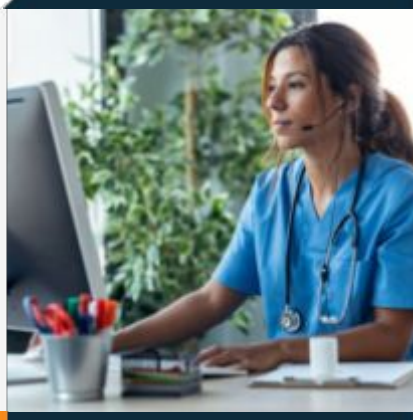
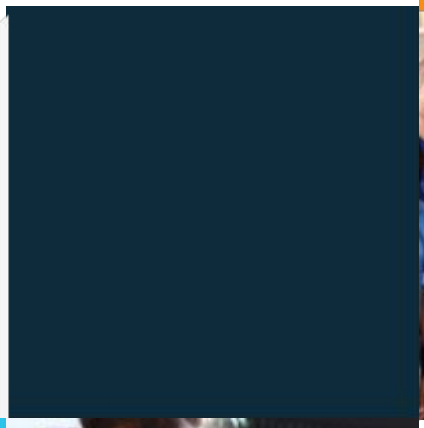
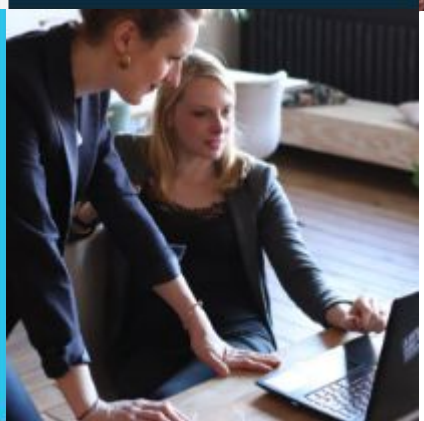
The Consolidation & Reinvention of **Site Networks**

Part 2 (2023)

CRIO
clinicalresearch.io







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Introduction

In a 2019 CRIO eBook, "Scaling and Innovating: The Consolidation and Reinvention of Clinical Research Sites," we explored the emerging trend of clinical research site consolidation. Our predictions were prescient: today, the number of institutional investors in the space has increased by more than seven-fold, and the trend shows no sign of abating. To the contrary, at CRIO, we predict that this trend will continue, and the consolidation trend that occurred within the medical and CRO industries will happen within the site industry as well.

There is inexorable business logic behind this, which we will discuss in this eBooklet, and the recent industry trends towards Decentralized Clinical Trials and Diversity will only accelerate this, as they heighten the need to find new patients from the community.

As a software provider, we service a large number of these networks and are privy to confidential insights. In writing this eBook, however, we have been extremely careful not to divulge any information that is not either (1) public or (2) expressly permitted by the source of the information itself. As such, we may be a bit general in how we express our thoughts, but all of our insights are supported by an upfront seat at the table.

Regards,
Raymond Nomizu
CEO & Co-founder at CRIO

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Industry Update: Clinical Research Site Consolidation

THE RISE OF PRIVATE RESEARCH SITES

To complement research done at academic medical centers, many independent research sites in the 1980's and 1990's started to offer sponsors alternative sources for enrolling patients. Many were private physician practices branching into research, or free-standing research sites dedicated solely to research, with no provision of medical care. Today, we estimate that 25% of the research sites in the U.S. are freestanding research sites (i.e., with no connection to a health care service).[1]

There also emerged a business model for the "site management organization," now often rebranded as "trial management organization" or "integrated research organization". In this model, a professional research site operator partners with physician practices who want to offer research options to their patients but lack the capabilities to do so. These operators install and manage the research staff onsite, while the practice furnishes the patients, real estate and investigators. To sponsors and patients, the research operation appears to be an extension of the physician's practice, but actually represents a separate legal and operational entity.

From the 1990's through the 2010's, these private research site operations became an integral part of the research landscape. Unlike Academic Medical Centers (AMCs), these businesses are able to start up quickly, work with the sponsor's central IRB, and often enroll more patients at lower price points. Often located outside of the major urban centers where AMCs cluster, these private sites offer more geographic breadth, allowing sponsors to reach deeper into local communities - a critical access point given the industry's recent mandate for more diversity.

From ACRP survey conducted in Oct-Nov 2022, 25% of 128 research sites surveyed did not utilize Electronic Medical Records software at all in the conduct of trials, a good indicator that they source their patients from outside of a physician setting.

Read:
Scaling & Innovating: The Consolidation & Reinvention of Clinical Research Sites

Indeed, many trials are bifurcated between what we call “institutional” sites such as AMC’s, major hospitals, and cancer centers, and “private” sites such as physician practices and freestanding sites. Protocols that require access to very specific and more advanced medical conditions such as late stage cancer, surgery, rare disease, or simply advanced forms of chronic conditions often go with institutional sites because they represent centers of excellence to which these patient populations are referred. But for **protocols that need access to a broader population base, such as vaccines or everyday chronic conditions frequently managed by PCP’s, sponsors often select mostly private sites because of their faster startup times and superior enrollment.**

Overall, we estimate the total market size for investigative sites in the United States is $8 billion, and that private sites represent $3 billion of this.[2]

[2]2021 payments to investigators per Sunshine Act was approx. $7.1B per CMS; however, this excludes payments by companies who do not have approved drugs (i.e., numerous biotechs); also, the U.S. CRO market is generally sized at $16B, and roughly half of that is pass-through of site expenses. Of these sites, we estimate 60% goes to cancer centers and academic medical centers, which are not accessible to private network operators.

