicine, rare diseases and specialty drug trials (see The Prism Doctrine), per-patient trial costs are rising, enrolling patients becomes increasingly complex and more competitive and retention of those patients has become also become a prominent issue.

The emergence of large, sophisticated PAOs will influence clinical trial budgets and pressure certain centralized services such as patient recruiting and certain clinical trial execution technologies.

PAO Channel Strategies



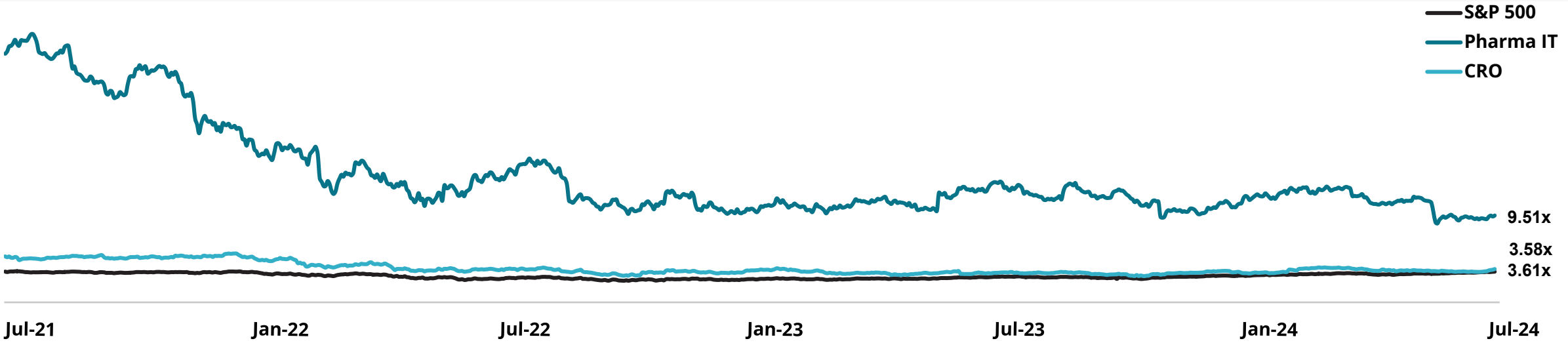
Channel Overview

Patient access organizations can be divided into verticals based on the channels used to connect with patients. Decentralized clinical trial (DCT) firms utilize virtual visits to connect with patients and provide strong geographic and demographic flexibility. Home health firms allow access to mobility-limited patient populations and provide convenience for patients. Mobile clinics offer transportable access points to clinical trials which can greatly increase geographic flexibility and patient diversity. Clinical care provider sites connect with patients at the site of care and can offer a strong pipeline of subjects within a therapeutic area through clinical trials as a care option (CRAACO). Consolidated platforms combine site networks within a larger research organization to efficiently connect and engage with patients. Academic medical centers can offer robust resources and access to particularly uncommon patient groups. IROs offer CRAACO through integration with health systems and hospitals. Delivery models are often mixed within PAO organizations, leading a complex continuum of delivery options.

TRANSACTIONS: A BULL IN A BEAR MARKET

Historical Market Valuation Trends

Average Historical TEV / LTM Revenue



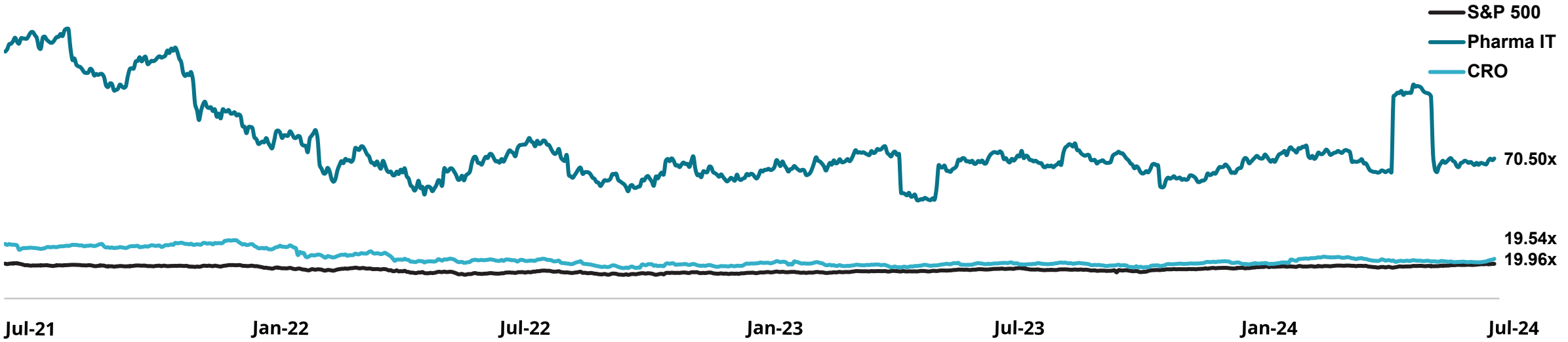
	Pharma IT Index				*CRO Index*			
	SimulationsPlus	Veeva	Schrödinger	Model N	MEDPACE	IQVIA	ICON	Fortrea
TEV / Rev High *(Date)*	**36.7x** *(Feb 2021)*	**34.1x** *(Aug 2021)*	**27.8x** *(Apr 2021)*	**8.8x** *(Apr 2021)*	**7.2x** *(Oct 2021)*	**4.8x** *(Dec 2021)*	**6.9x** *(Dec 2021)*	**1.7x** *(Mar 2023)*
TEV / Rev Low *(Date)*	**9.7x** *(Nov 2023)*	**10.5x** *(Oct 2022)*	**9.3x** *(Oct 2023)*	**3.5x** *(Nov 2023)*	**3.6x** *(Jun 2022)*	**2.6x** *(Oct 2023)*	**2.4x** *(Apr 2023)*	**0.8x** *(Aug 2023)*

Source: Capital IQ (as of July 2024)

Note: Due to the limited number of public comps strictly focused on clinical research, Crosstree analyzes the Pharma IT Index and CRO Index as a proxy

Historical Market Valuation Trends

Average Historical TEV / LTM EBITDA

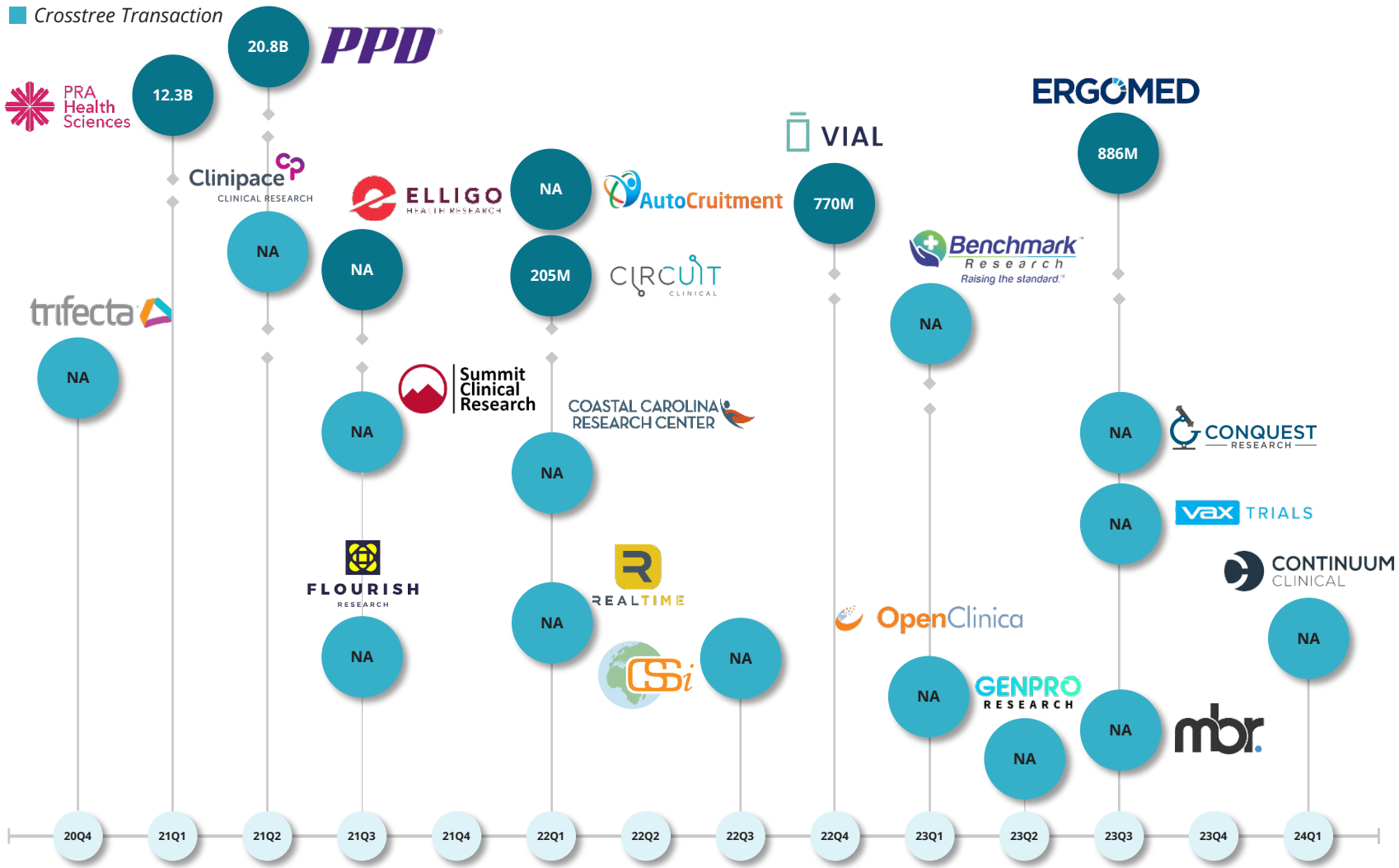


	Pharma IT Index				*CRO Index*			
	SimulationsPlus	Veeva	Schrödinger	Model N	MEDPACE	IQVIA	ICON	Fortrea
TEV / EBITDA High *(Date)*	**78.1x** *(Apr 2021)*	**108.8x** *(Aug 2021)*	**122.6x** *(Jul 2023)*	**300.0x** *(Jul 2021)*	**31.7x** *(Oct 2021)*	**26.9x** *(Jul 2021)*	**11.9x** *(Jun 2021)*	**24.5x** *(Apr 2024)*
TEV / EBITDA Low *(Date)*	**34.4x** *(Dec 2022)*	**39.0x** *(Oct 2022)*	**50.3x** *(May 2023)*	**90.0x** *(Nov 2023)*	**16.1x** *(Jun 2022)*	**15.3x** *(Oct 2022)*	**1.5x** *(Apr 2023)*	**6.8x** *(Aug 2023)*

Source: Capital IQ (as of July 2024)

Note: Due to the limited number of public comps strictly focused on clinical research, Crosstree analyzes the Pharma IT Index and CRO Index as a proxy

PAO Financings & Recapitalizations



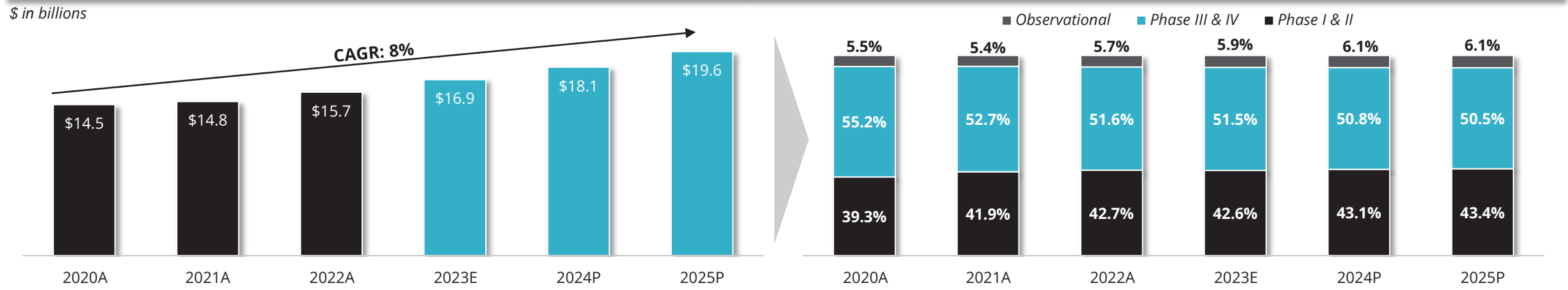
Acquirer	Target	TEV	Date
Spectrum Science	Continuum Clinical	NA	Feb-24
Emmes	VaxTrials	NA	Sep-23
Permira	Ergomed	$886	Sep-23
Reynolda Equity Partners	Conquest Research	NA	Sep-23
New Harbor Capital	Monroe Biomedical Research	NA	Aug-23
Catalyst Clinical Research	Genpro Research	NA	Jul-23
IQVIA	Benchmark Research	NA	Apr-23
Thompson Street	OpenClinica	NA	Jan-23
ACRS	CSSi	NA	Oct-22
Alcanza Clinical Research (Martis)	Coastal Carolina Research Center	NA	Mar-22
LLR Partners.	RealTime Software Solutions	NA	Jan-22
QHP Capital	AutoCruitment	NA	Jan-22
LongueVue Capital	Summit Clinical Research	NA	Sep-22
Flourish Research (NMS Capital)	Clinical Trials of Texas	NA	Jul-21
Thermo Scientific	PPD	$20,881	Apr-21
ICON	PRA Health Sciences	$12,277	Feb-21
WCG	Trifecta Clinical	NA	Dec-20

[1] S&P Capital IQ * Pitchbooks (as of July 2024), Crosstree Capital Partners
*Implied TEV from growth capital, Pitchbook (as of July 2024)
Note: Line break indicates a break in scale

