BOURNE PARTNERS

MARKET INSIGHT

eClinical & Ancillary Clinical Trial Services

October 2019

www.bourne-partners.com

INTRODUCTION

Key Market Trends

After speaking with a wide range of CRO executives, including CEO's of multi-national corporations, Heads of Corporate Development, Founders, as well as leading niche-service providers, we've identified three of the most important trends within tech-enabled/ancillary clinical trial services that seek to improve the clinical trial landscape:

- Improve efficiency of patient enrollment
- Utilize wearable technologies
- Optimize the capture and management of additional patient data

In aggregate, these three areas of opportunity will improve the entire spectrum of clinical trials – from patient enrollment, adherence, and retention to improving trial efficiency through new, real-world patient data collection.

Current Market Landscape

The increase in demand for specialized clinical trials, in conjunction with advancement of technology within the space, has led to the growing need for eClinical and Ancillary Clinical Trial Services. These value-added, niche-focused services seek to lower drug development costs, while expanding study populations through novel clinical trial models (such as virtual trials and/or decentralized trials), as well as optimize data collection and analysis. Ultimately, the goal is to improve the patient journey and move a drug from development to market faster and cheaper.

This report serves as a follow-up to the *Clinical Site Networks & Site Management Organizations (SMOs)* Market Insight Report (June 2019), which highlights the key industry trends and growth drivers within the clinical sites space. A copy of the report can be found in the link above.

Key Trends in Clinical Trial Services

We spoke with Chris Porter, current VP of Marketing & Digital Strategy at ERT, and former Founder & CEO of Clinipace

> **"Many CROs tout their adoption of technology as a differentiator, and the CROs that successfully separate themselves from the pack will be those that leverage technology to re-engineer the trial model to be more efficient in terms of both time and cost"**

Decentralization of Data Collection

One of the most promising near-term advancements to clinical trials is trial decentralization. As Chris Porter described, "these technologies, both existing and emerging, are found all along the clinical trial value chain, and include expanded use of electronic clinical outcome assessment, wearables, sensors, and other devices that enable organic data collection, meaning they collect regulatory quality data with minimal patient burden, and in some cases, completely passively as trial participants go about their daily lives, helping them live more full and normal lives while participating."

"The Patient Journey"

There is a clear focus of investment and energy on improving "anything that makes the patient journey easier." Through virtualization and decentralization, along with the incorporation of wearables, clinical trial data collection can be vastly improved. If the patient journey can be less-intrusive, yet more inclusive, while improving real-world data points, the clinical trial process becomes easier, more accurate, and more cost effective. Chris stated this idea best when he said, "While we use terms like virtual, decentralized, and patient centric, it really boils down to making participation easier for the patient, and prioritizing the patient experience including their assessments of progress and outcome."

Specialization

Despite the highly fragmented industry, with multi-national CROs leaving middle-market firms to fight for remaining market share, middle-market CROs can be successful through specialization. That specialization can take many forms. In addition to the specialization through the use and implementation of technological innovation, there are also opportunities to specialize in patient engagement and patient reported outcomes, therapeutic expertise, as well as other strategies that allow smaller service providers to better align their focus with smaller pharma and biopharma sponsors.

> **"As long as the overall market continues to expand, I think PE interest will in clinical trial services continue. Of course there are waves of activity and the next wave I would expect to be around novel models and technologies that support them. As a result, both private equity and strategic buyers will be more drawn to software and data-focused platforms and solutions"**
>
> **– Chris Porter, *VP of Marketing & Digital Strategy* at ERT**