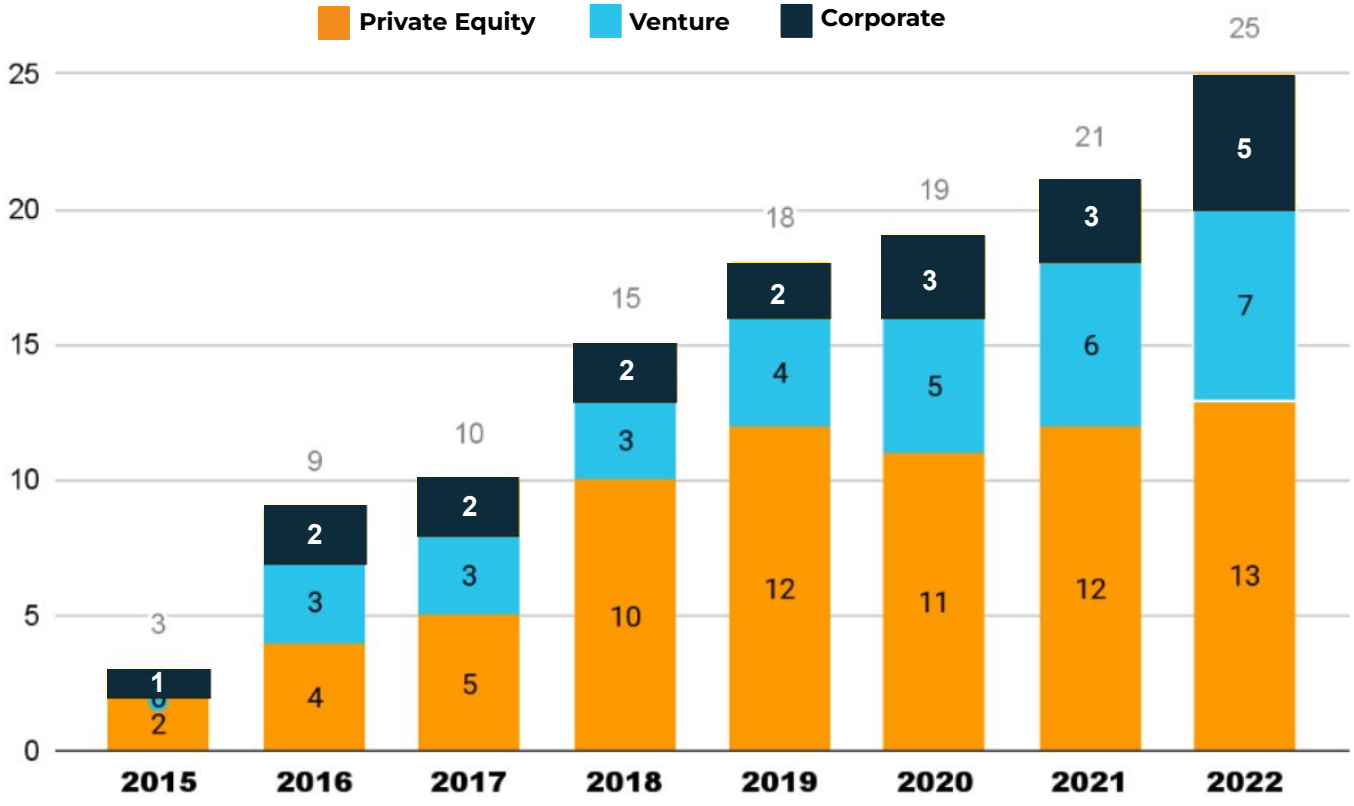
Industry Update: Clinical Research Site Consolidation

THE RISE OF SITE NETWORKS

Starting in 2016, we saw a large increase in the number of institutional investors entering the space by acquiring or investing in new research sites to create multi-site footprints. These investors saw an opportunity to offer sponsors and CROs a single point of contact for multiple PI's and locations, and to standardize and improve best practices in recruiting and operations.

Since then, the industry has seen a large growth in the number of sites operating under a network structure. More investors have entered the market - the below graph shows that as of December 1, 2022, there are now 25 institutional investors in the space, up from only 3 in 2015. In addition, each of these networks is doing their own organic and inorganic growth, acquiring or developing new sites and expanding the throughput at existing sites. As a result, an increasing share of clinical trial subjects are participating in trials run by site networks.

NUMBER OF NEW ENTRANTS BY YEAR (STARTING POINT: 2015)



When the world needed a COV19 vaccine quickly, and the sponsors had to recruit huge numbers of patients in a short period of time, the site networks were critical in these trials. Of the U.S. sites on the Pfizer and Moderna COV19 vaccine trials, we classified 49% as major site networks; 23% as independent sites, smaller networks or community practices; and 28% as institutional sites (academic medical centers or hospital-based health systems).

Driving this is an underlying business logic. **A site network can centralize business development opportunities**, placing studies at multiple sites and negotiating contracts and budgets centrally. They can **augment local recruiting efforts** with central recruitment centers that manage nationwide digital marketing campaigns and utilize call center technology. They can **standardize operations using technology**, developing a single electronic source template to push to sites, and centralizing and even offshoring EDC entry and other activities.

As sponsors require more specialized populations, including access to diverse populations, networks are getting more creative. Rather than rely solely on acquiring larger mature sites, they are investing in greenfield development, striking partnerships with community practices to operationalize research. In fact, there are three broad models of site expansion:

1. Large site acquisition: Acquire an established large site. Usually, networks look for sites with at least $2 million in annual revenue. This strategy is the fastest way to scale, but is also expensive, as the competition for high performing sites can be extremely intense.

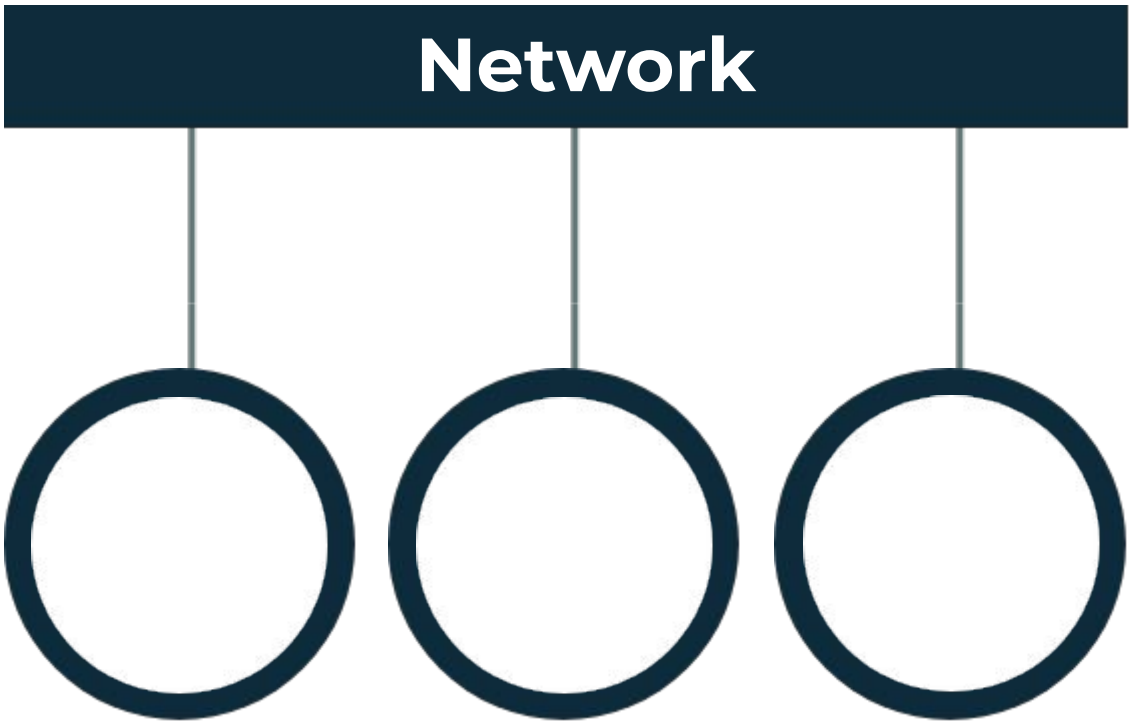
2. Hub and spoke: After establishing a beachhead in a local market, a network can start partnering with local practices, and use their central facility's scale to house operations and staff roving coordinators. CRIO sees this model a lot with private entrepreneurs, and with technology, this strategy can easily scale.