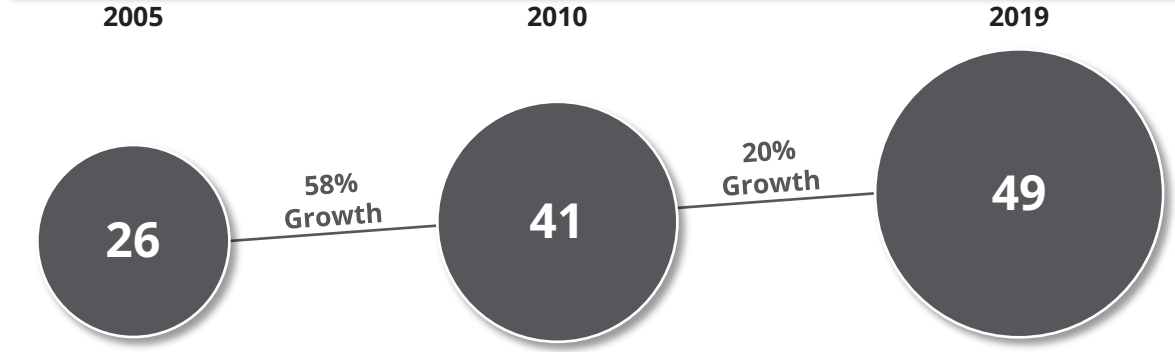
Clinical Research Site Market Trends

The site segment is highly fragmented, particularly relative to other pharmaceutical services sectors such as CROs. This fragmentation, combined with increasing pressure from the CROs to professionalize trial execution and predictably deliver trial subjects, is driving consolidation

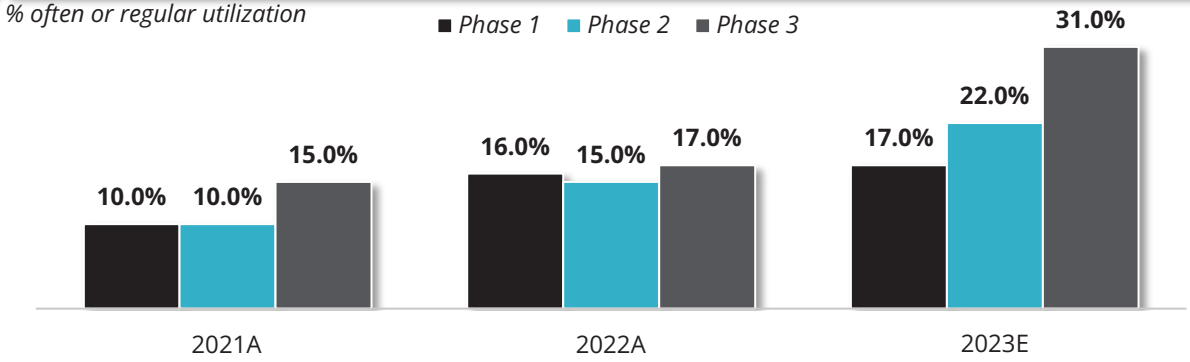
Clinical Research Site Industry Growth and Trial Phase Breakdown[1]



Average Number of Sites per Trial[2]



Sponsor / CRO Percent Regular Utilization of SMOs by Phase[3]

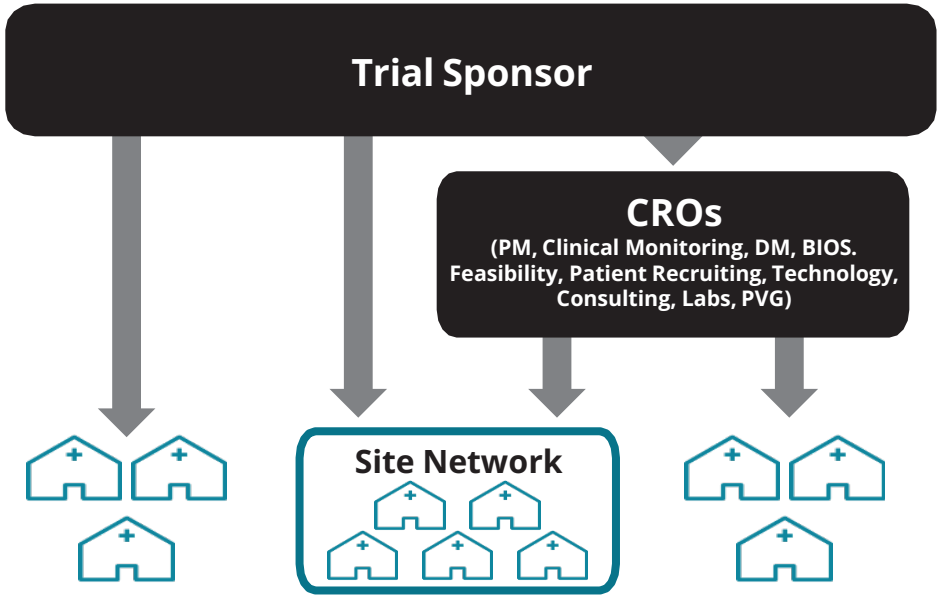


[1] IBD, [2] HealthAdvances, [3] LEK Clinical and eClinical Pharma Services Survey 2022

Clinical Research Site Evolution

As Patient Access Organizations consolidate individual research site locations, they are evolving into increasingly important strategic partners for pharmaceutical sponsors and CROs and will eventually vie for market share via offering ancillary services currently offered by CROs

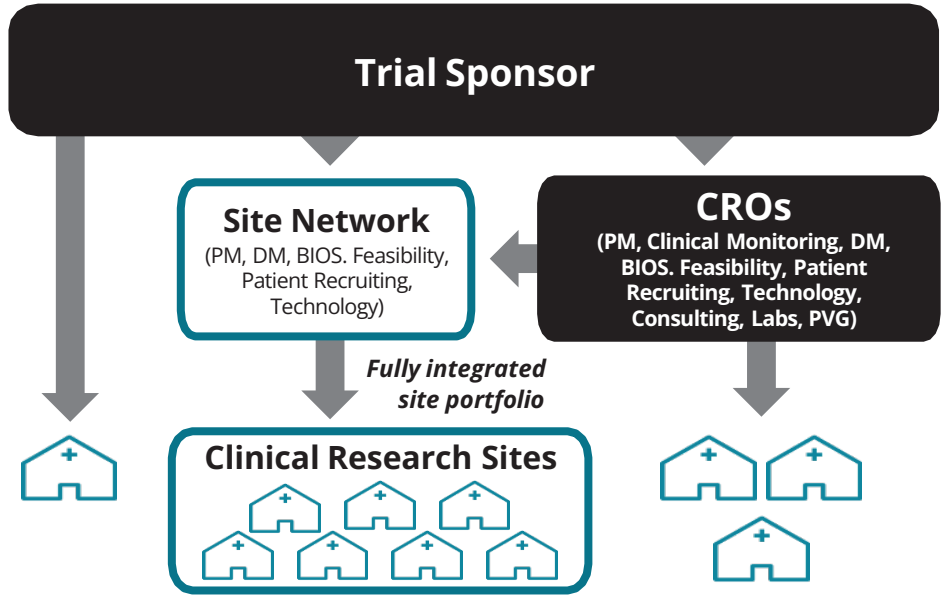
Current State



Overview of Site Responsibilities

- Site-specific activities are fully outsourced by sponsors and are undertaken by individual sites or small networks of commercial or academic sites
  - These activities have always been fully outsourced in order to ensure sponsors have access to a wide dispersion of patients and PIs
  - Site-specific activities include patient recruitment, patient retention, data collection and trial execution

Future State

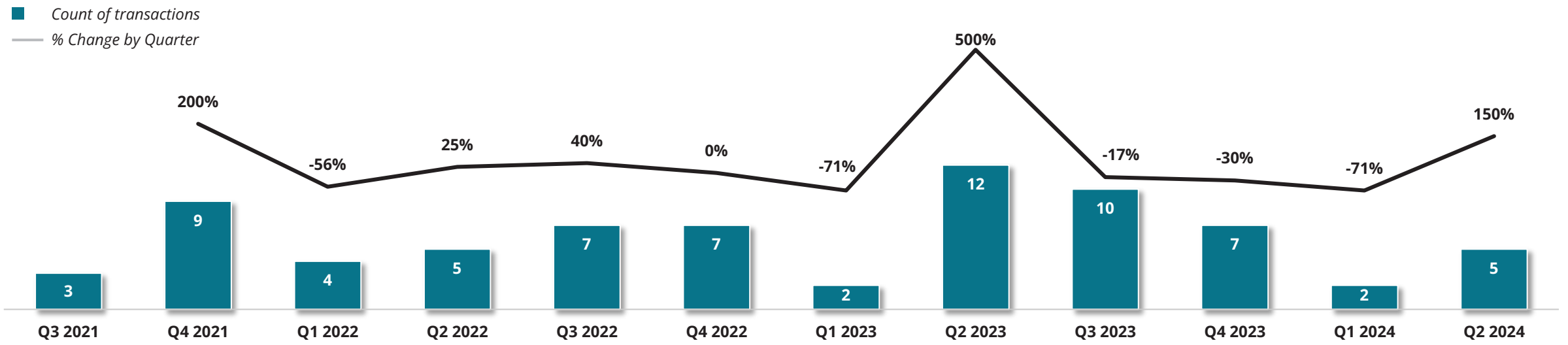


Overview of Site Responsibilities

- In the future, sites will consolidate into larger site networks that offer and increasing number of centralized services that will be offered by both site networks and CROs
  - Future services may include project management, data management, biostatistics and patient recruiting
  - Sites proximity to patients and PIs make them a more natural partner to their pharma sponsor customers than their CRO cousins

Increasing Popularity of Site M&A

Quarterly Research Site Transactions[1]



Clinical Research Sites are Outperforming the Broader Pharmaceutical Development Market

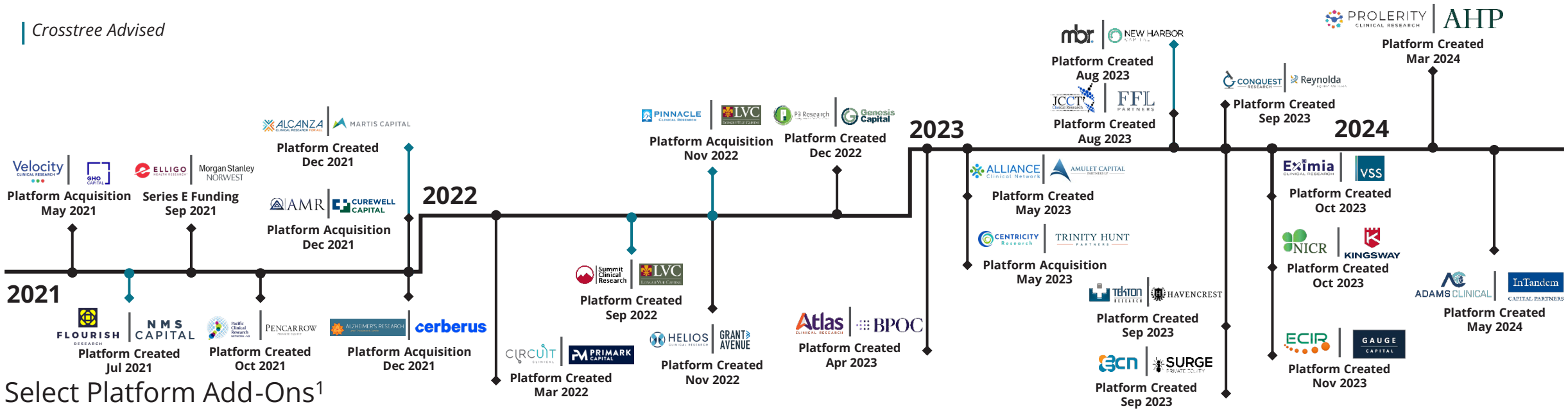
Transactions in the PAO space not only outperform the broader M&A market, but also outperform the pharmaceutical development market. This can be seen in the uptick of research site transactions in Q2 2023, a period including transactions which formed major network platforms Atlas Clinical Research and Alliance Clinical Network as well as the platform acquisition of Centricity Research. Since the global pandemic in 2020, there has been a drastic shift from approximately six notable research site transactions in 2020 to six transactions QTD in Q4 2023 alone.[1] The volume increase in the acquisition and formation of research site networks is a leading indicator of platform add-on rates. For example, the formation of Flourish Research was followed by a platform add-on in Q4 2021, two in 2022 and three in 2023[1].

Considering the current fragmentation of clinical trial site market, there is tremendous potential for further consolidation in both platform launches and continued add-ons. As sites continue to consolidate, they will increasingly be positioned to offer additive services that are more traditionally associated with CROs such as study feasibility, protocol development, patient recruitment, study design and data services.

[1]Crosstree Research
Note: Data from S&P Capital IQ (as of July 2024)

Rapid Consolidation of Clinical Research Sites

Crosstree Advised



Select Platform Add-Ons[1]

ACRS
- Nov 2021
- May 2023
- May 2024

IMA Group
- Sep 2021
- Oct 2021
- Dec 2021
- Mar 2022
- Jan 2023
- Apr 2023
- Jun 2023

ERG
- Apr 2018
- Nov 2017
- Mar 2020
- Nov 2021
- Nov 2021
- Jun 2022

Headlands
- Jul 2020
- Jul 2020
- Feb 2021
- May 2021
- Jun 2022
- Apr 2023
- May 2023
- Jul 2023
- Oct 2023
- Feb 2024

Flourish
- Jul 2021
- Oct 2021
- Oct 2022
- Dec 2022
- May 2023
- Sep 2023
- Nov 2023

Alcanza
- Mar 2022
- Aug 2022
- Sep 2022
- Sep 2022
- Sep 2022
- Jul 2023
- Apr 2024
- Apr 2024
- May 2024

Velocity
- Jul 2021
- Sep 2021
- Sep 2021
- Feb 2022
- Jul 2022
- Sep 2022
- Nov 2022
- Dec 2022
- May 2023
- Oct 2023

CenExel
- Mar 2021
- Aug 2021
- Dec 2021
- Jan 2022
- Jan 2022
- May 2022
- Jun 2022

[1] Does not include all add-on acquisitions
[2] 19+ total platforms created since 2021

INDUSTRY TRENDS: A FAMILIAR TRAJECTORY

Clinical Research Outsourcing Market Opportunity

The History & Inception of CROs

In 1988, academia serviced ~80% of industry-sponsored clinical research[1]

As development costs achieved unprecedented highs and mega trials became the new norm, pharmaceutical companies came under increasing pressure to better utilize their siloed clinical development assets. CROs initially emerged as a means of offering centralized, out-sourced development teams that could better utilize a highly specialized, but other fixed internal cost for pharmaceutical sponsors.

ICON parexel QUINTILES PPD

What began as outsourcing of specialized point solutions (biostatistics consulting, regulatory consulting, clinical monitoring, etc.), slowly diversified and evolved into full-service suites of clinical development capabilities in global organizations that are capable of replacing legacy internal / fixed-cost development teams within the large pharmaceutical companies. The success of these platforms has triggered a herd of followers looking to capitalize on the rising demand for more and more specialized and better utilized services.