How to Value Niche, Tech-Based Service Providers

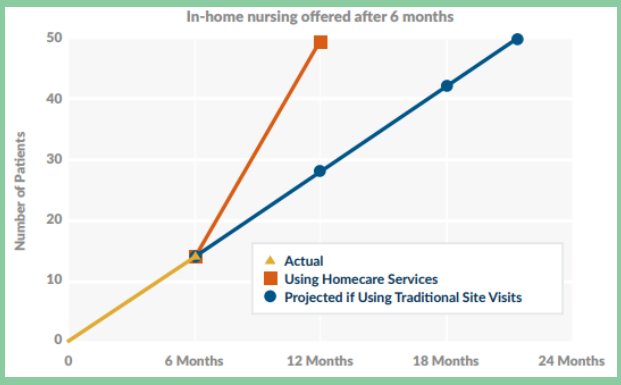
In many respects, valuing eClinical, niche clinical trial services is akin to valuing tech-based companies – companies are rewarded for their superior revenue and user growth, over wide margin profiles and stable cash flows. Technology companies are valued more on growth, customer uptake, and potential future earnings, as opposed to a traditional valuation based on current profitability. Many of the ancillary service providers act as tech-based service providers with a pharma-focused customer base, as opposed to a traditional pharma/pharma services company. As such, we would expect to see positive sentiment from investors in the space as these service providers continue to be plugged into more and more clinical trials in an ever-evolving outsourcing model.

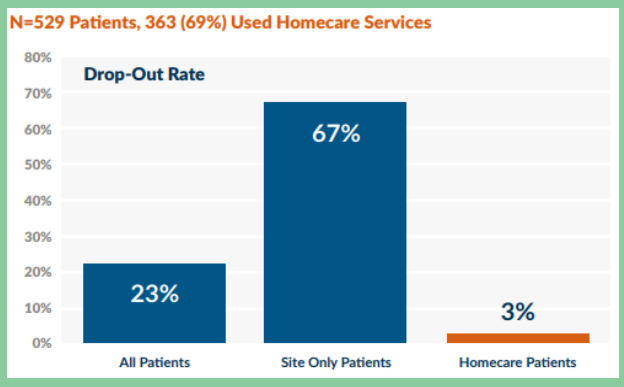
Case Study on In-Home & Alternative Site Services: Symphony Clinical Research

Symphony CLINICAL RESEARCH®
Orchestrating Trials in Motion℠

Symphony Clinical Research is a global leader in providing in-home and alternative site clinical trial services. By bringing clinical trial visits directly to patients in their home or another place of convenience, the company offers the ability to participate in a clinical trial with minimal disruption to one's daily life. This service eases the patient burden – meaning more patients are willing to enroll in a trial – allowing sponsors and CROs to meet their enrollment targets more quickly.

Symphony's home care services can be used to complement traditional clinical trial services and create a hybrid approach, working with sites to eliminate the time and travel burden for patients, leading to reduced dropout rates, and even easing the work burden for site staff.





> **"Bringing a new drug to market can take 10 years and more than $2bn, which is economically unsustainable. Because of this, drug sponsors and CROs are being forced to re-evaluate the traditional drug development model. Companies that would normally be resistant to change are eager to try new approaches, including patient-centric approaches that take the trial to the patient via homecare, virtual trials, telemedicine, etc."**
>
> **– Nicki Norris, CEO, Symphony Clinical Research**

Implications of the Shifting Clinical Trial Landscape

As demonstrated throughout this report, there is no question that the clinical trial landscape is evolving through the adoption of new, innovative technologies. We spoke with Sam Osman, CEO of Cenduit, to better understand the byproducts of this shifting environment.

Ownership of Trial Compliance

With virtual and hybrid trials likely continuing to gain momentum over the next 1 to 3 years, clinical trial integrity must be maintained throughout to ensure patient compliance, medication management, and protocol adherence. While ownership over clinical trial compliance has traditionally been a responsibility of study investigators, the shift to virtual trials requires a shift in study ownership. As Sam Osman described, "this onus shifts to technology companies who will be tasked with ensuring data integrity, as well as patient compliance and engagement."

Advanced Data Manipulation & Analysis

Given the growing implementation of wearable technologies and sensors, the question becomes: how can CROs and other ancillary players leverage this data in the most powerful way? The answer is Artificial Intelligence and Machine Learning. However, while sponsors and providers have been looking to capture more data through the use of wearables and sensors, the variables captured have been viewed as distinct and independent data streams. While utilization of this technological advancement has led to more data captured, the manipulation of this data has not yet reached its full potential. Sam Osman believes this is an avenue for further growth and innovation in the space: "With improved algorithmic models, the confluence of multiple streams of data to better predict adverse events exists: shifting the approach from retrospective analysis of a single data stream to a more proactive view of overall patient health by analyzing 'disparate' sensor streams in real time for improved intervention."