3. Integrated physician model: This is the model of embedding a research coordinator at physician sites, managing them centrally. This approach is a faster way to operationalize multiple locations, but has some risk because of the lack of redundancy at the local level. If the practices are clustered locally, or the site is a large health system, there will be built-in redundancy, as coordinators can cross-staff as needed.

3 SITE NETWORK **OPERATING MODELS**

1

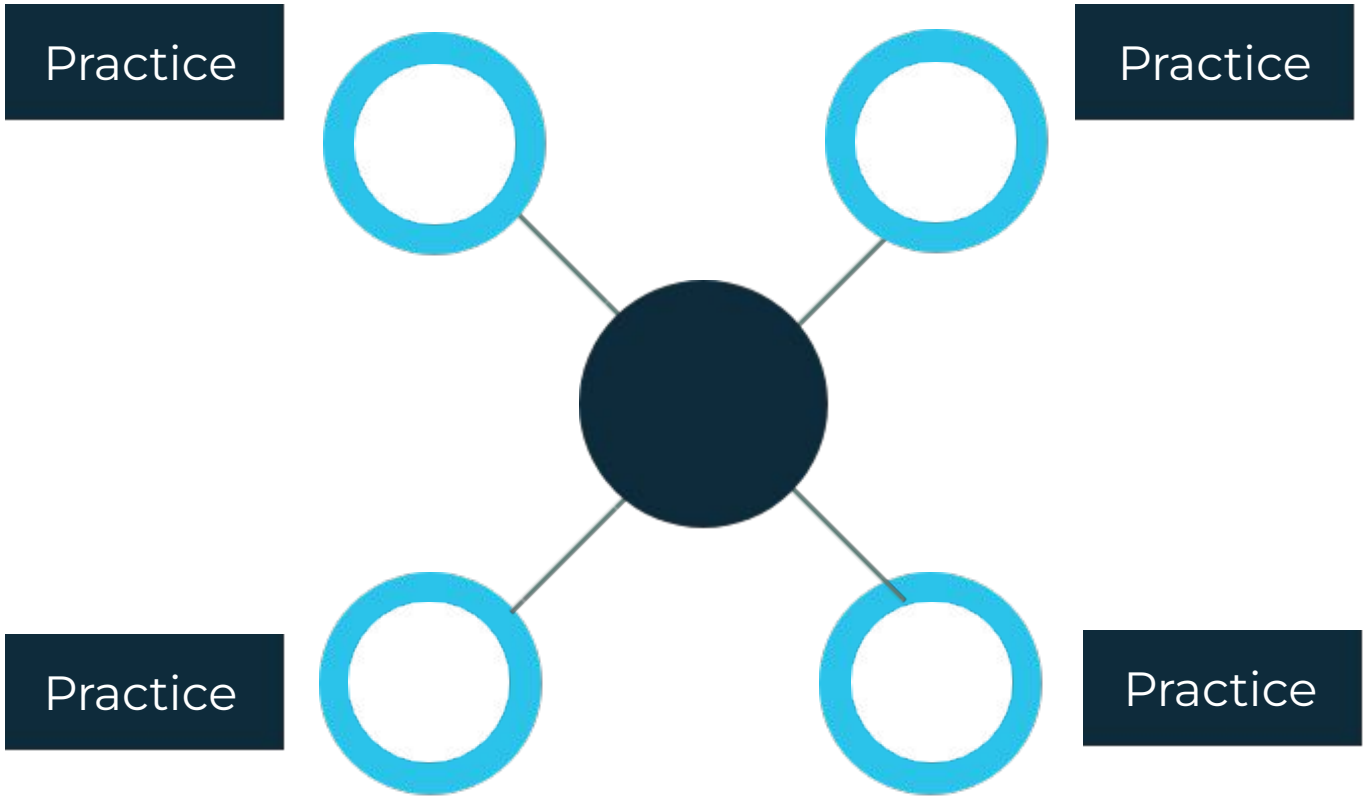
NETWORK OF FREE-STANDING SITES



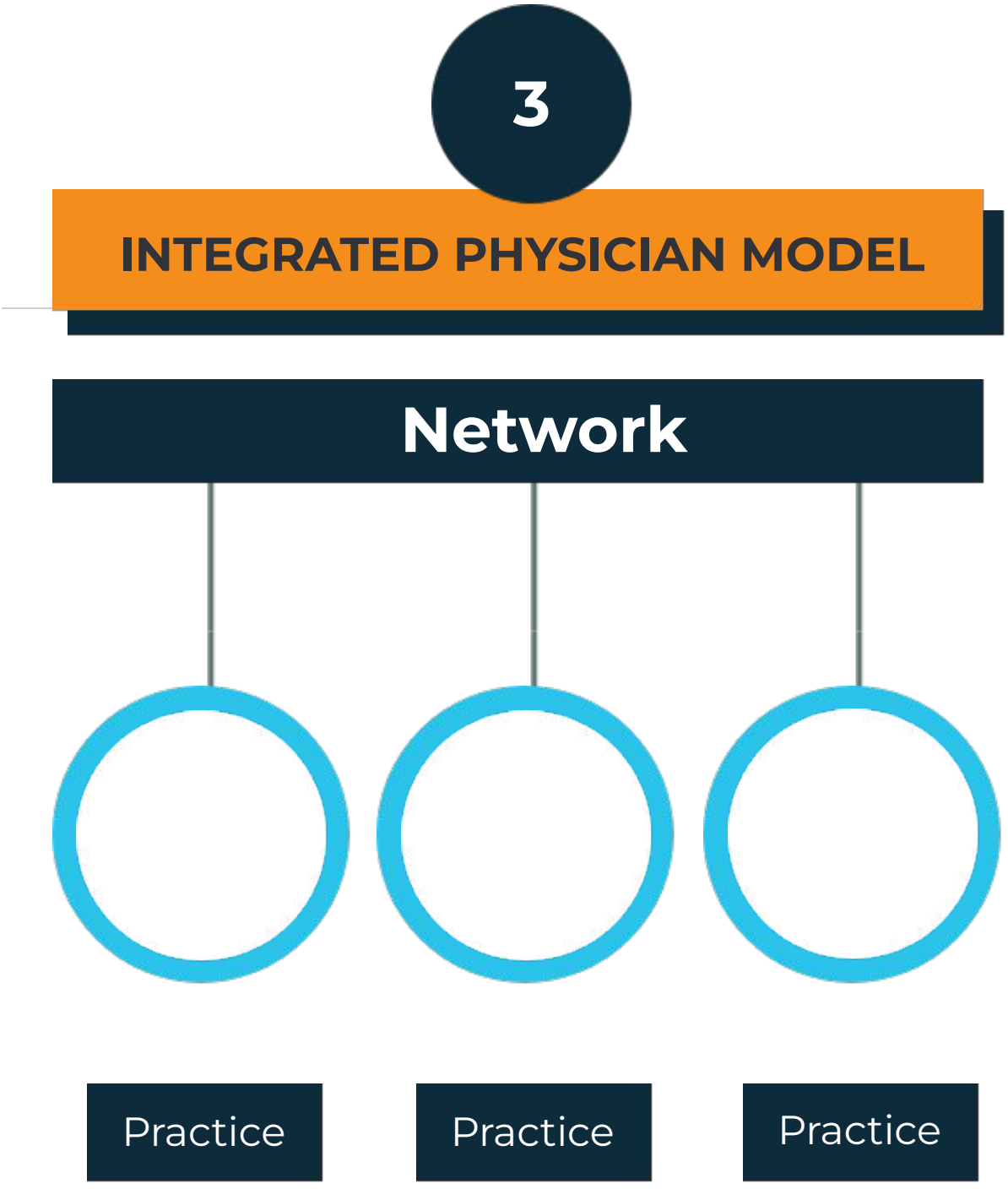
SITE NETWORK **OPERATING MODELS**

2

HUB-AND-SPOKE



SITE NETWORK **OPERATING MODELS**



What's Next? **The Network Players**

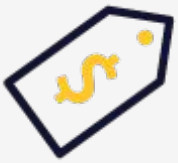
Networks will begin to merge and we will soon see global site **networks with over $1 billion in valuation** emerge.

Many independent site operators will align themselves with a network, and others will exit through retirement. Overall, the rise of site networks should bring more professional standardization and rigor to clinical trials.

THE **NETWORK** PLAYERS

Broadly speaking, the institutional investors can be divided into three types: **private equity, venture capital** and **corporate**.

Private Equity



PE firms prefer the acquisition model, buying up mature sites. For these networks, competition for site acquisition can be intense; and getting the “anchor” site can be particularly expensive. These firms often bring in experienced management teams; create centralized capabilities in business development, finance and operations, and standardize the tech stacks. Many firms will exit to another.

Venture Capital

VC firms prefer to invest in new operating models with disruptive potential, so there will be a wider variety of business models than with PE backed firms. Many of these VC backed startups have been targeting the 98% of research-naive physicians, seeking ways to bring them into research. Many have been developing their own tech stack, becoming both a service provider and a technology provider.

Corporate

A few large CROs have acquired their own site networks. More recently, pharmacy chains have jumped in, seeking to leverage their geographically broad footprints and access to millions of patient lives with insights into their medical conditions. A huge category - but one CRIO is not tracking because it’s so difficult - is the emergence of physician networks that are attempting to roll out clinical research as an independent revenue stream. Sometimes, these networks acquire practices that already have a research operation, prompting them to find ways of centralizing their research.

Ownership:

INSTITUTIONAL

www.clinicalresearch.io
sales@clinicalresearch.io

ACCEL **RESEARCH SITES**

Accel Research Sites is one of five subsidiaries of Accel Clinical Services. They conduct Phase I-IV research studies across numerous therapeutic specialties.

After acquiring AMPLIFY Clinical in 2020, Accel has established itself as the clinical research powerhouse in the Southeastern US. This acquisition brought the Meridien Research site network as well as the NeuroStudies destination research unit and InSearch site business development network to Accel. With more than 20 years of experience since its founding, Accel leverages its access to dozens of disease-specific social communities and patient databases to create a custom marketing plan for each study to attract patients.