By the early 2000s, CROs serviced ~70% of industry-sponsored research[1]

Market Size Today

Site Costs Represent Approximately 50% of the CRO Market[3]

IQVIA™ 2022 Site Pass Through: **$5.4B**

ICON 2022 Site Pass Through: **$5.5B**

$20.9B[2]
CRO Market Size - 2023 (Measured by Revenue)

IQVIA™ 2023 Total Revenue: [2] **$2.5B**

Fortrea 2023 Total Revenue:[4] **$3.1B**

MEDPACE 2023 Total Revenue: [5] **$1.9B**

Roughly half of the CRO market is from pass-through of site expenses, with an estimated 60% going to cancer centers and academic medical centers, and the remaining 40% attributable to private sites[3]

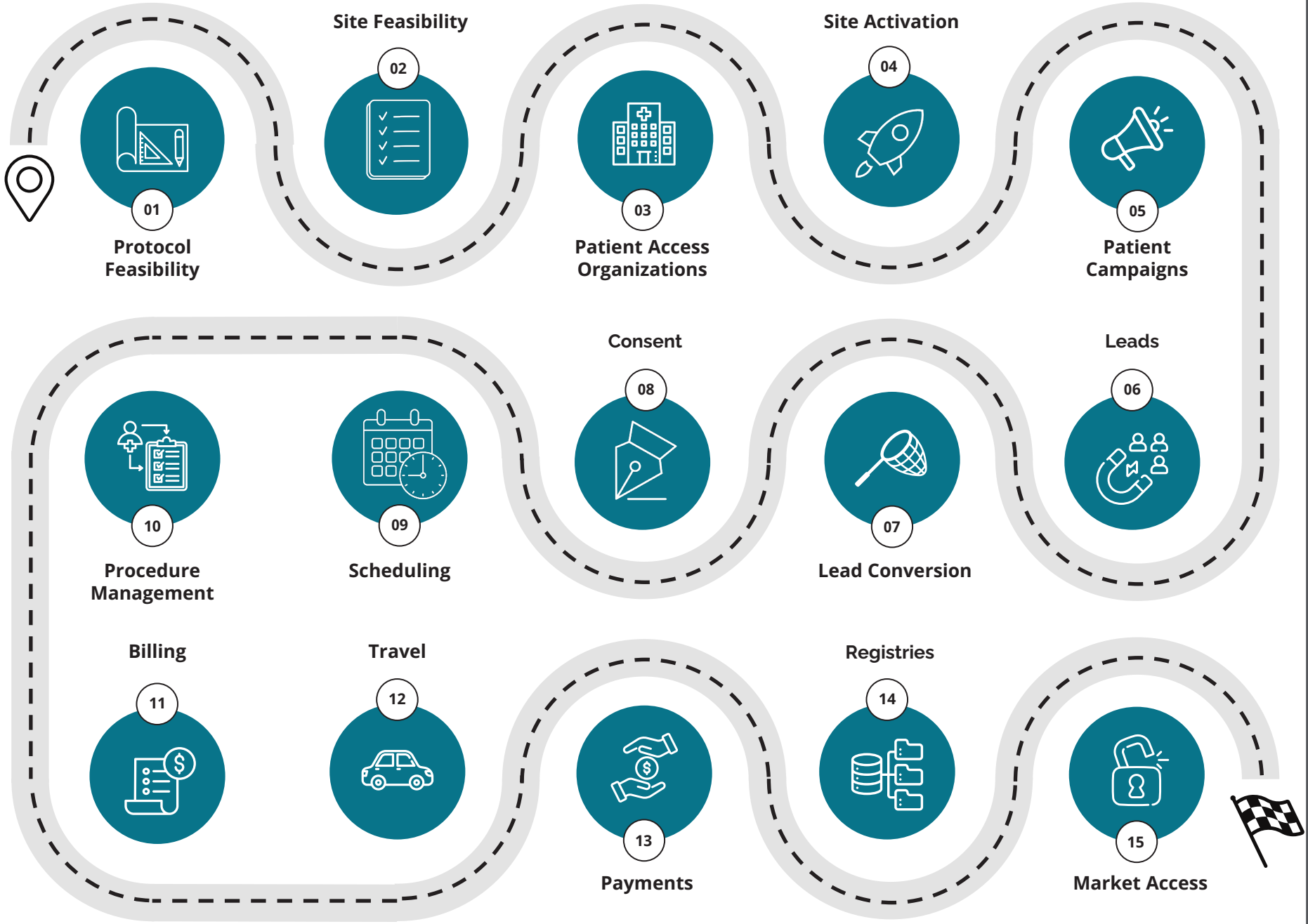
~$5B
Estimated AMC & cancer center site market[3]

~$8B
Estimated total research site market

~$3B
Estimated private site market[3]

[1]American Heart Association; [2]IBIS World, [3]ClinicalResearch.io, [4]Fortrea, [5]Medpace

Clinical Trial Execution Journey



Trial execution technology also remains fragmented with several point solutions being ripe for consolidation

Beyond Scale

Site Feasibility
PAOs can offer unparalleled visibility into site feasibility, and these capabilities only become more robust through more accurate enrollment predications as PAOs expand into patient recruitment and engagement

Patient Campaigns
As sites stand between patients and sponsors, they are placed in a position to excel in patient campaigns, better understanding effective recruitment strategies at the site-level

eConsent & eCOA
PAOs are embedded within their communities, connecting them to patient populations, supporting patient trust and facilitating directly recorded outcomes – supporting endeavors in registries and recruitment

Procedure Management / CTMS
As the executers of clinical trials, sites benefit from trial management systems and may develop in-house capabilities to take control of procedure management, driving expansion into areas conventionally run by CROs

Payments
Often outsourced by independent research sites, PAOs can offer payment services across their site network to streamline stipend payments and reimbursements for patients

Registries
Registries support long term patient recruitment and engagement initiatives by continuing to engage with patients, especially rare patient populations and deepen the value of PAOs to sponsors

Similarity to CROs

Prior to the large-scale consolidation and globalization of CROs, “core” CRO services (clinical monitoring, project management, data management and biostatistics) were limited and fragmented across many specialized CROs. The interconnectedness and complimentary nature of clinical trial service offerings encouraged expansion and further consolidation and integration of additional services into what are now large, full-service, global outsourced service providers to pharmaceutical sponsors.

Similarly, many independent clinical research sites are currently specialized in specific therapeutic areas or focused in one geographic area. As PAO platforms continue to acquire sites and build scale, the opportunity arises to expand service offerings organically or inorganically. Given the nature of site’s core purpose (connecting patients and physicians for the purposes of clinical research), they are more natural strategic partners to their pharmaceutical development customers.

Sites are expected to expand into key complimentary services that are supported by natural capabilities of PAOs, allowing for extreme growth and robust service offerings typically associated with CROs

A Challenger to CROs

The emergence of PAOs may have a potential impact on CROs as they challenge the incumbents for supremacy in the outsourced ph arma service arena

Drivers of Market Disruption		Implications for CROs
Emergence of Site-Centric Solutions	Emergence and advancement of site-centric tech solutions are avenues for PAOs to improve patient experiences and overall trial execution. The rise of these vendors specializing in site-centric solutions offers PAOs the chance to disengage from traditional reliance on CROs and assume greater control over the patient experience.	As PAOs evolve and invest in their site-centric solutions, CROs may face gradual erosion of their longstanding patient-centric / site-enablement value proposition. The traditional role of CROs in providing comprehensive trial support may be challenged as PAOs increasingly offer tailored, technology-driven solutions that prioritize the needs of sites and participants.
Increasing Protocol Complexity	The advancement of precision medicine drives increasingly complex clinical trial protocols, requiring more sophisticated data collection and tight timelines, and placing a premium on specialized expertise. PAOs are positioned to thrive in this landscape as PAOs evolve to improve data capture and management abilities, standardize start-up and training processes and deepen specialization in therapeutic areas.	CROs currently operate at the forefront of managing increasing protocol complexity through protocol design optimization, comprehensive study site training and leveraging various site-enabling tools. As PAOs grow and expand into these capabilities, CROs will need to continue to innovate their solutions to maintain their competitive edge.
Industry Demand for Efficiency and Standardization	The industry's growing need for efficiency and standardization in clinical trial processes creates an environment where PAOs, with their emphasis on streamlined operation through their site networks, can challenge traditional CROs by offering more agile and standardized solutions.	Through site feasibility, study start-up and protocol training, CROs are at a disadvantage on a cost / efficiency basis. PAOs' access to networks of standardized sites allows for quicker feasibility, start-up and training, reducing pharma development costs. CROs will need to continue to innovate to reduce costs to compete.
Innovative Patient-Centric Approaches	PAOs bring innovative, patient-centric methodologies to clinical trials, focusing on enhancing the participant experience. PAOs proximity and relationship with patients allow them to adopt and better utilize patient-centric approaches. This approach can attract more participants and streamline recruitment processes, challenging traditional CRO methods.	CROs often do not own patient relationships and typically outsource the recruitment directly to the site or through third-party vendors. This model may create a potential gap in understanding patient needs and preferences and gives PAOs a competitive advantage as they have a more direct impact on patient recruitment.
Industry Consolidation / Market Fragmentation	PAOs are best positioned to benefit from the continued trends of consolidation and a market that is still fragmented and underutilized. These trends will drive the inorganic growth for PAOs as they incorporate these underutilized sites, providing them with a unique advantage in building a comprehensive and diverse network.	As site networks expand and grow their capabilities, CROs will need to continue to compete and bolster their integrated site networks and site-related solutions and further develop their value proposition to focus on their pre and post capabilities.

EXECUTIVE INTERVIEWS: INSIGHTS FROM INDUSTRY LEADERS

Executive Interviews

ALCANZA CLINICAL RESEARCH FOR ALL

Carlos Orantes
CEO

DM CLINICAL RESEARCH

Mohammad Millwala
CEO

ERG Evolution Research Group

Lori T. Wright
President & CEO

Headlands RESEARCH

Kyle Burtnett
CEO

HELIOS CLINICAL RESEARCH

E.B. McLindon
Co-Founder & CEO

JAVARA

Jennifer Byrne
Founder & CEO

pratia

Tomek Dąbrowski
CEO

Summit Clinical Research

Gail Hinkson
CEO

Velocity CLINICAL RESEARCH

Paul Evans, PhD
President & CEO

ALCANZA CLINICAL RESEARCH

CROSSTREE

Website
alcanzaclinical.com

DESCRIPTION

Alcanza is an integrated network of research facilities dedicated to reducing barriers to clinical research participation, especially in underrepresented patient populations. The network includes 22 dedicated research units and seven additional sites integrated within specialty clinics. These facilities are strategically located across the Southeast, Northeast and Midwest regions of the United States. Alcanza supports studies that span all trial phases and major therapeutic areas.

KEY STATISTICS

Year Founded
2021

Headquarters
Lake Mary, FL

Employees
500

Locations
29

Carlos Orantes
CEO

As CEO, Carlos Orantes provides leadership and strategic direction for the site network**.** With greater than 30 years of experience within the life sciences industry, his career has included executive leadership, operational management, LEAN Six Sigma process improvement, as well as systems and technology deployment. Most recently, Carlos served as Executive Director, Site Operations for Accelerated Enrollment Solutions, a business of PPD and ThermoFisher Scientific. There, he led the site operations for the Americas in support of the company's vast global clinical trial network.

How many sites does Alcanza operate? And what is the mix of dedicated vs embedded sites?

Today, we have 22 dedicated centers and seven embedded centers. When it comes to headcount, we are hovering around the 500 mark. That is inclusive of W-2s and 1099s that work with us, including over 100 investigators.

When it comes to constructing site networks, what is the benefit of leaning into therapeutic specialization compared to adopting broader therapeutic coverage? Are there advantages to one strategy over the other?

We approach site selection strategically by considering the enterprise's therapeutic goals first. We assess the therapeutic capabilities of existing and incoming sites to leverage strengths in both directions. Rather than restricting sites to a single therapeutic area, we aim for versatility to maximize access for local populations. This approach allows us to expand into adjacent therapeutic areas for comprehensive coverage.

Embedded sites versus owned sites. How do you decide if you want to expand via an embedded site vs. an owned site? Do you have a general preference for one model versus the other?

Our preference leans heavily towards dedicated sites due to the control they offer over study execution, physical capacity and growth trajectory. Embedded models, while potentially offering larger capacity, often come with limitations inherent in operating within someone else's infrastructure. Moreover, the focus misalignment between research and host businesses can pose challenges. Access to specialized physicians can also be more complex in dedicated sites compared to hiring general practitioners.

ALCANZA CLINICAL RESEARCH

CROSSTREE

In an embedded model, do you access the patient database of the practice you are embedded within? And in dedicated sites, how do you obtain access to patient data from local physician practices? How important is this access to Alcanza's success?

Access to electronic medical records (EMR) is crucial in an embedded model, ranging from direct login credentials to data reports. Technologies like BEK Health streamline data mining by refining patient lists based on study criteria. In dedicated sites, obtaining access may require outreach efforts to medical practices, from receiving patient profiles to directly accessing EMR data. Building relationships, especially with larger medical centers, is key to ensuring smooth data access and successful study recruitment.

What proportion of recruited patients come from existing patient relationships with your principal investigators (PIs) compared to efforts outside of that network, such as direct recruitment or third-party recruiting?

Our patient recruitment strategies differ by region and therapeutic area, primarily involving outreach to communities and medical practices. Dedicated centers prioritize relationship-building, advertising and expanding their patient database. Partnering with medical practices enables specialized services, enhancing patient care and retention.

How does the emphasis on technology and efficiency intersect with the importance of people in the industry, and what challenges arise regarding diversity initiatives?

Despite the industry's technological focus, its core remains driven by people, extending the call for diversity not only to patients but also to staff. However, this emphasis on diversity can pose financial challenges for many sites. Consequently, these demands may lead to further consolidation or the demise of smaller sites, creating unintended consequences despite good intentions. We continue to also invest in technology to achieve a fully integrated suite of platforms.

When it comes to acquiring or starting new sites, what is at the top of your checklist?

When considering acquisitions, we evaluate factors like geography, therapeutic focus, financial health and operational structure. Chemistry and alignment with our culture are crucial during discussions with potential partners. If all criteria align, we prioritize meeting in person to assess facility culture and dynamics. For new builds, geography, patient profile, disease prevalence and competition are key considerations, with a focus on establishing robust healthcare networks.

"We prioritize meeting in person to assess facility culture and dynamics. For new builds, geography, patient profile, disease prevalence and competition are key considerations with a focus on establishing robust healthcare networks."

Can the outcomes of a clinical trial vary based on how the trial is conducted? Do you believe the trial setting—remote versus traditional—affects the results?