Technology Takes Precedence?

While the implementation of new technology and related services will ultimately improve clinical trial efficiency and outcomes, Sam described that the core deciding factors for drug sponsors when selecting a CRO remain focused on two key aspects: 1) how will the CRO recruit patients, and what is its access to these patients, and 2) what therapeutic expertise does that CRO offer that can reduce operational risk of the study? However, it is possible that in the future sponsors will place more value on technology services, if the new eClinical-based models can successfully dethrone traditional methods.

> **"The next wave of cost reduction will come from drug supply savings – more effective distribution strategy and pooling of studies to reduce expired or wasted active and comparator drugs."**
>
> **– Sam Osman, *CEO of Cenduit***

Cenduit is an industry leader in the Interactive Response Technology ("IRT") market and eClinical field, and has implemented over 1,500 clinical trials requiring patient randomization, clinical supply distribution and returns/destruction accountability. In over 10 years of operation, Cenduit has worked closely with more than 100 global biopharmaceutical companies and has deep integrations with many CROs across all geographies.

RECENT M&A ACTIVITY

eClinical & Ancillary Clinical Trial Services – Transaction Comps

Announced Date	Target	Target Description	Buyer	Enterprise Value	Geographic Location
Sep-19	Forte Research Systems	Forte Research Systems develops and markets clinical trial management, clinical data management, and research management software for cancer centers, academic medical centers, and health systems.	Advarra	NA	USA
Aug-19	THREAD	THREAD operates as a virtual research platform for capturing clinical study data during and instead of clinic visits.	JLL Partners; Water Street Healthcare Partners	NA	USA
Jun-19	Medidata Solutions	Medidata provides cloud-based solutions for life science companies worldwide. It offers the Medidata Clinical Cloud, analytics, and clinical technology for drug development.	Dassault Systemes Americas	$5,822.3	USA
Feb-19	Linguamatics	Linguamatics develops text mining solutions for the pharmaceutical industry. The platform creates analytics, advanced research, and improved patient outcomes.	IQVIA Holdings	NA	United Kingdom
Jan-19	Velos	Velos develops clinical research management software solutions to organizations across the world.	WIRB-Copernicus Group	NA	USA
Dec-18	SNBL USA	SNBL conducts preclinical drug development studies in the United States. Its specialized capabilities include safety assessment of biologics, toxicology, pharmacology, immunotoxicology, and carcinogenicity.	Altasciences Company	NA	USA
Dec-18	Advanced Health Media	Advanced Health Media provides software and services to manage healthcare professional engagements. The company offers six different software platforms.	IQVIA Holdings	NA	USA
Nov-18	159 Solutions	159 Solutions provides analytical solutions to life sciences clients.	IQVIA Holdings	NA	USA
Oct-18	goBalto	goBalto offers a data-driven approach to the identification of sites and target populations for studies; The company also provides updates across studies and insights to streamline operational processes.	Oracle	NA	USA
Aug-18	Kinapse	Kinapse offers services in the areas of quality and compliance, medical affairs, development operations, clinical operations, pharmacovigilance, medical writing, among others.	Syneos Health	121.0	United Kingdom
Jul-18	CRF Health	CRF Health develops electronic clinical outcome assessment (eCOA) solutions for home and site-based phase I-IV clinical trials for various therapeutic areas and patient populations.	Bracket Global	NA	USA
Jun-18	Sciformix Corporation	Sciformix provides knowledge-based consultancy and services to life science companies. It offers services in the areas of biometrics, scientific writing, safety and risk management, and regulatory affairs.	Covance	NA	USA
Mar-18	Applied Clinical Intelligence	Applied Clinical Intelligence provides specialty services to mitigate risk and ensure patient safety in clinical trials through decision support tools to the clinical research industry.	WIRB-Copernicus Group	NA	USA
Nov-17	MDDX	MDDX develops software for biomedical data collection.	BioClinica	NA	USA
Oct-17	DrugDev	DrugDev operates as a data sharing platform for clinical trials. It offers solutions in the areas of site selection and feasibility, patient feasibility, eConsent, site engagement, patient engagement, and trackers.	Quintiles IMS Holdings	NA	USA
Aug-17	Parallel 6	Parallel 6 develops and provides enterprise cloud-based technologies that enable customer engagement and real-time data insights across multiple industries.	PRA Health Sciences	$49.7	USA
Jul-17	MAPI Developpement	MAPI Developpement engages in creating studies to evaluate drugs. It provides risk management plan, direct patient management, signal detection, strategic consulting, and linguistic validation.	ICON	$139.5	France
Apr-17	Mytrus	Mytrus specializes in patient-centered electronic consent and data collection tools. The company develops remote consent and virtual data collection solutions for running clinical trials.	Medidata Solutions	$14.0	USA
Sep-16	ExecuPharm	ExecuPharm offers clinical trial management, monitoring and site management, clinical trial administration, document management, medical writing, regulatory, among others.	PAREXEL	$155.0	USA