First Founded: 1998

First Investment: 2006

Ownership: Institutional

Investor: C3 Capital

CEO: Lora Parahovnik

ACCEL Research Sites Network

Links: Acquisition of AMPLIFY Clinical

ALCANZA **CLINICAL RESEARCH**

After acquiring 5 high-performing clinical research companies, **Alcanza's site network** spans Massachusetts, Michigan, New Hampshire, South Carolina and Virginia, offering full-scale Phase I-IV capabilities in multiple therapeutic areas. Their emphasis on providing diverse patient access is reflected in their geographic coverage as well as their clinical training programs.

Alcanza announced a partnership in June 2022 with Clinical Research Fastrack that will provide full scholarship funding for minority students to attend the Clinical Research Fastrack Bootcamp Training Program. The program effectively provides a talent pipeline for personnel at Alcanza's research sites to meet the industry's increased staffing demands. Alcanza is in the hyperCORE international super network. As an alliance partner, it operates as an independent company but has access to hyperCORE's common functions to streamline business and clinical operations through harmonization and sharing of best practices.

First Founded: 2021

First Investment: 2021

Ownership: Institutional

Investor: ICP Group, Impact Capital, Martis Group

CEO: Carlos E. Orantes

Links: Investment from Martis Capital, Alcanza Joins hyperCORE, Clinical Research Scholarship

ALLIANCE FOR MULTISPECIALTY RESEARCH (AMR)

AMR was founded as an affiliation of independent research sites before merging into a cohesive single platform in 2017. Its 27 locations across the US execute Phase I-IV clinical trials in complex inpatient populations, special populations and healthy volunteers.

In addition to its numerous other therapeutic specialties, AMR prides itself on its vaccine expertise including its involvement in a number of the first Operation Warp Speed COVID-19 trials. Their focus on rapid start-up and enrollment has won them awards as top performers in clinical studies, notably in the vaccine industry.

First Founded: 1994

First Investment: 2020

Ownership: Institutional

Investor: CureWell Capital

CEO: William B. Smith, MD

Articles: CureWell Capital Acquisition, Vaccine Expertise, Top Performer IQVIA

CenExel **CLINICAL RESEARCH**

CenExel conducts Phase I-IV clinical trials at its wholly-owned 19 sites, or Centers of Excellence. With therapeutically-focused sites, CenExel positions itself as a leader in each of the therapeutic areas in which it specializes. These areas are Psychiatry, Neurology, Pain, Human Abuse Liability, Vaccines/Immunology, Dermatology, Ethnic Bridging, Sleep, and Clinical Pharmacology/Phase I.

The Clinical Sciences business unit at CenExel was launched in November 2022 to provide support to the Centers of Excellence and as a standalone consulting service. The business unit is composed of scientists and key opinion leaders in the therapeutic specialties who can support study development and conduct within CenExel and beyond.