Without sufficient data, it is challenging to determine whether outcomes differ between trials conducted remotely versus those in traditional settings. Ensuring proper administration and monitoring of medications, especially remotely, remains crucial for data integrity. While remote data collection methods like tablet entries may introduce potential biases, the impact on trial outcomes is uncertain without comprehensive comparative studies.

ALCANZA CLINICAL RESEARCH

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When you think about geographic coverage, what does "done" look like and where do you go next?

We are strategically expanding our presence, initially focusing on the East Coast for logistical advantages like operating within the same time zone but have started moving into Missouri, Texas and Puerto Rico this year. Opportunities in therapeutic areas aligning with our growth goals are driving our expansion, with recent explorations in other geographies closer to the West Coast. Our expansion strategy prioritizes a balanced therapeutic mix and sustainable financial performance to attract investors.

When you are talking about geographic presence, what kind of radius around an embedded site vs. freestanding can you recruit a patient? Is it different for embedded versus freestanding? Does it differ by protocol and are there ways to extend your geography?

Patient recruitment radius varies by geography, with embedded sites often drawing from their existing patient pool regardless of location. For dedicated sites, the radius depends on factors like therapeutic area complexity and population density, impacting patient willingness to travel. While decentralized tools like DCT offer convenience, patient choice remains paramount for successful implementation.

Are you in discussions around preferred providers? Are you seeing that in this market yet? Do you expect that is coming?

Yes, but it is not new. Discussions around preferred provider relationships are ongoing in the market, although they are not entirely new, particularly for CROs. While these arrangements offer visibility into upcoming studies, the current process remains largely traditional and inefficient, with multiple CDAs and PSVs for each site. Efforts to streamline processes and improve efficiency are underway, emphasizing strategic planning based on therapeutic area needs and patient demographics. However, significant changes in industry practices are necessary to fully leverage the potential benefits of preferred provider networks.

As a seasoned professional in the industry, how have you observed its evolution over the past 20 years, particularly concerning the dynamics between sites, CROs and sponsors?

Over the past two decades, the clinical industry has experienced intensified consolidation efforts, leading to a significant shift in relationships between sites, CROs and sponsors. Sponsors are now increasingly inclined to collaborate directly with sites or specialized functional service providers (FSPs) instead of relying solely on CROs. This shift empowers sites to offer a broader range of services directly to sponsors, enhancing efficiency and cost-effectiveness in project management. As the industry evolves, sites are strategically positioning themselves to explore innovative collaboration models with sponsors, parallel to traditional approaches with CROs.

"Over the past two decades, the clinical industry has experienced intensified consolidation efforts, leading to a significant shift in relationships between sites, CROs and sponsors."

What KPIs do you use to manage either the enterprise or individual sites? And what are the ones that are most relevant to you that you track?

We track key performance indicators (KPIs) for business development, operations and quality. For business development, we focus on funnel size, conversion rates, multi-site awards and revenue roadmap at both enterprise and site levels. Operationally, we monitor top-line revenue, bottom-line profitability, labor metrics and capacity utilization targets to ensure alignment with budgets and anticipate future needs. Quality metrics are also closely monitored to maintain standards across the board.

DM CLINICAL RESEARCH

CROSSTREE

Website
dmclinical.com

DESCRIPTION

DM Clinical Research, founded in 2006 and headquartered in Houston, Texas, is a national network of clinical trial sites. It includes 24 dedicated research centers and embedded sites, specializing in various therapeutic areas such as vaccines, internal medicine, pediatrics and more. In 2022, the company received the Society for Clinical Research Sites Excellence in Patient Centricity Award. Partnering with global pharmaceutical sponsors, DM Clinical Research offers the community opportunities to participate in cutting-edge research under the supervision of qualified physicians and professionals.

KEY STATISTICS

Year Founded
2006

Headquarters
Houston, TX

Employees
600

Locations
24

Mohammad Millwala
CEO

With a lifelong dedication to helping others and a keen business sense, Mohammad was naturally drawn to a career in the clinical space. As CEO and Founder of DM Clinical, he built a responsive enterprise that serves a crucial societal need. Mohammad values that DM Clinical supports individuals, recognizing that each patient is someone's loved one. This commitment has distinguished DM Clinical through effective business practices like organization, collaboration and flexibility to empower patients. Millwala views DM Clinical as a lifelong mission, aiming to expand its patient-driven approach to a national level. Mohammad has also won the 2023 Gulf South Regional E&Y Entrepreneur of the Year Award and was a National Finalist.

How did you get started? How was DM structured when it started compared to how it is structured today?

I started DM in 2006 after gaining experience in my family's healthcare business. We began with an embedded model in Houston but shifted to growing both embedded and dedicated model in 2016 after acquiring a dedicated site. With a focus on quality and mentorship from the late Christine Pierre, founder of SCRS, we started building the business. We grew from 87 employees in 2019 to nearly 600 employees in 2024.

Did you experience an impact from COVID?

COVID greatly impacted DM Clinical as we were already involved in vaccine work, making us a significant player in Houston, a diverse and populous city. With the influx of vaccine projects from major pharmaceutical companies, DM Clinical expanded its operations rather than downsizing during COVID. We strategically opened new sites in Houston, then expanded to Chicago, Detroit and other locations, becoming a company with a nationwide presence.

How many dedicated and embedded sites do you have now?

We currently have 15 dedicated sites and nine embedded sites. Our plan is to prioritize expanding our number of embedded sites significantly. We are aiming for a total of 40 to 45 sites in the next three to four years. We will also consider acquisitions using generated cash to further enhance our portfolio.

DM CLINICAL RESEARCH

CROSSTREE

Are you thinking of the embedded growth as your hub and spoke?

Yes, embedded growth will follow a hub-and-spoke model. We will establish hubs with 15 to 20 employees and then open embedded sites in those locations.

What is your experience with the differences between a dedicated site versus an embedded site?

It is about managing risks while balancing growth. A mix of dedicated and embedded sites helps mitigate risks while expanding. Dedicated sites offer better margins, but a blend ensures broader offerings and scalability. Embedded sites take longer to set up and require careful management due to physicians' primary focus being on their practices. Balancing these factors is crucial for success. In addition, embedded sites also give us access to patients and improved conversions for enrollment, especially for certain specialty disease states.

When you have your dedicated sites, are your PIs contractors, or do you have dedicated employees that are PIs?

In our dedicated sites, the PIs are primarily employees, not contractors. While some may have their own practices, they work extensively with us. Most are full-time W2 employees along with the rest of the staff, ensuring their consistent oversight and commitment to the research.

What are your top therapeutic areas and how do you view therapeutic expansion?

Our strategy involves balancing revenue mix and customer concentration while expanding operational offerings. We prioritize expertise in therapeutic areas where we can enroll effectively, focusing on mastering a few areas before expanding. Our main focus areas are in rheumatology, immunology and general medicine. We align our growth in therapeutic areas based on drug development pipeline.

"We prioritize expertise in therapeutic areas where we can enroll effectively, focusing on mastering a few areas before expanding."

What is your perspective on the future exit strategy for clinical sites amidst the presence of private equity investments?

The future exit strategy for clinical sites amid private equity investments remains uncertain. While some networks may prioritize fast cash over operational stability, others with robust infrastructures are likely to endure. As long as there are no regulatory barriers to starting new sites, there will always be an influx of newcomers. The long-term landscape may involve mergers or acquisitions among networks, with questions lingering about the fate of newer entrants in five to seven years.

DM CLINICAL RESEARCH

CROSSTREE

How do you think the relationships you have with sponsors will change as you continue to scale?

Sponsor relationships have evolved significantly as our scale has increased. Now, they approach us for a specific number of sites rather than individual physicians, reflecting a shift towards a network-driven model. While some sponsors still operate with outdated systems, the conversation is changing to prioritize network capabilities over individual site preferences. We also engage and maintain strategic partnerships with sponsors that allow us to create site offerings to meet their needs.

Houston is one of the most diverse cities in the country. What do you do in terms of assuring diversity in your in your patient mix for your trials?

Ensuring diversity in patient trials is a three-pronged approach for us. First, we prioritize diversity in our physician roster to build trust with patients. Secondly, our workforce boasts 76% diversity among employees, including coordinators. Lastly, our strategic city selection focuses on metropolitan areas known for their diverse populations, ensuring broad patient access.

What are your patient recruitment strategies at DM Clinical?

Recruitment strategies differ between dedicated and embedded sites. For dedicated sites, we focus on constant advertising and pre-marketing efforts to build a patient database. Meanwhile, for embedded sites, access to Electronic Medical Records (EMRs) is crucial for efficient patient recruitment, enabling us to identify eligible patients through proper HIPAA and BAA compliance.

How do you think the technological landscape has changed over time and where do you see it going?

The technological landscape is undergoing fragmentation as new players enter with solutions for various industry challenges. Over time, this fragmentation may lead to consolidation by private equity, similar to what is occurring with clinical sites. The goal is to create a more efficient and interconnected system, which may take about a decade to fully mature and consolidate.

What are your thoughts on the role CROs play as this part of the market matures? Do you see them as partners or as competitors?

Despite advancements driven by private equity, CROs remain integral in managing the complexities of clinical research. While some overlap may occur in areas like project management and site identification, CROs will likely continue to play a vital role due to the ongoing fragmentation in the industry.

“Despite advancements driven by private equity, CROs remain integral in managing the complexities of clinical research. While some overlap may occur in areas like project management and site identification, CROs will likely continue to play a vital role due to the ongoing fragmentation in the industry.”

EVOLUTION RESEARCH GROUP

CROSSTREE

Website

ergclinical.com

DESCRIPTION

Evolution Research Group is one of the largest, independent site company in the U.S. focused on the execution of early and late phase CNS disorders with an industry leading clinical and operational team of professionals. ERG's portfolio includes twenty (20) fully owned and operated clinical research units, a network of affiliate sites. With over 400 beds and 40+ PIs and KOLs in several therapeutic specialties, ERG is frequently used by industry teams planning early or late phase, complex inpatient and outpatient trials in psychiatry, neurology, addiction, sleep disorders, post-surgical pain models, chronic and neuropathic pain, renal insufficiency, hepatic impairment, diabetes, MAFLD / MASH, obesity, diabetes and other metabolic disorders, among others. Lotus Clinical Research, LLC, is under common ownership with ERG and is a scientifically driven, full-service CRO.

KEY STATISTICS

Year Founded
2014

Headquarters
New Providence, NJ

Employees
127

Locations
21

Lori T. Wright
President & CEO

Lori Wright is the Founder and serves as Board Member & Chief Executive Officer at Evolution Research Group (ERG). DFW Capital Partners established ERG in 2014 by merging Thievon-Wright Consulting Group, LLC, (TWCG) founded by Lori in 1998, with three of her affiliate network sites. ERG became the platform for what is now the largest, independent clinical research site / CRO company in the U.S. with a neuroscience and early phase focus. DFW Capital exited ERG in 2018 when it was acquired by Linden Capital Partners. Lori has led the M&A strategy and completed the acquisition of ten additional clinical research site companies, a rater training company and completed a merger with Lotus Clinical Research, LLC, a full-service CRO, which included additional clinics which were then integrated into the ERG platform. DFW acquired Lotus after exiting ERG and post-merger, has partnered with Linden on this investment. Andria Chastain is President of ERG and Dr. William (Bill) Martin is President of Lotus and both report to Lori directly.

How did ERG get its start?

Evolution Research Group was the result of a merger of my consulting company and several of the sites that I represented. In 1998, I founded Thievon-Wright Consulting Group to provide marketing, business development and budget negotiation support to independent neuroscience research sites who did not want to join an SMO. Over time, the company expanded its services and grew its site network to 35+ high-performing, quality focused, inpatient and outpatient CNS sites, offering sponsors efficient access to top investigators through a single point of contact.

Did the business expand into back-office support?

Yes, we expanded to include back-office support services such as quality management, staff placement, training, contract negotiations, pipeline management and financial forecasting. Our approach improved the sites' operational efficiency, allowing investigators and their staff to focus on their clinical duties. It also strengthened our relationships with sponsors and CROs as they could communicate efficiently with many investigators through their account directors at TWCG, and sometimes relied on us as mediators when issues arose.

Why did some SMO models fail in the early 2000s, and how did yours succeed?

SMOs often struggled with financial and contractual management, delaying payments to the sites, which discouraged experienced investigators from joining. Our model prioritized site autonomy and direct control over finances and contracts. This approach, partially driven by sponsor recommendations, created a responsive and effective network that met evolving clinical trial needs.

EVOLUTION RESEARCH GROUP

CROSSTREE

How was compensation structured?

It was a shared risk compensation structure based on the revenue generated by the sites, aligning our incentives with their performance. Initially, sites paid a “start-up” fee when joining the network, but the primary revenue source was a percentage of the site's earnings. We were able to command higher budgets, for many reasons, and both investigators and sponsors found value in the model, as our payments for our services ultimately depended on site performance. We were all aligned.

What led you to CNS neuroscience and the therapeutic area?

I started my career at a CRO, but always wanted to be closer to patients. I was fortunate to meet Dr. Ronald Fieve, a well-respected KOL in New York City, who recruited me to run his research practice Fieve Clinical Services, and I learned a tremendous amount from him. After four years managing a research site, I knew what I wanted to do.

How did you transition to owning freestanding sites?

As network members began to transact with CROs or private equity investors, I had to really explore my exit strategies. Recognizing that some of our sites had incredible growth potential, and the founders did not want to invest additional capital, I sought out a PE partner. DFW Capital had an investment in pharma services, specifically an IRB, and was interested in exploring the site space. We decided to merge TWCG with three of our IP psychiatry locations that were in high demand, and formed Evolution Research Group, LLC. We maintained the original affiliate network and continued to support them, and also eventually acquired some of those, in addition to others.

Why focus on CNS instead of a broader therapeutic range?

Focusing on CNS has been a strategic decision due to the significant unmet needs and consistent demand for treatments. Additionally, I have a personal commitment to addressing mental health challenges. As we built the neuroscience network, we grew it based upon our sponsors’ needs, which is driven by patient needs. We expanded heavily into inpatient psychiatry, then neurology, specifically Alzheimer’s disease, followed by pain, sleep disorders, addiction, among others and early phase clinical trials. Ultimately, we are a special population company that executes highly complex trials. The complexity and continuous evolution within CNS aligns with my professional interests, specifically as it relates to ensuring that these vulnerable populations have access to new treatment options and medical care.

How did you expand into providing CRO services?