Key Takeaways from M&A Activity

The market is demonstrating a demand for innovation by the larger traditional players as evident by the number of significant acquisitions and consolidation activity

Consolidation Among Proven Services

- The buyers above are some of the largest global and diversified CROs
- The acquisition targets are mostly ancillary service providers, but have been proven to deliver niche, value-added services and capabilities

Wide Range of Service Offerings

- Of note, the acquisition targets represent a large spectrum of service offerings across the clinical trial supply chain
- However, a large number of the targets are centered around data – collection, sharing, analysis, etc.

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1) $USD in mm

RECENT PARTNERSHIP ACTIVITY

eClinical & Ancillary Clinical Trial Services – Partnerships & Alliances

Announced Date	Partnership Between		Description
Sep-19	Bayer	Accenture	Accenture Life Sciences annouced that its AI clinical data collection and management tool, Intient, is being used by Bayer. Under the collaboration agreement, Bayer will also join the Life Sciences Cloud Coalition.
Sep-19	Micron	AMRA	The digital health company AMRA has entered into an exclusive agreement with the largest imaging CRO in Japan as part of its work to provide 'critical informatics' to the drug development industry.
Jul-19	Pfizer	Syapse	Pfizer and Syapse annouce strategic collaboration that will generate insights from de-identified real-world data and advance oncology outcomes research.
Jun-19	PAREXEL	Clariness	PAREXEL entered into a strategic partnership with Clariness, a global patient recruitment company, to speedup clinical trial recruitment and patient engagement in China.
Feb-19	Boehringer Ingelheim	IBM Canada	The alliance aims to test whether blockchain technology in clinical trials provides a decentralized framework that enables data integrity, provenance, transparency, and patient empowerment as well as automation of processes, ultimately improving trial quality and patient safety at reduced cost.
Jan-19	WIRB-Copernicus Group	Prudentia Group	WCG Clinical Services has partnered with Prudentia, a provider of drug safety and pharmacovigilance consulting services, to deliver a comprehensive solution aimed at enhancing the quality, safety and regulatory compliance of adverse event monitoring in drug development.
Nov-18	PAREXEL	SHYFT Analytics	SHYFT Analytics, a Medidata Solutions company, and PAREXEL, have entered into a strategic partnership that establishes SHYFT's technology as an integral part of PAREXEL's foundation for Real-World Evidence generation and outcomes research for biopharmaceutical and medical device clients.
Sep-18	PAREXEL	Datavant	The collaboration aims to enable the linking of healthcare data from a variety of real-world and clinical study data sources to improve drug development and commercialization processes.
Aug-18	Innovate Biopharmaceuticals	Amarex Clinical Research	Under the agreement, Amarex will provide Innovate with electronic data capture solutions and associated services for data management and biostatistics.
Jun-18	ICON	AG Mednet	ICON plc has signed an agreement with AG Mednet to use Judi, a comprehensive electronic endpoint adjudication system, to manage workflow and help to ensure data quality for enhanced endpoint event adjudication services.
Jun-18	PPD	NeoGenomics Laboratories	As part of the collaboration, NeoGenomics will provide a wide range of lab testing services to support PPD Laboratories' oncology clinical trial activities in the US, Europe, and Asia.
Apr-18	ICON	Intel Corp	Jointly configured by ICON and Intel's AI and analytics, the Intel Pharma Analytics Platform aims to increase speed, simplify trials, and gather more objective evidence by transitioning to automatic collection of consistent, remote monitoring for data analysis, and delivering improved patient experience.
Mar-18	Novartis	Science 37	The studies will blend virtual and traditional models, with increasing degrees of decentralization towards a mostly "site-less" model. Novartis was an early investor in Science 37 and together have already initiated virtual trials for cluster headache, acne and nonalcoholic steatohepatitis (NASH).
Feb-18	Elligo Health Research	Saama Technologies	The partnership will seek to improve awareness of, access to, and participation in clinical trials for US physicians and patients.
Jan-18	PPD	Quotient Sciences	The companies will support pediatric drug development from concept to market launch through an end-to-end service that aims to speed development. The new service is in response to key regulatory agencies promoting the development of new medicines for children earlier in the product development life cycle.