First Founded: 2018

Ownership: Institutional

CEO: Tom Wardle

First Investment: 2018

Investor: Webster Equity Partners (majority investment)

Links: Acquisition of Apex, Clinical Sciences Business Unit

CENTRICITY **RESEARCH**

Centricity was founded when Georgia-based IACT Health and Toronto-based LMC Manna Research merged in December 2021. After acquiring two more site networks, **Centricity is now the largest consolidated research network in North America**, with 45 sites spanning the United States and Canada.

With a single source approach that grants access to all the sites and therapeutic specialties within Centricity, the network leverages the combined experience across all its sites to produce a highly-productive system of integrated standard operating procedures, contracting and quality assurance. Centricity is also in the hyperCORE international super network.

First Founded: 2021

Ownership: Institutional

CEO: Jeffrey Kingsley, DO

First Investment: 2021

Investor: Persistence Capital Partners

Articles: Founding of Centricity, Aventiv Research Merger

EVOLUTION **RESEARCH GROUP (ERG)**

Evolution Research Group (ERG) comprises 21 portfolio sites and 4 affiliate sites, a full service CRO through Lotus Clinical Research, and CNS Ratings. With access to specialty units including a Phase I clinical pharmacology unit, a research facility with dedicated operating rooms, and two postoperative surgical analgesic facilities, ERG positions itself as a leader in the early phase CNS research space.

The network launched its full-service CRO capabilities after acquiring Lotus Clinical Research, a niche CRO and site service provider for CNS studies. Its acquisition of CNS Ratings, which provides rater training and surveillance services, further expanded ERG's service offerings. In response to staffing demands, ERG also developed an internal CME program for its clinicians in collaboration with the University of Miami Miller School of Medicine.

First Founded: 2014

Ownership: Institutional

CEO: Lori Wright

First Investment: 2014

Investor: Linden Capital Partners (majority investment)

ERG
Evolution Research Group

Articles: ERG Expands Services, Internal CME Program

FLOURISH **RESEARCH**

Flourish Research was formed by NMS Capital from recapitalization of Clinical Trials of Texas followed by rapid expansion through acquiring additional sites. Their sites conduct Phase I-IV studies in the therapeutic areas of cardiology/metabolic disorders/renal, CNS, pulmonology, and vaccines.

Flourish presents some of their value propositions to be their centralized operations, which have allowed for award-winning excellence in patient recruitment, and their 24/7 e-access capabilities possible through shared tech platforms.

First Founded: 2021

Ownership: Institutional

CEO: Reinhold Schultz

First Investment: 2021

Investor: New MainStream Capital (majority investment)

Links: Keystone Acquisition, Founding of Flourish Research

HEADLANDS **RESEARCH**

Headlands Research is a site network backed by KKR with a mission to integrate high quality research with technological innovation and diversity. Originally based in San Francisco, its acquisitions and expansions have established its presence across the U.S. and Canada.

Headlands acquisitions pride themselves on retaining site autonomy, allowing sites to keep their names and decision-makers after acquisition. One of its key value propositions is its expert recruiting strategies to access diverse patients through its site databases and physician partnerships. Headlands was able to further leverage this differentiator in May 2022 through its partnership with Pfizer to establish diversity-focused sites, including de-novo sites. This initiative plans to target communities with limited research resources and diverse patient populations to bring new investigators and new patients into the clinical research landscape.

First Founded: 2018

Ownership: Institutional

CEO: Mark Blumling (Founder)

First Investment: 2018

Investor: KKR
(majority investment)

Headlands RESEARCH

Links: Pfizer Headlands Partnership, Mark Blumling SCRS Interview

HELIOS **CLINICAL RESEARCH**

Helios is a recently announced network that owns over 20 research sites in Texas, Florida, Tennessee and Indiana across a wide range of therapeutic areas.

As a new entrant, not much has been written about Helios, but what's notable is that its Chairman, Stephen DeCherney, MD, MPH, and its CEO, E.B. McLindon, were both senior executives with global CROs.

First Founded: 2022

Ownership: Institutional

CEO: E.B. McLindon

First Investment: 2022

Investor: Grant Avenue Capital

Link: Launched by Grant Avenue Capital

IMA **CLINICAL RESEARCH**

IMA Clinical Research, a division of The IMA Group, is a physician-founded network of integrated clinical research sites specializing in Phase II-IV clinical trials in multiple therapeutic areas. With more than 150 sites that span 40 states, IMA Clinical Research capitalizes on its expansive geographic coverage and range of therapeutic areas to provide a robust database of 400,000+ patients for sponsors.

For sites, IMA Clinical Research leverages its expertise and ability to deliver various study designs from traditional site-based to hybrid to fully decentralized clinical trials. They provide support services to sites with their Patient Outreach Center to connect with patients who aren't typically seen onsite as well as centralized contracting, and rigorous regulatory adherence to allow quick startup and high-quality studies.

First Founded: 2011

Ownership: Institutional

CEO: Mark I. Weinberger

First Investment: 2018

Investor: The IMA Group

Links: Most Recent Acquisition of Amici Clinical Research

M3 **WAKE RESEARCH**

M3 Wake Research is an integrated network of wholly owned Phase I-IV clinical research sites. With 35 years of experience and thousands of completed trials, Wake Research has access to a database of over 2 million patients and is known for being high performers on large vaccine trials, including those in Operation Warp Speed.

The sites capitalized on their telehealth capabilities to continue patients through studies during the peak of the pandemic despite periodic lockdowns. Their brand new pharmacy and state-of-the-art-confinement unit also positioned the network to specialize in specialty Phase I studies.

First Founded: 1984

Ownership: Institutional

CEO: Ella Grach, MD

First Investment: 2011

Owners: M3 USA

Links: Top CRO Companies of 2021, Acquisition of MSRA

OBJECTIVE**HEALTH**

(formerly Objective G.I.)

ObjectiveHealth provides proprietary technology and expertise to integrate clinical research into healthcare practices. With an original focus on GI indications, their recent name change from ObjectiveGI to ObjectiveHealth in 2021 reflects rapid expansion into new therapeutic areas including dermatology, urology, and oncology.

ObjectiveHealth leverages their proprietary technology, ObjectiveScreen, ObjectiveView, and ObjectiveCare, to identify at-risk patients for providers using artificial intelligence and direct them to ongoing relevant studies. Their technology and virtual solutions also allow for a DCT model to reach a wider range of patients.

First Founded: 2018

Ownership: Institutional

CEO: Colleen Hoke (Co-Founder)

First Investment: 2019

Investors: Panoramic Ventures, First Cressey Ventures, SPRIM Ventures

ObjectiveHealth
TRANSFORMING CARE

Links: Press Release on Name Change, Technology Solutions

VELOCITY **CLINICAL RESEARCH**

Velocity Clinical Research is the largest dedicated research site organization in the world with approximately 80 sites in the U.S. and Europe. It has grown rapidly in the last few years from acquiring several networks, including the highly-regarded Meridian Clinical Research in December, 2022. The size of the network allows sponsors and CROs to circumvent the individual site-selection process to significantly reduce the start-up and recruitment processes. The expansive reach of its networks also boasts a database in excess of one million patients for future recruitment.