When we acquired Clinical Pharmacology of Miami, it complemented our phase one work with CNS populations. In addition to healthy volunteer studies, CPMI was a leader in special population studies including patients with renal insufficiency, hepatic impairment, diabetes, obesity and others. We were so successful growing this unit that many of our clients requested that we provide CRO services as well. We began subcontracting, but it was not ideal. When the opportunity arose to merge with Lotus Clinical Research, with whom we conducted several acute pain studies and whose owner we knew well, we had our solution. We immediately formed an Early Development Services team at Lotus and have now conducted more than a dozen early phase studies together.

Does your model's success vary by phase or therapeutic area?

Where our specialty Site / CRO model excels is in the delivery of early and late stage, healthy and special population trials. We have conducted many “fully-captive” studies in which Lotus acts as the CRO and all patients or healthy subjects are enrolled at ERG owned sites. We have been particularly successful in phase one, pain, psychiatry and more recently metabolic studies, including obesity. Currently, we cannot service global trials without partnering due to our limited international reach.

EVOLUTION RESEARCH GROUP

CROSSTREE

Is ERG's footprint insufficient for certain phase three trials?

ERG regularly conducts large phase three acute pain studies due to our extensive capabilities and capacity in post-surgical pain. Our clients have met their primary and secondary endpoints in all cases to date, which is due to the consistency across our sites, stemming from extensive methodology training with some of the most well-respected experts in the field. However, in trials requiring large numbers of outpatient sites to enroll thousands of patients, for example in vaccine studies, our footprint is insufficient. Companies like Velocity are better suited for those types of studies.

Is there a need to reach patients outside your network?

Expanding patient access beyond established geographic areas presents significant challenges, but we are constantly finding new ways to do just that. In 2023, we outfitted and deployed Mobile Health Units for pre-screening and launched a proprietary mobile app called “MyTrialApp”, which is used solely for patient recruitment, education, communication and engagement across all ERG sites. Operational complexities and patient education barriers hinder the effectiveness of fully decentralized clinical trials (DCTs), in my opinion. The idealized vision of DCTs often clashes with practical issues, including regulatory responsibilities and patient safety concerns, highlighting ethical and operational challenges, though we must continue to evolve in this area.

“The idealized vision of DCTs often clashes with practical issues, including regulatory and patient safety concerns, highlighting ethical and operational challenges, though we must continue to evolve in this area.”

Is site selection more important than CRO choice?

The importance varies based on the trial's phase and scope, in my experience. In early-phase studies, site selection is crucial, particularly around clinician expertise, biomarker capabilities such as CSF sampling, TQT, assessing abuse potential and other. Conversely, in larger, phase three, global trials, proper CRO selection is essential for project management, logistical coordination, regulatory expertise, etc. Sponsors increasingly involve sites in protocol design, recognizing their pivotal role in patient access and trial success even before selecting a CRO, which is a trend that we are thrilled to see rising over the past four to five years.

“Sponsors increasingly involve sites in protocol design, recognizing their pivotal role in patient access and trial success.”

Could ERG become central raters?

When we acquired CNS Ratings, they were integrated into the Lotus infrastructure under their Scientific Services division and yes, they can do centralized ratings. ERG and Lotus are firewalled from one another, so ERG would not provide central rating services directly, though we are able to rate across sites and remotely, which was a capability we built during the COVID pandemic.

How do you ensure study quality and reliability?

We focus on patient selection and staff training. Rigorous, standardized training programs for investigators and staff are critical. Similarly, ensuring we have robust community outreach initiatives, maintain community referral sources and customize our prescreening processes help us maintain high standards and optimize study outcomes.

HEADLANDS RESEARCH

CROSSTREE

Website
headlandsresearch.com

DESCRIPTION

Headlands Research is a multinational integrated clinical trial site organization with a mission to improve lives by advancing innovative medical therapies. Its group of exceptional sites focuses on large-volume recruitment of diverse and specialty patient populations while delivering the highest quality data. Headlands Research's principal investigators are proven industry leaders in their fields with expertise in a wide variety of indications. Utilizing expert recruitment strategies and access to diverse patients through its site databases and physician partnerships, Headlands Research has successfully completed more than 5,000 clinical trials.

KEY STATISTICS

Year Founded
2018

Headquarters
Lake Worth, FL

Employees
500

Locations
18

Kyle Burtnett
CEO

Kyle has over 20 years of executive leadership in healthcare, with experience in scaling and managing large organizations. He recently served as President of GI Alliance, the largest gastroenterology physician practice management organization in the U.S., overseeing 800 physicians in 15 states. Previously, he worked at Tenet Healthcare, a Fortune 250 company, where he led two divisions and significantly grew the businesses. Before his healthcare career, Kyle was an active-duty officer in the US Air Force. He holds a B.S. in Management from the United States Air Force Academy and an MBA from USC's Marshall School of Business.

Describe your background and your career at Headlands.

My career has been an interesting and rewarding journey leading up to joining Headlands. Before this role, I spent over 20 years in healthcare operations, focusing mainly on multisite healthcare operations like Tenet Healthcare. There, I helped transformed the company from primarily acute care hospitals to a diversified business that included ambulatory surgery centers and revenue cycle services. I later moved into private equity, working with GI Alliance, a physician-led gastroenterology group. Joining Headlands, I found an exciting mission in a supportive environment with a top-tier team and significant infrastructure investments, making it an exciting opportunity.

What is your take on the difference in managing your clinical research site versus your prior experience on the healthcare side?

Managing a clinical research site has its differences from traditional healthcare operations, but there are also a number of parallels. The strategy of investing in capabilities (people, process, technology) and the extension of those capabilities and knowledge across the organization to better support sites is consistent. This includes professionalizing functions like budget negotiations and business development, centralizing data for real-time analysis and expanding services or therapeutic areas. Sharing best practices across the network is key to success as our team works collaboratively to raise the bar on performance and help accelerate and improve the process of bringing therapeutics to market.

HEADLANDS RESEARCH

CROSSTREE

How many sites do you have?

We currently have 18 sites, with five of them being de-novo sites and the remainder acquired through acquisitions. Our approach emphasizes shared values and partnership alignment for successful collaborations. Staying true to our strategy has proven beneficial amid industry trends.

How do you view the standalone site model versus embedded model?

Our strategy primarily focuses on standalone sites, of which we have 18, including some acquired practices that we have maintained. We concentrate on four key therapeutic areas: CNS, vaccine and immunology, metabolic and endocrine and mental health. Standalone sites often provide a more dedicated focus on clinical trials versus the competing priority of the physician practice. It sounds silly but space requirements can also be a real factor making the embedded model more challenging.

When you build a de novo site, are you building around a PI and specific geographic area?

For de novo site development, diversity is a key focus, driven by strategic partnerships like with Pfizer. We aim to invest in areas with diverse patient populations and prioritize strong principal investigators and site directors. It is a multifaceted approach combining diversity and talent acquisition.

"We aim to invest in areas with diverse patient populations and prioritize strong principal investigators and site directors. It is a multifaceted approach combining diversity and talent acquisition."

What are sponsors looking for and how has this contributed to consolidation in this space?

Sponsors seek dependable, high-performing partners who can enroll diverse participants and ensure retention for successful trials. I think this suggests that sponsors will increasingly choose to work with networks that can most efficiently and effectively deliver those results. However, the industry's historical approach of engaging a vast number of sites to perform studies is deeply engrained. While we are seeing a change in behavior from sponsors, the transition will not happen over night. I think that many stand-alone sites see and feel this longer-term trend, and it is leading many owners to consider whether they should partner with a network.

Are you observing increased enthusiasm and opportunities within the market for companies over the next 5-10 years?

Yes, there is significant enthusiasm regarding the market's potential over the next five to ten years. Key discussions are centered around contracting for larger studies and aligning stakeholder interests to optimize performance. Furthermore, there are potential strategies being considered, such as implementing incentives for exceeding performance expectations and penalties for underperformance, which are anticipated to drive market growth and efficiency.

Are you seeing a common frustration with networks of multiple sites that are not seen as a unified entity by sponsors, despite the progress in efficiency and contracts?

We are making great strides and certainly creating efficiency, but there is still room for improvement in this area. Despite efforts to streamline contracts, there is still some frustration with sponsors not recognizing networked sites as a unified entity. Even with master contracts, signing can be complicated due to site-specific nuances.

Is moving beyond North America a topic of conversation right now?

Expanding beyond North America is not a priority yet. There is significant opportunity in the US and Canada, focusing on new site development and operational improvement. While there is competition for M&A, discussions about growth tend to be focused on domestic opportunities. International expansion could be on the horizon in the future, offering a long-term growth pathway.

How do you view the CRO's role and the interplay between sites, as well as CROs in the future?

The relationship between sites and CROs is symbiotic. CROs provide essential services for sponsors, complementing the role of sites. As sites grow, the dynamics of this relationship may shift, possibly allowing CROs to focus more on specialized services beyond site management.

What are your thoughts on sponsors increasingly recognizing the value of direct engagement with networks like yours, rather than relying solely on CROs?

Direct engagement between sponsors and networks like ours is increasingly valued, reducing the need for sponsors to interact with individual sites. This shift means our relationship with sponsors will likely become more direct over time, akin to that of CROs. Our business development team, operations team and principal investigators are already actively engaging with sponsors to pursue relationships, a crucial aspect of our growth strategy.

"Direct engagement between sponsors and networks like ours is increasingly valued, reducing the need for sponsors to interact with individual sites. This shift means our relationship with sponsors will likely become more direct over time, akin to that of CROs."

When it comes to the evolution of systems and technology, how are you utilizing them and what are you highlighting in conversations with customers?

We have been focusing on several areas in our conversations with sponsors and CROs, particularly highlighting our ability to manage different therapeutic areas programmatically, ensure quality, retain participants and prioritize diversity in patient populations. We have made significant investments in infrastructure and quality assurance to deliver consistently high performance across these key metrics.

HELIOS CLINICAL RESEARCH

CROSSTREE

HELIOS
CLINICAL RESEARCH

Website
heliosclinical.com

DESCRIPTION

Helios Clinical Research is an integrated clinical site organization that partners with patients, physicians and biopharma sponsors to optimize clinical research. Its world-class clinical development team engages patients and physicians to improve the patients' research experience, while accelerating the sponsor's ability to obtain valuable data due to Helios' expertise in recruiting and retaining patients. Helios' integrated clinical research sites expedite the drug approval process by focusing on key delivery components such as study startup, patient recruiting and engagement and regulatory and quality compliance.

KEY STATISTICS

Year Founded
2022

Headquarters
New York, NY

Employees
140+

Locations
25

E.B. McLindon
Co-Founder, CEO

E.B. is an entrepreneur experienced in executive management, startup and turn - around situations, clinical development, business development, strategic planning / development and enabling technologies in various industries. Prior to starting Helios, E.B. was a Senior Vice President at ICON and led the development of their site and patient strategy – including ICON's global clinical research site network, its home health provider (home nursing), global patient recruitment and retention services and developing operating solutions to deliver decentralized clinical trials (DCTs). He is the author of many white papers focused on patient engagement and site support, as well as DCT technologies deployment.

What does your site footprint look like right now? How many are dedicated vs embedded?

Currently, Helios has 25 sites in five states. Eight of which are dedicated research centers, and 17 are embedded. Sixteen of the sites were acquired and nine of them were de novo.

When you think about an embedded site versus a dedicated site, do you have a preference?

A mixed model is essential to address diverse study requirements. Dedicated sites excel in consumer-oriented studies and recruit more effectively; however, embedded sites are increasingly valuable due to the growing complexity of protocols requiring access to medical records. By incorporating both approaches, researchers can tackle various study types effectively, adapting to evolving trends in clinical research.

As this market continues to evolve, would you expect more focus on the embedded model to capture therapeutic areas?

In the evolving market landscape, both embedded and dedicated research sites are expected to see increased activity (particularly in capturing diverse therapeutic areas). The embedded model offers a cost-effective entry point into building out expertise in specific areas like CNS. Sites often begin as embedded clinics and expand into dedicated centers as they grow, leveraging existing patient bases and physician relationships. This strategic approach allows for flexibility in scaling research capabilities based on demand and therapeutic focus areas.

HELIOS CLINICAL RESEARCH

CROSSTREE

Where do you think the market focuses on embedded opportunities – at the health system or the specialty practice level?

Helios focuses on both health system and specialty practice levels, aiming for three site models: dedicated research, embedded in specialty practices (like OBGYN, DERM, etc.) and a community health model akin to Javara's approach. The community health model offers higher value return due to its repeatability process, enabling more efficient leveraging of infrastructure and accommodating multiple physicians across various studies under one roof.

What is your take on the role of commercial sites and site networks in oncology research. What does it take to get commercial sites involved in this research given it is 50% of the spend or so?

Commercial sites and networks face challenges in engaging with oncology research due to low patient accrual rates and resource allocation concerns. Larger hospital-based research institutions excel in oncology studies by triaging patients into appropriate trials, leveraging their infrastructure effectively. While some commercially-focused networks may explore oncology through dedicated centers or affiliate models, the community health setting offers a promising avenue for broader participation and operational ownership, facilitating impactful research in oncology and other therapeutic areas.

What is your organization's biggest bottleneck?

The biggest bottleneck lies in the reluctance of pharma and CROs to fully utilize the infrastructure developed by site networks. Despite efforts to streamline processes like CDA signing, inefficiencies persist hindering the study progress. There is a disconnect between acknowledging the potential efficiency gains and implementing practical solutions, leading to repeated administrative burdens on sites. Collaboration and leveraging existing infrastructure could significantly alleviate these bottlenecks.

Where do you think the technology landscape is going from a site perspective? What do you think consolidation is going to do to technology?

In general, technology deployment to create efficiencies at the site (eSource, CTMS) coupled with study-based tech deployment such as DCT, increases the training and compliance factor on clinical sites. While DCT offer promise (such as more efficiency in patient follow up visits and data monitoring), deployment challenges persist which could be met by a more adaptable trial tool selection rather than trying to force tech solutions. Site staff training increasingly emphasizes technology, reflecting the integral role of tech in modern clinical research practices.

Do you think these newer technologies, techniques and strategies should derive from sites? Or do you think they can be built and deployed into sites?

Personally, I think sites are best to develop solutions that fit their needs for patient engagement and trial management; whereas CROs and tech companies are best to develop trial-based solutions due to the complex security and data alignment requirements. Some great products have come from site owners, such as Realtime (a CTMS) and Devana (CRM), but these have taken many years to develop a scalable product.

What do you think happens as site networks continue to grow and consolidate? Do you think patient recruitment solutions continue to exist? Are they threatened by site networks?

Site networks' growth and consolidation may challenge the traditional role of patient recruiting companies, as local expertise becomes crucial in executing effective recruitment strategies. While larger networks gain influence, recruiting companies must adapt to focus on complex disease states, leaving local, community level engagement to the sites. However, as site networks evolve, the need for effective patient engagement remains vital, potentially reshaping the landscape over time as networks become more sophisticated and patient-aware.

HELIOS CLINICAL RESEARCH

CROSSTREE

It is interesting that you now must wait until sites have a big enough customer base to justify the investment from a technology development perspective. If you are planning on selling it into the sites, then must the sites get paid for it too?

While technology development may be led by companies like Signant Health, site networks could potentially acquire existing solutions tailored to their needs. Collaboration between technology providers and site networks is essential for successful integration and adoption of decentralized tools.

> *"Collaboration between technology providers and site networks is essential for successful integration and adoption of decentralized tools"*

Ultimately, you can deliver patients provided you have the infrastructure needed to deliver on a study. Are you required to qualify each of your 25 sites individually rather than qualifying Helios for a study?

Each site (whether we provide one or 25) is individually qualified for a specific study. A lot of this is because this is the way it has been for 40 years, but maybe in the 41st year we can create change. Most CROs and sponsors setup their site database based on the physician's name — sometimes tagging them to a network and many time ignoring that. The goal for a network is to provide efficiency and effectiveness through the entire lifecycle of a study from site selection to close out. Rather than contacting ten physicians in our network, the CROs could contact one person and get access to more than ten to help them deliver their protocol under one contract and budget.

Do you believe CROs would rather keep you as 25 individual sites in the minds of the sponsor?

The battle lies in aligning CRO incentives with site efficiency. While some CROs may prioritize meeting contract metrics over optimizing site engagement, forward-thinking ones will recognize the value in leveraging site infrastructure. The challenge for CROs is understanding how to effectively utilize site assets, especially as smarter site networks aim to educate sponsors on the mutual benefits of collaboration. Ultimately, it is about fostering dialogue between sites and CROs to maximize study engagement and efficiency.

Do you think CROs are allies in the ongoing consolidation efforts in the market?

The bigger consolidations will be separate, and their strategy will not be to eliminate CROs but will be to minimize CROs. CROs will not go away, but as site networks become larger, they will become a more natural partner to sponsors for various services that CROs currently provide. Since the clinical trial service businesses operate on a time basis, innovations that reduce the time and can face natural resistance, as CROs are reluctant to undermine their own resources.

> *“the bigger consolidations will be separate and their strategy will not be to eliminate CROs but will be to minimize CROs”*

Will PAOs continue to consolidate separately from CROs?

Consolidation amongst sites and CROs will continue — with site networks getting larger via acquisitions and CROs being a natural strategic investor of the larger networks. The key buying decision for CROs is to understand where the targeted site network can help them amongst therapeutic areas (not just for vaccine research).

Website

javararesearch.com

DESCRIPTION

Javara, a top Integrated Research Organization (IRO), partners with large healthcare institutions to deliver clinical trials directly at the point of care via trusted physician relationships. By integrating research staff and infrastructure, Javara ensures broad access to diverse patient populations, enhancing enrollment and retention rates for quality data. Centralized resources and streamlined operations accelerate study start-up, improving outcomes and expediting product approval. Pioneering Clinical Research as a Care Option (CRAACO), Javara revolutionizes healthcare by innovating the clinical trial process for better patient outcomes.

KEY STATISTICS

Year Founded
2018

Headquarters
Winston-Salem, NC

Employees
200

Locations
45

Jennifer Byrne
Founder, Board Chair and CEO

Jennifer Byrne's career has focused on leading organizations, building teams and fostering partnerships to advance clinical research and connect patients with clinical trials. She founded Javara to revolutionize the industry by improving research access for patients, biopharma companies and healthcare systems. Jennifer's dedication to integrating clinical research into healthcare drives Javara's mission. As the former CEO of PMG Research and founder of Greater Gift, her extensive involvement spans collaborations with numerous pharma, device, CROs, technology and research service providers. Her excellent track record in enhancing patient, provider and client experiences in research trials highlights her professional achievements.

Please provide an overview of your career background and the current status of Javara.

Throughout my career, I have specialized in clinical research at the site level, with a focus on enabling practicing physicians to engage in research within their patient communities. At Javara, our priority is enabling physicians to contribute to research while maintaining exceptional patient care. This involves providing comprehensive services, technology and support to empower physicians without burdening them with administrative, operational and regulatory complexities

Were you involved with PMG from its inception?

I joined PMG during its early stages as the company was readying to expand beyond gastroenterology and into new therapeutic areas. In addition to the therapeutic expansion, PMG grew geographically. As the company matured, we recognized the necessity for centralized functions such as regulatory, training of staff and investigators and contract management. This evolution towards integration was driven by practical needs for consistency and scalability rather than a predefined business strategy.

What was the scale of PMG at the time of its acquisition by ICON?

PMG employed approximately 220 staff members, conducted 7,500 clinical trials and operated with an annual revenue of approximately $35 million. The company achieved sustained profitability and organic growth without external funding. The decision to pursue acquisition arose unexpectedly following the passing of one of PMG's founders, prompting interest from multiple top ten CROs and resulting in a favorable transaction despite PMG not initially optimizing for an exit.

What prompted the establishment of Javara?

Following PMG's acquisition by a CRO, it became evident that pivoting towards a global CRO with a healthcare focus, at that time, was impractical within that existing framework. Javara was founded to modernize existing models based on universal insights from previous experiences, establishing direct relationships with healthcare institutions. This approach addresses the evolving complexities of patient demographics and pharmaceutical needs.

"Following PMG's acquisition by a CRO, it became evident that pivoting towards a global CRO with a healthcare focus, at that time, was impractical within that existing framework"

Can you elaborate on your decision to maintain an integrated model with Javara, compared to standalone or brick-and-mortar facilities?

The decision to maintain an integrated model rather than adopting standalone or other approaches was deliberate. Integration extends beyond physical placement within healthcare systems to align with workflows, seamlessly integrating with communication channels and educational efforts. This partnership model minimizes complexity and additional work for healthcare providers while enhancing research impact and reach across the health organization's enterprise.

Why did you opt for a more challenging approach, and what advantages does it offer?

Choosing a more challenging path initially facilitates adaptability and future scalability. While standalone research sites offer benefits, an integrated approach addresses current barriers and provides opportunities to meet evolving healthcare needs effectively and my co-founders and I were well equipped and up for the challenges.

How does Javara's approach cater to patient preferences in integrated care settings for complex diseases, compared to standalone research sites?

Javara acknowledges the preference for integrated care settings, particularly for complex diseases. By embedding research within trusted healthcare environments, Javara facilitates direct patient access to research-based treatments while maintaining continuity in care pathways. This approach prioritizes patient convenience and consistency. Right patient to the right trial with the trusted provider at the right time.

Does Javara focus on specific therapeutic areas, and how does this strategy compare with other site networks like Velocity?

Javara concentrates on primary care, mainstream subspecialties and vaccine research, with expanding expertise in cardiometabolic areas. This diversified focus offers benefits such as high-volume repetition and robust investigator development. Moving forward, Javara aims to align its therapeutic focus with patient and healthcare partner priorities.

From your perspective, does patient demand primarily drive pharmaceutical interest or healthcare provider value seeking?

Pharmaceutical interest in patient demand predominantly influences clinical trial pipeline decisions. However, Javara adopts a balanced approach, responsive to signals from both pharmaceutical companies and healthcare providers. Endorsement from healthcare organizations enhances Javara's patient value proposition.

JAVARA

CROSSTREE

What distinguishes Javara's model as beneficial for patients?

Our model integrates clinical research seamlessly within patients' trusted healthcare organizations, ensuring uninterrupted care continuity. Patients receive research-based options without disruptions to their existing care paths, offering convenience and reliability.

> *"Our model integrates clinical research seamlessly within patients' trusted healthcare organizations, ensuring uninterrupted care continuity"*

How does Javara's model benefit healthcare providers by expanding their patient networks?

Integrating research within healthcare practices enhances patient loyalty and reduces patient leakage to competing healthcare systems. This fosters economic opportunities and market differentiation, potentially increasing lifetime patient value significantly.

Does Javara's business model mitigate financial losses for healthcare systems involved in trial research?

Integrating research within healthcare systems enhances brand perception and patient attraction, factors that may not be fully reflected in financial analyses. For Javara's partners, clinical research offsets fixed costs and generates revenue upon patient enrollment, diverging from grant-funded research models prone to financial strains.

What primary advantage does Javara's model offer from a pharmaceutical feasibility perspective?

Javara's integrated model offers pharmaceutical companies a broader feasibility view by leveraging dynamic patient data sets. This approach enhances accuracy in feasibility assessments compared to registry-based methodologies.

Does Javara leverage real-world data to compete with platforms like TriNetX for protocol feasibility or design?

While not currently prioritizing real-world data utilization, Javara considers this capability for future development. Initial efforts focus on establishing trust with healthcare systems, avoiding commercialization concerns over patient data.

How does Javara's model benefit healthcare providers post-trial?

Javara maintains continuous patient-provider linkages post-trial through tools like the Jenesis app as it facilitates ongoing communication and updates. This approach also supports post-market surveillance and sustains patient engagement, enhancing retention rates and study quality.

PRATIA

CROSSTREE

pratia
your catalyst for
healthcare innovation

Website
pratia.com

DESCRIPTION

Pratia is the largest European research platform and the world's largest oncology network, running over 700 studies in 90 sites across seven European countries, covering 85% of therapeutic areas. It leverages cutting-edge technology for reliable and timely data delivery, supported by advanced data warehouses and analytics. Pratia's flexible approach allows for seamless management of all types of clinical trials, from traditional to modern formats, making Pratia the preferred choice for diverse research projects. Pratia is part of Humaneva Group.

KEY STATISTICS

Year Founded
2012

Headquarters
Raleigh, NC

Employees
650+

Locations
90

Tomek Dąbrowski
CEO

Tomek is a serial entrepreneur with extensive experience in scaling up global healthcare businesses through digital transformation, M&A and building high-performing teams. With deep knowledge in clinical trials, telemedicine, technology, the pharmaceutical industry and hospital management, he has successfully built and sold multiple organizations. His approach is data-driven and focused on patient-centric solutions, always seeking ways to leverage technology to streamline business processes and improve patient care. His motto is "patient obsessed," reflecting his commitment to enhancing the patient experience in all his ventures.

What are the advantages and disadvantages of an embedded site model versus an independent site model?

Close connections with research sites are crucial for ensuring integrity, delivery and quality in the research space. While independent research sites offer greater daily business influence, they may lack the flexibility needed for global operations. Embedded models, though potentially less controllable, offer adaptability across projects, especially when well-integrated with customizable technology. While dedicated research models are costlier, they can yield higher margins and better control when well-scaled.

What are your views on the emergence of decentralized clinical trials (DCT) and DCT technologies as it pertains to the future of clinical research sites? Is that a competitive threat to site businesses or an enabling technology?

I believe the full DCT model can be implemented in very few types of projects, typically those that are relatively easy to manage, such as medical devices or vaccines. I do not foresee a complete shift to DCTs but see tremendous potential for integrating remote technologies into the research flow. These include teleconsultations, remote consent, remote labs and medical devices at patients' homes. However, I think these should be part of a study design that integrates the traditional model rather than stand-alone remote studies. I predict that DCT will follow the same path as the entire healthcare industry, adopting a blended model with both on-site and remote services working together.

How do independent sites address a lack of direct access to an existing EMR?

Independent sites typically utilize their own eSource / EMR platforms. This setup ensures that they maintain control over their data management and can still adhere to high standards of data integrity without direct integration into external EMR systems.

PRATIA

CROSSTREE

Do you focus in any specific therapeutic area? What are the advantages and disadvantages of therapeutic specialization for research sites?

At Pratia, we excel in oncology and hemato-oncology, managing 200+ projects yearly. While we cover 85% of therapeutic areas with over 600 trials annually, oncology remains our primary focus and the fastest-growing sector. Specializing in challenging fields like oncology, psychiatry and CNS sets us apart and enhances our reputation. Choosing to specialize or operate across multiple areas depends on long-term vision, shaping growth and adaptability in clinical research.

What have you found to be the most successful patient recruitment strategies and why?

Our patient recruitment strategy relies on direct relationships with healthcare professionals; leveraging referrals from doctors, investigators and sub-investigators. We also utilize extensive databases, targeted online campaigns and collaborations with healthcare associations and events. Tailored to local contexts, this approach ensures efficient and ethical recruitment globally, enhancing participant engagement and retention for successful trials.

What makes a clinical research site successful?

Scaling clinical research sites requires a strong team, advanced technology and skilled investigators. Engaged and experienced investigators are crucial for site success. Unlike fast-food chains, clinical research must align with local healthcare environments even when expanding globally. Balancing global strategy with local adaptation ensures seamless operations and long-term success.

"Scaling clinical research sites requires a strong team, advanced technology and skilled investigators. Engaged and experienced investigators are crucial for site success."

What are the major considerations when growing or establishing a site network? What about when you acquire a new site?

Expanding site networks involves choosing between organic growth, joint ventures, or acquisitions, with each option presenting unique challenges. At Pratia, achieving unified operations across 90 research sites took years despite initial expectations of seamless integration. To address this, establishing an adaptable post-merger strategy and prioritizing cultural alignment are essential for successful network expansion.

If you could change one thing about the current site market what would that be?

My vision is for research sites to be seen as genuine partners and decision -makers, and not just patient recruitment resources. Recognizing the vital role of research centers in driving clinical trials is crucial for fostering a more balanced and beneficial relationship among sponsors, CROs and sites. While progress is underway, there is still much to achieve in ensuring that research sites are properly valued and respected in the industry, paving the way for a more equitable future in clinical research.

"Recognizing the vital role of research centers in driving clinical trials is crucial for fostering a more balanced and beneficial relationship among sponsors, CROs and sites."

What role do you see CROs playing in the current market consolidation?

Pratia and Kapadi, both under the Humaneva capital group, operate independently despite potential synergies. CROs like Kapadi are vital for market consolidation, fostering strategic partnerships for integrated services. Future trends suggest SMOs like Pratia will influence consolidation, with diverse models coexisting, from CRO acquisitions to strategic partnerships, all emphasizing collaboration with independent sites.

Compare / contrast oncology studies from other therapeutic areas. Is there a role for oncology research at commercial site networks?