Velocity has completed two additional acquisitions of tech platforms that will further enhance its recruiting capabilities. The acquisition of India-based digital clinical trials platform TrierHealth has created a hub for patient-focused technology development while a partnership with Ripple Recruit provides Velocity access to direct-to-patient recruitment software.

First Founded: 2017

First Investment: 2019

Ownership: Institutional

Owner: GHO Capital

CEO: G. Paul Evans

Links: Acquisition of Meridian, New Technology with Acquisition of Tierhealth, Acquired by European Investor GHO Capital, Ripple Recruit Software

Ownership:

VENTURE CAPITALISTS

CARE ACCESS

Care Access markets itself as the industry's leading Decentralized Research Organization (DRO). More similar to a single site with multiple branches than a site network, they operate as one connected team of physicians and research experts.

Care Access employs a "plug-and-play" model to rapidly mobilize entire clinical trial operations to facilities and places where research doesn't exist, including patient homes, long-term care facilities, and community centers. They provide investigators, on-demand research teams, infrastructure, and management capabilities to meet patients where they are.

Their proprietary model with Mobile Site Vehicles has welcomed multiple partnerships with Eli Lilly and AstraZeneca in their COVID-19 trials. Most recently, Eli Lilly announced another partnership with Care Access in its Phase III breast cancer trial with the specific intention of engaging in diverse patient populations that are traditionally under-enrolled in oncology trials.

First Founded: 2016

First Investment: 2016

Ownership: Venture Capital

Owners: Reify Health

CEO: Ahmad Namvargolian (Co-Founder)

Care Access

Links: COVID-19 Trial with Lilly, Oncology Trial with Lilly, COVID-19 Trial with AstraZeneca

CIRCUIT **CLINICAL**

Circuit Clinical is an integrated research organization with a network of 90+ investigators and a database of more than 2.5 million patients. They place an emphasis on clinical research as a care option to reach diverse patients with DCT capabilities for physician groups, health systems, and Federally Qualified Health Centers (FQHCs).

Circuit Clinical offers technological solutions to serve the decentralized model with their own award-winning patient experience platform, TrialJourney, as well as new partnerships with NexGen Healthcare and Medidata. NexGen Healthcare provides Circuit Clinical with access to the 15 million patients at the FQHCs that utilize NexGen's cloud-based healthcare platform. Their exclusive partnership with Medidata creates an innovative DCT turnkey solution with the combination of the myMedidata patient portal and Circuit's TrialJourney. The combination of their digital solutions allows for increased access to patients for recruitment and improved patient engagement for retention.

First Founded: 2016

First Investment: 2020

Ownership: Venture

Owners: Primark Capital

CEO: Irfan Khan, MD (Founder)

Links: Diversity Initiative with NexGen HealthCare, Partnership with Medidata, Partnership with Labcorp

ELLIGO **HEALTH RESEARCH**

Elligo is an integrated research organization that uses EHR mining and their proprietary technology solutions to provide clinical research services for sites and sponsors in the US and Europe. Their model consists of Patient*Select* for patient recruitment and Site*Select* for site support services. Their key value proposition is in their proprietary technology solutions including their own eSource solution IntElligo Research Stack, which launched in 2019. IntElligo aims to integrate into the workflow of any physician's office to facilitate data entry, as well as generate real-time financial management, reports, and analytics across research sites.

Acquisition of AI virtual assistant Root Health further enhanced Elligo's technology offerings. After securing their Series E investment, Elligo significantly expanded support services through acquisition of ClinEdge and its research practice management and clinical services.

First Founded: 2016

Ownership: Venture Capital

CEO: John Potthoff

First Investment: 2017

Investors: Ally Bridge Group, Morgan Stanley Expansion Capital, Norwest Venture Capital, Syneos Health (all in most recent Series E)

Links: Acquisition of ClinEdge, IntElligo Research Stack Technology, Acquisition of Root Health, EHR Mining

JAVARA

Javara is an integrated research organization (IRO) which partners with academic centers and health organizations to deliver research as an embedded option within a value-based care delivery system. As the first IRO in the industry, their mission is to promote Clinical Research As a Care Option (CRAACO) through effective integration with healthcare systems to improve patient outcomes and lower operational costs for these systems with funding from pharmaceutical companies as sponsors.

Javara's key players are its Clinical Trial Navigators (CTN), experienced clinical research professionals who are embedded into the healthcare systems to work alongside clinicians, allowing expansion of research trials to include research-naive sites.

First Founded: 2018

Ownership: Venture Capital

CEO: Jennifer Byrne (Co-founder)

First Investment: 2019

Investors: General Atlantic, FCA Venture Partners, FCA Health Innovators

JAVARA

Links: Recent Partnership with Mankato Clinic, CRIO Interview (Amanda Wright), Javara's CTNs

SITEBRIDGE **RESEARCH**

SiteBridge is a portfolio company of Health2047, a Silicon Valley-based innovation subsidiary of the American Medical Association. Operating under the "Trial-in-a-Box" model, SiteBridge facilitates the participation of a broader set of physicians from small practices to conduct clinical research.

They emphasize the opportunity to represent a more diverse set of patient populations by providing clinical research as a care option in the community setting.

First Founded: 2021

First Investment: 2021

Ownership: Venture Capital

Investors: Health2047

CEO: Chris Komelasky (Co-founder)

Articles: Health 2047 Launches SiteBridge, Co-Founders on Launching SiteBridge

TOPOGRAPHY **HEALTH**

Topography Health provides full-stack clinical research support services for community physicians to break into research, expand, and scale clinical trials. With a software and services platform, they support medical practices and clinicians in understanding their patient populations, identifying suitable clinical studies, recruiting patients, and providing operational and personnel support in clinical trial conduct at no cost to physicians.

For sponsors, Topography offers the opportunity to unlock new patient populations by training research-naive physicians in areas historically excluded from or overlooked by research trials.

First Founded: 2022

Ownership: Venture Capital

CEO: Alexander Saint-Amand (Co-Founder)

First Investment: 2022

Investors: Bain Capital Ventures, 75 & Sunny, Andreessen Horowitz, FJ Labs

TOPOGRAPHY HEALTH

Articles: Topography Health Launches, Named Top 150 Digital Health Companies of 2022

VIAL

Vial is a CRO that connects 50+ sites in their Vial Preferred Site Network to sponsors. Their CROs are divided by therapeutic specialty into Oncology, Dermatology, Ophthalmology, Gastroenterology, Neurology, and Cardiology CROs each led by ClinOp leaders and Scientific Advisors in the specialties.

Vial emphasizes their Silicon Valley-trained tech team that is behind the development of their technology platform that combines Vial eSource, Vial EDC, and Vial ePRO. To distinguish themselves from traditional CROs, Vial's fixed-fee pricing model provides upfront attractive costs for sponsors that are more transparent and lower than variable pricing models.

First Founded: 2020

Ownership: Venture Capital

CEO: Simon Burns (Co-founder)

First Investment: 2021

Investors: Byers Capital, General Catalyst, BoxGroup

Articles: Closes Series B Funding, Fixed-Fee Pricing

Ownership:

CORPORATE

ACCELLACARE

Accellacare is a global clinical research site network launched by ICON in September 2020. The site network includes PMG Research and MeDiNova previously acquired by ICON. A 2021 expansion through global partnerships further boosted its presence to include six countries with 100+ active research sites and connected it to 8.5+ million patients. As a subsidiary of ICON, one of the largest CROs in the industry, Accellacare provides feasibility and central process management that enables fast study start-up and robust recruitment capabilities even for research-naive sites and staff.

Its operations are integrated with ICON-owned Symphony Clinical Research, a leading global provider of at-home care and nursing for clinical trials. Their in-home service sector is one of their key value propositions that aims to increase patient recruitment, retention, and diversity.

First Founded: 2020

First Investment: 2020

Ownership: CRO

Owner: ICON

CEO: Steve Butler (ICON)

Accellacare

Links: Accellacare Launch, Accellacare 2021 Expansion

CVS HEALTH CLINICAL TRIAL SERVICES

Strategy:

This is a new business arm launched in May 2021 by **CVS Health**, initially started to facilitate clinical trials for COVID-19 vaccines and treatments. As the leading health solutions provider in the U.S., CVS has access to a population of a hundred million patients across their retail pharmacies, Aetna insurance plans, and MinuteClinics.

CVS mines their extensive database for recruitment purposes and directly contacts patients with whom they have already built a relationship of trust. MinuteClinics were easily transformed into research sites at locations convenient for a broad range of patients to operate decentralized trials. In addition to Phase III/IV clinical trials, CVS is also able to use their existing database to conduct retrospective and real-world evidence studies.

First Founded: 2021

Ownership: Pharmacy

CEO: Karen Lynch (CVS Health)

First Investment: N/A

Owners: N/A

Links: Interview with CVS Executive, CVS Launches Clinical Trial Services

PPD

PPD's global network of sites includes sites that it owns under its business unit Accelerated Enrollment Solutions (AES) and the PPD Select site network of partnered sites. As one of the largest CROs in the world, it provides full service, customized strategies to sponsors.

Notably, PPD acquired Acurian in 2013 to augment its patient recruitment and retention services. AES under PPD operates a novel approach to patient enrollment where patients are identified first from their existing databases before selecting sites in patient-rich locations. During the COVID pandemic, AES capitalized on its large size by launching a patient-transfer program that transferred patients from other struggling research facilities impacted by the pandemic to AES sites. The research sites in AES were the result of three major networks acquisitions: Radiant in 2015, Synexus in 2016, and BioClinica's network in 2019.

First Founded: 1985

First Investment: N/A

Ownership: CRO

Owners: N/A

CEO: David Simmons

Links: PPD Acquires Acurian, PPD Acquires Bioclinica, Patient-Transfer Program, Inverted Enrollment Model

WALGREENS

Following CVS Health, **Walgreens** also announced the launch of its clinical trial business. Coinciding with the FDA's diversity initiative, Walgreens promotes their research trials similarly to CVS in providing convenient access to clinical research as a trusted presence in the community.

Of note is their partnership with PlutoHealth, a technology care-coordination service that aggregates health information from multiple providers and locations within 30 minutes. They also provide clinical care guidelines based on evaluation of the collective health information. PlutoHealth's system allows smart analysis and mining of Walgreen's data to enhance patient recruitment and retainment as well as perform retrospective studies to collect real-world evidence.

First Founded: 2022

Ownership: Pharmacy

CEO: Rosalind Brewer

First Investment: N/A

Owners: N/A

Walgreens

Links: Walgreens Launch Clinical Trial Offerings

The Deal Landscape: A Banker's Tale

An interview with Jason Layton, Director, Site Consolidation & Private Equity at **CrossTree Capital**

Q. Who is Crosstree?
A: Crosstree Capital is a financial advisory firm focusing exclusively in the health sciences sector, with an emphasis on pharma services. In the site network space, we've been very active representing private owners interested in selling their sites, as well as site networks interested in acquiring sites.

Q: Are you seeing any slowdown in interest in site network consolidation?
A: I am not seeing a slowdown. The interest is still strong from private equity (PE) firms to get in on the game. They've realized that the site world is quite fragmented, which makes it attractive for investment. There has been more conversation about patient recruitment, and therefore patient recruitment firms get a lot of exposure. Yet the actual recruitment is happening at the research sites. So there's a lot of room for improvement at the site level, in terms of technological advancements, scaling, business development, etc. Oftentimes, networks can acquire smaller sites that have great potential to scale because of their access to specific patient populations, but aren't living up to their potential, and that's where the networks can add a lot of value relatively quickly.

Q: What has changed in the industry dynamic?
A: The idea of site networks was completely unheard of when I was starting in the business. For example, you could not own a site that you would also monitor. Then PPD and ICON broke this barrier by acquiring site networks. Additionally, sites used to be predominantly owned by physicians who were very entrepreneurial and not willing to become employees. However, in today's healthcare landscape, most physicians are employees, so that mindshift has already occurred.

The Deal Landscape: A Banker's Tale

Q: How will this trend progress, in your opinion?
A: It will definitely continue, there's no going back. At some point, though, sponsors will only need a certain number of sites to feed their studies, and with the law of diminishing returns, you'll see networks start merging with each other to drive further consolidation. Some open questions are whether networks should focus on specific therapeutic specialties or be multi-therapeutic, and whether networks can go truly global, given that the site market in EU is much more institution-based.

Q: What type of sites are investment firms looking for?
A: Firms approach these decisions from an enterprise perspective. Networks love to find low-performing sites who have a lot of research experience and a large patient database. These sites have a lot of potential and room for growth, and are selling at prices below their true potential. For example, as an investment adviser, we generally would not consider representing sites with less than $3 million in EBITDA - but many such sites would be attractive to networks. Additionally, one trend that we are seeing is an abundance of sites that were doing COVID trials who now may have lower revenue forecasts. A lot of buyers struggle with how to remove the COVID bump. On the one hand, we all recognize that the COVID vaccine work was somewhat transient, but on the other hand, a lot of strong, diversified sites took on these trials because they were the best opportunities available, so you wouldn't want to over-penalize them.