Oncology research demands specialized facilities, technology and financial processes, setting it apart from other therapeutic areas. At Pratia, we have developed dedicated and embedded oncology models over a decade, recognizing the unique challenges and rewards of this field. While daunting, investing in oncology research infrastructure offers profound impact and rewards for those committed to meeting its intensive needs.

How common are “preferred provider” relationships with sponsors and / or CROs? What impact do you see those types of relationships having on this industry?

"Preferred provider" collaborations between clinical research sites, CROs and sponsors are growing, fostering closer and more strategic alliances. These partnerships boost efficiency by improving communication and project management, leading to faster study start-up and better trial execution. As these relationships deepen, they are likely to reshape how stakeholders interact, promoting a collaborative and integrated approach to clinical research focused on long-term strategic alignments.

Are you considering sites outside of Europe? If so, what regions / features are most attractive to you?

We prioritize regions with strong demand for oncology trials and adapt our site models accordingly. Our flexibility in choosing between dedicated and embedded formats enables efficient entry and scaling in new markets, aligning with regional demands and regulations. While the U.S. remains key, other regions are gaining appeal for their expanding market potential and strategic significance in global research networks.

Do you expect other companies will ultimately follow suit with Pratia, ERG and the larger global CROs?

Other companies are likely to mirror Pratia and large CROs by prioritizing integration and strategic partnerships to improve service delivery and expand their market presence. This trend highlights the multifaceted role of CROs in market consolidation, evolving towards seamless integration of research flows and blurring the lines between CROs and SMOs for more efficient and unified clinical research services.

As you look out over the next three to five years – what technologies and / or practices do you foresee as having the greatest impact on future operations / performance?

I believe we will see a continuous effort to integrate workflows between sites, sponsors and CROs. While it is easier to execute with dedicated research sites, integrating large hospitals with their own EMR systems into clinical research adds complexity. We will witness significant growth in remote monitoring, which will replace on-site visits, leveraging AI and RBQM along with large-scale data analytics. Over the next few years, I expect seamless integration between eSource and EDCs, greatly enhancing data consistency.

Discuss Pratia’s unique / proprietary technology and how that helps to differentiate your offering.

Pratia leverages advanced technology from its strategic partner, Hyggio, seamlessly integrating the entire clinical research workflow. This includes patient engagement, protocol creation and execution (eSource), remote monitoring and financial settlements. With a robust data warehouse and SAS Viya collaboration, the platform offers real-time data insights and improved decision-making, managing trials across seven countries with a single eSource template integrated with EDCs like Medidata (integration underway). Meeting EMR-class standards, it ensures compliance with local regulatory requirements, maintaining data integrity and regional adaptability. The platform supports Pratia's flexible model, accommodating embedded research sites, dedicated research sites and large, sophisticated oncology and cell-gene projects.

SUMMIT CLINICAL RESEARCH

CROSSTREE

Website
summitclinicalresearch.com

DESCRIPTION

Headquartered in San Antonio, Texas, Summit Clinical Research is an Integrated Research Organization dedicated to clinical trials in metabolic-associated steatohepatitis (MASH), metabolic disease, obesity and Alzheimer's disease. From its inception in 2018, Summit delivers a full spectrum of study enrollment and site enrichment services to sites in the network, as well as scientific consultation to sponsors. Summit has increasingly built a leadership team of uniquely specialized physicians, key opinion leaders and clinical operations professionals.

KEY STATISTICS

Year Founded
2018

Headquarters
San Antonio, TX

Employees
64

Locations
100+ sites globally

Gail Hinkson
CEO

Gail Hinkson has been involved with the conduct and oversight of human subject research and clinical trials since 1994. She served as the Associate Director of Clinical Operations for a 130-bed early phase clinical research unit. Her research experience includes management of late phase clinical trials and human subjects research in all major therapeutic areas, acquired during her role as Clinical Trials Director for a 501C3 organization specializing in the conduct of industry sponsored research within the United States Military and Federal Institutions. In addition, she has worked as the Clinical Research Director for an international medical device company.

How did you become CEO of Summit?

My journey in clinical trials began in the early nineties where I specialized in phase one research across multiple therapeutic areas. After a hiatus to start a family, I authored industry protocols before assuming the role as Clinical Trials Director for a 501C3 organization focused on industry sponsored research and education within the Military. Invited by Dr. Harrison to Texas, I initiated the development of Pinnacle Clinical Research, a clinical research site that executes highly effective patient enrollment strategies. In 2018, Summit emerged from Pinnacle aiming to replicate the successful strategies used by Pinnacle across diverse sites.

Was Pinnacle only a single site when you launched Summit?

When Summit launched in 2018, Pinnacle was operating as a multi-site organization. Summit was initially comprised of 15 high-performing sites. The Pinnacle sites were part of that group. Summit's first project had a challenging enrollment target of 175 patients within 12 months. We exceeded expectations by enrolling 181 patients in under ten months, setting a precedent for subsequent trials.

How is your business relationship between Summit, the sponsors and the sites?

Summit aims to support clinical research sites by removing obstacles and focusing on enhancing the sites' effectiveness. Summit has direct contracts with sponsors and works alongside the CRO's. Our model centers on facilitating mutual success between sponsors, CRO's, sites and ourselves by providing scientific and operational expertise, as well as access to a network of high-performing sites which are selected based on performance data.

SUMMIT CLINICAL RESEARCH

CROSSTREE

Do you negotiate budgets on behalf of the sponsor?

At Summit, we may be contracted to negotiate site budgets on behalf of the sponsor. Summit endeavors to ensure fair compensation for the efforts involved in clinical trials. We emphasize transparent rates cards for procedures upfront to prevent misunderstandings and maintain positive relationships between the sponsor and site throughout the trial.

Is part of your job to minimize the cost of the clinical trial with your sites?

Our approach is to accurately reflect the costs involved with the clinical trial execution to sponsors. We advocate for justifiable compensation based on performance data, encouraging higher compensation for high-performing sites that effectively enroll and retain patients.

"Our approach is to accurately reflect the costs involved in clinical trial execution to sponsors"

Is there a quid pro quo that requires high performance and quality for financial justification?

Yes, equitable compensation is fundamental. Sites must demonstrate high performance in patient enrollment and retention to justify compensation and contribute meaningfully to advancing scientific research.

How is Summit different from other SMOs or site networks?

Recognizing the diverse strengths of independent research sites, we initiated Summit to empower sites within a collaborative network rather than through site ownership. This model aims to amplify site voices and enhance trial execution efficiency.

How much of what you do is specific to your therapeutic area of focus?

Summit is fundamentally based on our deep knowledge of the therapeutic areas we work within. We balance scientific knowledge in our therapeutic areas of focus with extensive logistical experience.

How would you compare yourself to Javara?

Summit positions itself along a continuum of research entities. We accommodate the embedded site model as well as independent research centers within our network. Our flexible approach caters to the unique site needs, emphasizing tailored strategies for successful clinical trial execution.

Could you have Javara sites in the Summit network? Would there be overlap?

If a site has the requisite resources, equipment, dedication to the therapeutic area as well as a commitment to quality, they can be a candidate for our network. We aim to adapt our support based on the site's structure.

SUMMIT CLINICAL RESEARCH

CROSSTREE

Do you think about expanding into other therapeutic areas?

Although we initially focused on liver disease, particularly MASH, our strategic expertise extends naturally to related diseases like metabolic disorders, obesity as well as other complex diseases such as Alzheimer's disease, where we can leverage our scientific and logistical strengths to improve trial outcomes.

How do you see the sponsor and site relationship evolving in the next one, three and five years?

There is a growing trend towards streamlining sponsor-site engagement while maintaining direct communication channels. We believe that sites play a vital role in clinical research and the connectivity with sponsors directly enhances their role in trial participation. Summit aims to enhance and facilitate this connectivity.

> *"There is a growing trend towards streamlining sponsor-site engagements while maintaining direct communication channels"*

How do you see the current CRO, sponsor and entity evolution unfolding?

The evolving landscape involves a shift towards more science-driven partnerships between sponsors, CROs and entities like Summit, focusing on advancing patient outcomes through collaborative, strengths-based approaches.

From a site's perspective, what core systems could drive consolidation and have the most impact?

It is ideal for there to be an integration of CTMS, e-regulatory systems, eTMF, IVRS and EDC into a unified platform to enhance research efficiency and data quality.

Is it difficult working with multiple sponsors when they select their own technologies?

Managing multiple technologies within and across studies can lead to inefficiencies and add strain to site resources. Sites consistently seek streamlined, user-friendly systems to support quality research.

How do you see patient recruitment evolving within the Summit network?

Patient recruitment strategies within the Summit network incorporate diverse methods such as database utilization, EMR integration, community engagement and targeted marketing campaigns, based on criteria of the protocols. We continually refine these approaches to enhance recruitment effectiveness.

As sites consolidate, how do you view the sophistication of patient recruitment strategies?

Increasing site consolidation necessitates more strategic patient recruitment approaches and more effective strategies for patient engagement, enabled by tech supported platforms.

VELOCITY CLINICAL RESEARCH

CROSSTREE

Website

velocityclinical.com

DESCRIPTION

Velocity Clinical Research, headquartered in Durham, NC, is the leading integrated site organization for clinical trials, offering dedicated site capabilities to help biopharmaceutical and contract research organization customers find the right patients for their studies. Velocity supports global drug development in primarily conducting phase two and phase three clinical trials. The company has nearly 90 locations globally, including a technology hub in Hyderabad, India. With sites that have conducted more than 15,000 studies since 1986, Velocity has refined its patient recruitment strategies while maintaining a focus on delivering timely and reliable data quality.

KEY STATISTICS

Year Founded
2017

Headquarters
Durham, NC

Employees
1,700

Locations
90

Paul Evans, PhD
President & CEO

Paul joined Velocity Clinical Research as President and CEO in 2018 after 26 years of "perfect symmetry" in the site business — he ran sites for 13 years and spent another 13 years managing them on the Sponsor / CRO side. He has served as Corporate VP, Global Site Solutions at Parexel; VP, Global Site Management at IQVIA; and was a Founder and Managing Director of Synexus. Paul joined Velocity to address one of the fundamental industry challenges. "Patient recruitment is still the biggest problem in clinical trials," he says. "I want Velocity to set a new industry standard for delivering high-quality study data as quickly and efficiently as possible." Paul holds a PhD in Biomedical Engineering from the University of London. He has served on the Association of Clinical Research Professionals (ACRP) Board of Trustees since 2017 and chaired the committee in 2020.

How did you get into the clinical research industry?

I was working at a government research institute in the UK, where our Dexa machine led us to osteoporosis trials due to a shortage of such equipment in the early nineties. Initially focusing on osteoporosis, I realized our expertise was in clinical research and patient recruitment. NaviMed, the private equity firm behind Velocity, bought its first two US research sites and sought a CEO for a classic roll-up model. They chose me, and I moved to the US.

Do you prefer adding sites through acquisition or de novo builds?

Our preference for acquiring established sites over starting new ones stems from the faster path to success and ultimately lower costs. Starting from scratch requires significant time and investment to break even, and the industry's focus on experienced investigators makes it challenging to gain traction with new sites. Additionally, in Europe, where the site landscape is less developed, acquisitions are limited and lead us to pursue more de novo ventures, albeit selectively based on country potential and site availability.

When clinical trials serve as access to medical care in Eastern Europe, does it affect therapeutic areas or patient access?

Using clinical trials for medical care is common in both the US and Europe, especially for the uninsured. While methods may vary, the concept is consistent across therapeutic areas. Enhancing clinical research professionalism aims to make it a full-time occupation, regardless of the therapeutic area.

VELOCITY CLINICAL RESEARCH

CROSSTREE

Why are there fewer commercial sites in Europe than in the US?

In Europe, the presence of fewer commercial sites can be attributed to the socialized education and healthcare systems. European doctors, benefiting from debt-free medical education, experience less financial pressure and are less driven by monetary incentives. Culturally, healthcare is regarded as a government responsibility, which discourages profit-oriented ventures. This cultural and systemic context results in fewer physicians and research sites, with former Eastern European countries being a notable exception.

Does this provide you with a competitive differentiation? Is the value proposition different in Europe versus North America?

Yes, it provides competitive differentiation. While the U.S. accounts for about a third of the research site market, the real opportunity lies in building a global solution for patient recruitment. This approach better aligns with our customer base's needs, offering a distinct advantage.

> *"The real opportunity lies in building a solution for patient recruitment globally...this global approach aligns us more closely with the needs of our customer base, offering a distinct advantage."*

Does the underdevelopment of healthcare impact overall access to healthcare in Eastern Bloc countries compared to Western Europe?

Yes, the underdevelopment of healthcare in Eastern Bloc countries significantly impacts access compared to Western Europe. In Eastern Europe, it is challenging for physicians to earn a substantial income. Consequently, many Contract Research Organizations (CROs) hire physicians as Clinical Research Associates (CRAs) for better financial opportunities, driving greater interest in the commercial success of clinical research.

Are pharmaceutical sponsors changing their approach to clinical trial selection?

Pharma's approach to clinical trial site selection is evolving due to changes in the market landscape. Previously, the scarcity of multisite vendors led to a site-by-site licensing mentality. However, with the emergence of more comprehensive vendors, Pharma is recognizing the potential to consolidate sites under fewer vendors, signaling a shift towards a global site business model. The pace of this transition remains uncertain, but the trajectory suggests a move away from part-time physician-led research toward full-time research sites.

How do you address diversification of patient populations represented in clinical sites?

We address minority participation by strategically placing research sites in regions with diverse populations rather than trying to alter demographics in homogenous areas. For instance, we focus on recruiting Hispanic participants in Florida and Southern California, and African American participants in Cleveland and areas around Louisiana. This approach ensures a more representative sample without imposing unrealistic expectations on individual sites.

How is your team leveraging technology to address key challenges in the industry?

Our team in India has developed a technology platform called VISION to tackle a significant industry challenge: most technologies are designed to meet sponsors' back-office needs rather than the needs of site operations. VISION collects and refines extensive patient and site performance data, empowering the 1,000,000 patients in our database to self-screen and self-schedule visits at our Velocity sites. This self-service capability streamlines the patient journey, reduces the administrative workload on our staff and accelerates recruitment. By enabling patients to actively manage their healthcare process, we achieve significant efficiency gains, enhancing both patient experience and site operations.

VELOCITY CLINICAL RESEARCH

CROSSTREE

What are your thoughts on the current consolidation in the market?

Consolidation in the market is uncertain, with potential mergers still in early investment cycles. The reaction of the market to possible failures among new entrants remains a significant factor, considering the financial implications. As larger companies begin to merge to achieve scale, the landscape may shift, emphasizing the importance of size in the industry's evolution.

> *"As larger companies begin to merge to achieve scale, the landscape may shift, emphasizing the importance of size in the industry's evolution."*

Where is this industry going? The sites, the business, etc.

The industry is witnessing increased acquisition activity with more private equity firms entering the market. Companies like Velocity, Headlands and Centricity are expanding through classic roll-up strategies. The next probable trend could involve consolidation among these consolidators, although it is not yet widely evident. This trajectory suggests a continued evolution towards larger, more integrated entities within the clinical research landscape.

Are you gaining access to real-world data to address the challenges in clinical trial protocol feasibility and patient journey optimization?

A lot of the thinking around feasibility is thinking about the data. The one flaw in getting too far down that route is that none of the data ever shows you willingness. People complain all the time about "I had all of these eligible patients and none of them ended up on the study". When they were all eligible, but none of them were willing. This is interesting because if you look at the way that organizations like ours operate, everybody in my database is willing to do a clinical trial because that is the only reason they have been in touch with us. So, when we look at their eligibility, we already know something about their willingness as well.

What are your struggles with protocol design when it comes to patients?

Balancing patient eligibility and willingness to participate is challenging. Though not heavily involved in protocol design, we see the difficulty of creating protocols for diverse populations and international settings. We are exploring AI to analyze past protocols and outcomes for improvement. Using data in clinical trials aims to better understand patient demographics and behaviors, despite challenges like data reliability.

Is there a role for decentralized clinical trials? Is there a need for identifying more patients that make that model viable?

The hype around decentralized clinical trials (DCTs) has been excessive, especially during the COVID-19 pandemic when patient access was a priority. While technology facilitates some remote patient interactions, the economic viability of full-scale DCTs remains uncertain. Successful integration of decentralized models is likely to complement existing research site operations rather than replace them entirely.

Does it seem like the evolution of this is to get access to more patients?

Decentralized clinical trials (DCTs) present challenges, particularly for sicker patient populations who may benefit most but are harder to monitor remotely. However, for less critically ill patients, like younger demographics with time constraints, DCTs may offer more feasibility. Currently, studies are often structured around decentralized components to fit the protocol rather than patient needs, limiting the true potential for patient-centric trial participation.

NO. 1 ADVISOR FOR PAO M&A TRANSACTIONS*

* Based on the number of announced global transactions

Dedicated Patient Access Team

CROSSTREE

Senior-Level Advisory

Shane Senior
Managing Director
Co-Founder

Responsibilities: Client relationship liaison, buyer outreach

Relevant Deal Experience:

- Continuum Clinical — Acquired by Spectrum, A portfolio company of Knox-Lane
- Flourish Research — Recapitalized by NMS | Capital
- Coastal Carolina Research Center — Acquired by Alcanza Clinical Research for All, Martis Capital
- Genstar Capital — Has acquired Advarra

Jason Layton
Managing Director,
Pharma Services

Responsibilities: Client relationship liaison, buyer outreach

Relevant Deal Experience:

- Benchmark Research — Acquired by IQVIA
- Accel Research Sites Network — Acquired by Alcanza Clinical Research for All, Martis Capital
- Monroe Biomedical Research — Acquired by New Harbor Capital
- Summit Clinical Research — Acquired by LVC, LongueVue Capital

Experienced Transaction Support

Adam Johnston
Vice President

Responsibilities: Transaction execution lead, project management, QA / QC

Relevant Deal Experience:

- Continuum Clinical — Acquired by Spectrum, A portfolio company of Knox-Lane
- Coastal Carolina Research Center — Acquired by Alcanza Clinical Research for All, Martis Capital
- Monroe Biomedical Research — Acquired by New Harbor Capital
- Vax Trials — Acquired by Emmes

Anne Juarez
Associate

Responsibilities: Transaction execution, marketing support, financial modeling, QA / QC

Relevant Deal Experience:

- Continuum Clinical — Acquired by Spectrum, A portfolio company of Knox-Lane
- Monroe Biomedical Research — Acquired by New Harbor Capital
- Alpha IRB — Acquired by Sabai Global, A portfolio company of Thompson Street Capital Partners
- Sabai Global — Acquired by Thompson Street Capital Partners

Rob Camejo
Analyst

Responsibilities: Transaction execution, marketing support, financial modeling

Relevant Deal Experience:

- Continuum Clinical — Acquired by Spectrum, A portfolio company of Knox-Lane
- Vax Trials — Acquired by Emmes
- Monroe Biomedical Research — Acquired by New Harbor Capital
- RMC Pharma — Acquired by Syner-G, A portfolio company of Riverside Partners

Scott Klein
Analyst

Responsibilities: Transaction execution, marketing support, financial modeling

Relevant Deal Experience:

- Continuum Clinical — Acquired by Spectrum, A portfolio company of Knox-Lane
- Alpha IRB — Acquired by Sabai Global, A portfolio company of Thompson Street Capital Partners

Recent Assignments

CROSSTREE

PINNACLE CLINICAL RESEARCH
A portfolio company of
LVC LONGUEVUE CAPITAL
Acquired
CRCNJ The Cognitive and Research Center of New Jersey, LLC

PINNACLE CLINICAL RESEARCH
A portfolio company of
LVC LONGUEVUE CAPITAL
Acquired
KERWIN MEDICAL CENTER

BBI Solutions
A portfolio company of
novo holdings
Acquired
IBEX

MYONEX YOUR CLINICAL TRIAL SUPPLY PARTNER
Acquired
SAVEWAY COMPOUNDING PHARMACY

MYONEX YOUR CLINICAL TRIAL SUPPLY PARTNER
Acquired
CREAPHARM GROUP

CALYX
Divested its 'Enterprise Technology' Division to
eNNOV Software for Life

physIQ
Acquired by
prolaio

CONTINUUM CLINICAL
Acquired by
SPECTRUM
A portfolio company of
KNOX-LANE

ECURIS
Acquired by
JANVIER GROUP BIOSCIENCES

Modular Devices
A portfolio company of
O2 Investment Partners, LLC
Partnered with
FLOW Cleanrooms & Supply

Alpha IRB
Acquired by
Sabai Global
A portfolio company of
THOMPSON STREET CAPITAL PARTNERS

VERSITI
Acquired
PearlPathways™

VAX TRIALS
Acquired by
Emmes

GRANT AVENUE
Recapitalized
creo

mbr Monroe Biomedical Research
Acquired by
NEW HARBOR CAPITAL

SSI Strategy
A portfolio company of
AMULET CAPITAL PARTNERS LP
Acquired
NDA

QDxPathology SERVICES
A portfolio company of
HADLEY
Acquired by
LabGenomics

CATALYST CLINICAL RESEARCH
A portfolio company of
QHP CAPITAL
Acquired
GENPRO RESEARCH

ACCEL Research Sites Network
Acquired by
ALCANZA CLINICAL RESEARCH FOR ALL
A portfolio company of
MARTIS CAPITAL

VERSITI
Acquired
QUANTIGEN.

Access MEDICAL LABS
Allied with
GRUPO DIAGNÓSTICO ARIES

Recent Assignments (Cont'd)

CROSSTREE

Benchmark Research Acquired by IQVIA	CSi Clinical Site Services Accelerating Patient Recruitment Acquired by A portfolio company of LATTICEWORK CAPITAL MANAGEMENT	ClinChoice Acquired CROM SOURCE advise | agree | deliver	anteris medical / anteris helvetia Acquired by Kymanox A portfolio company of WestView Capital Partners	OpenClinica Completed a growth recapitalization with THOMPSON STREET CAPITAL PARTNERS	CLAIRVEST Acquired BocaBiolistics	RMC PHARMA Acquired by SYNER-G BioPharma Group
Sabai Global Acquired by THOMPSON STREET CAPITAL PARTNERS	LVC LongueVue Capital Acquired a majority stake in Summit Clinical Research	H.I.G. ADVANTAGE Acquired a majority stake in NAVITAS LIFE SCIENCES	Lexitas Dedicated to Ophthalmics Acquired by NovaQuest Capital Management	GRENOVA Rethinking Laboratory Waste Received a strategic investment from peloton EQUITY	COASTAL CAROLINA RESEARCH CENTER Acquired by MARTIS CAPITAL	ASCENT DEVELOPMENT SERVICES Merged with PHARMALEX
BCT Acquired by MARTIS CAPITAL From HERITAGE HOLDING	REALTIME CLINICAL TRIAL MANAGEMENT SYSTEMS Received a strategic investment from LLR Partners	bbk Acquired by PUBLICIS HEALTH	PREVENTION GENETICS Acquired by EXACT SCIENCES	Protocol First Acquired by flatiron A subsidiary of Roche	PHARMASOL enabling excellence Acquired by PHARMALEX	UpStream Completed funding round led by DRAGONEER INVESTMENT GROUP

Recent Assignments (Cont'd)

CROSSTREE

FLOURISH RESEARCH Acquired ExcelMedical CLINICAL TRIALS	INTRINSIC CLINICAL SYSTEMS Acquired by PROPHARMA GROUP™	PHARMICA CONSULTING Acquired by PROPHARMA GROUP®	ZEBRASCI Acquired by BD	CTT CLINICAL TRIALS OF TEXAS, INC. Recapitalized by NMS | CAPITAL	QUARTESIAN Acquired by SUMMIT PARTNERS	pyxant LABS Acquired assets of the Salt Lake City Bioanalytical Operations from COVANCE
pyxant LABS Received a majority investment From ArchiMed Investors & Entrepreneurs in Healthcare	dMed 绵脉 Merged with Clinipace CLINICAL RESEARCH	trifecta Acquired by wcg WIRB COPERNICUS GROUP	INTEGREVIEW IRB Acquired by ADVARRA	ARRAY BIOSTATISTICS Acquired by CATO SMS Partnering from Strategy to Approval	gsk Sold assets to FOUNDATION CONSUMER HEALTHCARE | KELSO PRIVATE EQUITY	wcg WIRB COPERNICUS GROUP Has been recapitalized by LGP | LEONARD GREEN & PARTNERS
Haematologic Technologies INCORPORATED Acquired by EDGEWATER CAPITAL PARTNERS	chronometriq Received an investment from fi FULLINVESTMENT PARTNERS	OpGen Acquired by curetis	gsk Sold assets to Perrigo	HistoGeneX Received a strategic investment from ARSENAL CAPITAL PARTNERS	OmniComm eClinical Solutions for Life™ Acquired by anju	GENSTAR CAPITAL Has acquired ADVARRA

A GLOBAL LEADER IN HEALTH SCIENCES M&A

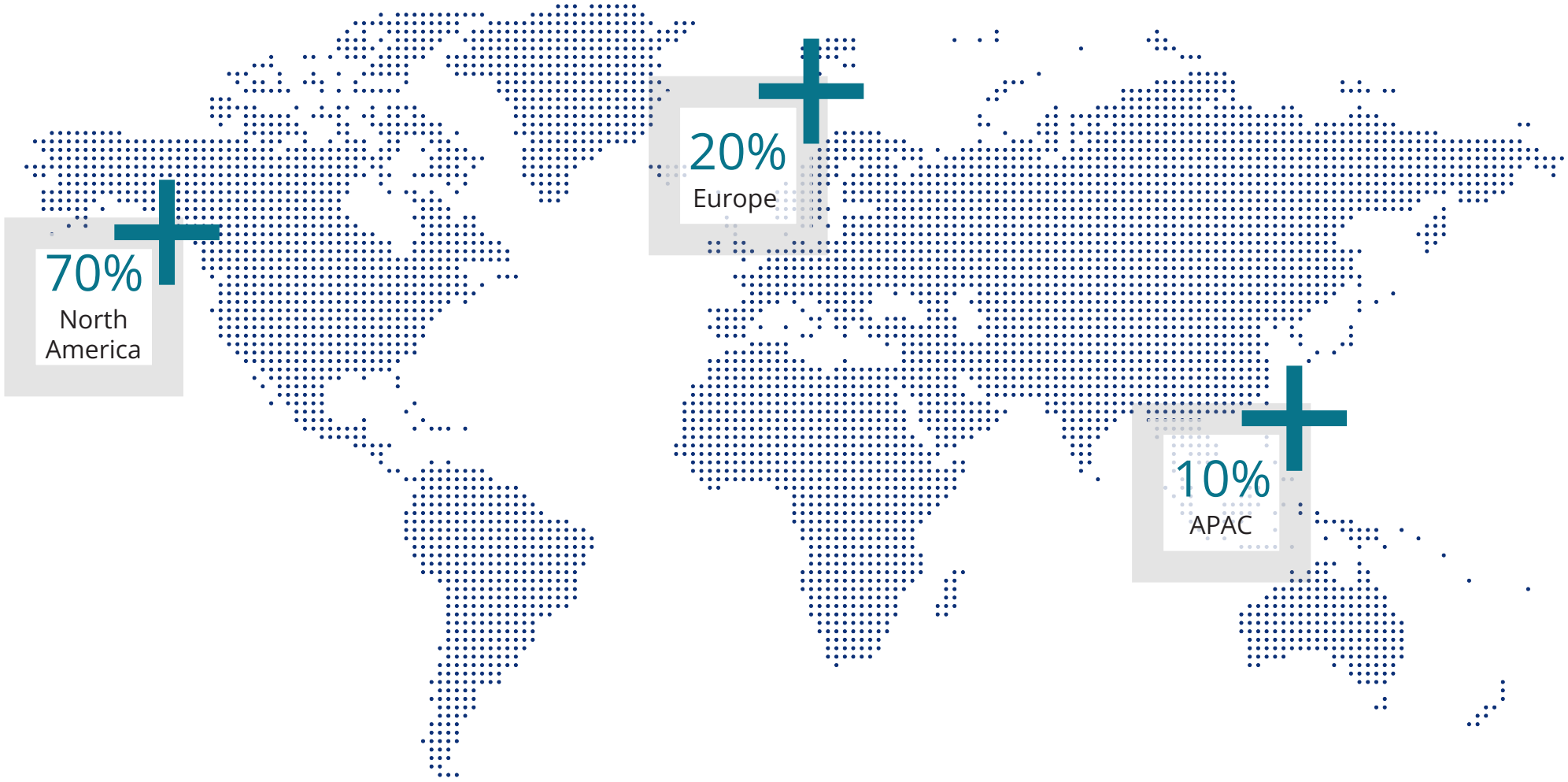
Crosstree consistently closes more Health Sciences and Pharma Services M&A transactions globally than any other firm

200+
Health Sciences Deals

100+
Pharma Services Deals

20+
Deals per Year

TRANSACTIONS BY GEOGRAPHY



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