Q: Ok, big question: What do sites trade at?
A: It's based on EBITA. For $5-10 million EBITDA range, we'd expect to see EBITDA multiples in the 7-9x range; for lower EBITDA, maybe 4-6x. When you clear $10 million in EBITDA, you might start seeing EBITDA multiples over 10. As a general rule, we see a 25-50% EBITDA range on mature research sites, so a $10 million revenue site might be doing $4 million of EBITDA so therefore could expect a $28-$36 million price point.

Q: Do you have any closing predictions for the industry?
A: I think we are already seeing less new platforms being built and much of the movement in the industry will occur through network M&A. Instead of having 10-15 large site networks, the site landscape will start to look similar to the CRO landscape where we have 3-5 major players. Site consolidation is professionalizing the industry.

What's Driving Network Consolidation?

There are plenty of instances where institutional capital goes into a sector, only to fizzle out. Why are we confident that the site network trend is real, and not hype?

We've identified 4 main levers of revenue and profit growth for network consolidation, as illustrated above. In order, from the "quick hit" to the heaviest lift.

4 MAIN LEVERS NETWORKS USE **TO CREATE VALUE AT NEW SITES**

Business Development

Increase study throughput by sourcing and placing more studies at sites

Budget Negotiation

Negotiate higher budgets by leveraging the network's scale and brand.

Centralized Recruiting

Use advanced digital marketing, central call center to recruit patients

Operational Standardization

Standardize operations to reduce inefficiencies

What's Driving Network Consolidation?

1

Business Development

Instead of multiple sites managing their study pipeline, a network can create a central team. This team offers sponsors a single point of contact to stand up multiple locations. One CEO reported that his network is usually able to place new study opportunities at acquired sites that they were not previously aware of. Thus, the network can augment revenue at an acquired site simply by bringing them into more studies..

2

Budget Negotiation

With scale and success comes negotiation leverage. A network may be able to negotiate higher rates across the board, higher than what a single site may achieve. This pricing lever is extremely powerful, as nearly all the incremental revenue realized goes to the bottom line.

3

Recruiting

A single site may have a large database and a strong recruiting team. But if 10 of them are housed in one roof, the network can move from 10 recruiting centers to a single centralized call center, operating with longer hours and incorporating more sophisticated VOIP technology. In addition, a network can invest in a patient marketing team that can bring digital marketing capabilities to augment the team's efforts. When partnering with practices, the network can bring in AI tools to mine the EMR for likely prospects, then centralize outreach and qualification.

4

Operations

Finally, the network can standardize operations, driving quality and consistency - and therefore efficiency - across multiple locations. The majority of networks adopt the full eClinical stack for sites - eSource, eConsent, eRegulatory - which embed quality into the design, thus reducing protocol deviations and coordinator re-work. For instance, Benchmark Research moved away from paper charts during the pandemic, incorporating CRIO's eSource tool across all their sites. In a subsequent, large-volume study, they quantified a 38% reduction in protocol deviations. This improvement in quality translates directly into efficiency by reducing rework, while augmenting their value proposition to sponsors. With more time freed up for coordinators, they can reinvest that time to recruitment and retention, critical revenue drivers.

Taken together, the four drivers make a strong case for revenue and cost synergies. To be clear, networks are at very different levels of maturity across the four levers, and operational models are still evolving. Nonetheless, the first network to master all four synergies would become a potent player and equip themselves for long-term success.

The **Tech Stack**

Networks are brick and mortar businesses, by definition, but their differentiation lies in their ability to incorporate and optimize technology in every step of the workflow. No single technology vendor will be able to service the full gamut of needs; instead, leadership teams should select and configure optimal solutions for different stages of the value chain, and drive as much interoperability across the solutions as they can. Here are the critical elements of the “tech stack:”

Business Development

Business development teams need a CRM system to manage the study pipeline and B2B selling opportunities. This requires a system to track sponsors and CROs as accounts, and studies as opportunities. When the studies convert, they enter the CTMS.

THE **TECH STACK**

CTMS

Historically, CTMS refers to scheduling, recruiting and financial management - the “back office”. The scheduling module should help sites manage study visit windows. The recruiting module lets sites manage patients *before* they become subjects in a study. And the finance module allows the sites to manage the specific complexity of clinical trial operations, tracking revenue recognition based on clinical events, ideally by tying revenue events to eSource data collection.

eClinical

eSource, eISF and eConsent make up the trio of technologies - the “exam room”. More recent additions, these technologies standardize and streamline data collection on clinical trials. They are critical to enhancing data quality and enabling centralized oversight. These technologies minimize re-work, free up valuable coordinator time (thus increasing throughput), and enable centralization and even off-shoring of functions historically done at the local level. They are critical to taking site operations to the next level.

Patient CRM

While the recruitment function at CTMS is adequate for coordinators to manage patient communications, most CTMS systems are not built to support sophisticated central marketing campaigns. Instead, networks should supplement local recruiting efforts with a centralized CRM system for online recruiting. The CRM system should manage campaigns, track lead sources, automate lead activities including all outbound communication efforts across channels (calls, texts and emails), incorporate customized pre-screening qualification activity, and present robust views of the marketing funnel.

Virtual Contact Center

Centralized recruiting teams require call centers to perform phone screenings for patient qualification and placement. Call centers need technology to optimize and streamline VOIP communications (e.g., autodialing, routing) for maximum efficiency. Many virtual contact center solutions can integrate seamlessly into the CRM system used, so that the calling cadence can follow pre-programmed campaign rules.

THE **TECH STACK**

Finances

While the financial function for CTMS helps manage revenue recognition for the clinical trials, they generally cannot manage the P&L, balance sheet or other components of a financial system. Large organizations need workflows and controls to manage all aspects of their financial operations, so ideally CTMS is used for study revenue recognition and can feed the underlying financial platform used.

Analytics

While each of the above systems will have their own reporting tools, enterprises need business intelligence to manage operations and gain insights to drive continuous improvement. Ideally, each of the components in the tech stack can feed a single data lake, with a business intelligence tool that can integrate and visualize data across the solutions. For instance, a BI tool could integrate the upstream marketing funnel from the patient CRM with downstream randomization from eSource to create an end-to-end funnel.

All this technology requires a dedicated CTO and a staff. This team's mandate is to identify, configure and implement the appropriate technology solutions, and ensure that the solutions operate with maximum interoperability to reduce redundant workflows or data discrepancies. The goal of the tech stack is to support the business objectives of the network, and allow the enterprise to scale.

At CRIO, we recognize that we're a critical piece of the puzzle, but not the only piece. We've built a best-in-class enterprise grade eSource solution with fully integrated eConsent, CTMS, eRegulatory and other solutions, but we're also committed to interoperability so that we can work with, and not against, the needs of the enterprise.