Key Takeaways from Collaboration Activity

In addition to robust M&A activity, we're beginning to see partnerships form to provide traditional CROs ready access and greater optionality with respect to their investments in innovative services; we expect this trend to continue, with competition putting pressure on CROs without partnerships

Strategic Partnerships

- The ever increasing cost of drug R&D is also driving the formation of strategic partnerships, with the end goal of decreasing costs, improving patient throughput, and gaining access to innovation more quickly

Technology Partnerships

- In addition to intra-industry alliances, we are also seeing technology companies beginning to partner within the clinical trial services space
- CROs are leveraging innovative technologies to improve their processes, while tech companies diversify and find a foothold in the healthcare space

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CRO INDUSTRY – TRADING & TRANSACTION COMPS

Bourne Partners covers a broad network of CROs and related clinical trial services providers. Highlighted below are publicly traded CROs that have a significant footprint in the healthcare and pharmaceuticals industry. CRO comps are trading at median multiples of 3.0x sales and 16.1x EBITDA.

CRO Trading Comps

USD in millions

			LTM			Margin Analysis			Enterprise Value/			Debt/		
Company	Ticker	Enterprise Value	Sales	EBITDA	EBIT	Gross Profit	EBITDA	EBIT	Sales	EBITDA	EBIT	Enterprise Value	Equity Value	EBITDA
Charles River Laboratories International, Inc.	NYSE:CRL	$8,461.2	$2,449.0	$541.2	$361.5	36.6%	22.1%	14.8%	3.5x	15.6x	23.4x	26.0%	34.1%	4.1x
ICON Public Limited Company	NasdaqGS:ICLR	7,994.7	2,704.0	470.4	407.8	29.6%	17.4%	15.1%	3.0x	17.0x	19.6x	5.7%	5.7%	1.0x
IQVIA Holdings Inc.	NYSE:IQV	40,253.7	10,706.0	1,857.0	870.0	34.9%	17.3%	8.1%	3.8x	21.7x	46.3x	29.8%	41.0%	6.5x
Linical Co., Ltd.	TSE:2183	214.0	104.2	16.4	11.7	32.9%	15.7%	11.2%	2.1x	13.1x	18.4x	22.6%	23.4%	3.0x
Medpace Holdings, Inc.	NasdaqGS:MEDP	3,033.7	786.2	151.0	118.7	63.8%	19.2%	15.1%	3.9x	20.1x	25.5x	1.8%	1.8%	0.4x
PRA Health Sciences, Inc.	NasdaqGS:PRAH	7,416.9	2,932.6	461.8	349.2	48.8%	15.7%	11.9%	2.5x	16.1x	21.2x	17.9%	21.3%	2.9x
Syneos Health, Inc.	Nasdaq:SYNH	8,459.7	4,546.2	565.0	304.9	21.9%	12.4%	6.7%	1.9x	15.0x	27.7x	36.2%	55.6%	5.4x
Median						34.9%	17.3%	11.9%	**3.0x**	**16.1x**	**23.4x**	22.6%	23.4%	3.0x
Mean						38.4%	17.1%	11.8%	2.9x	16.9x	26.0x	20.0%	26.1%	3.3x

Highlighted below are 11 of the most recent M&A deals in the CRO space. M&A transaction comps for CROs show median multiples of 2.9x revenue and 15.0x EBITDA.

CRO Transaction Comps

USD in millions

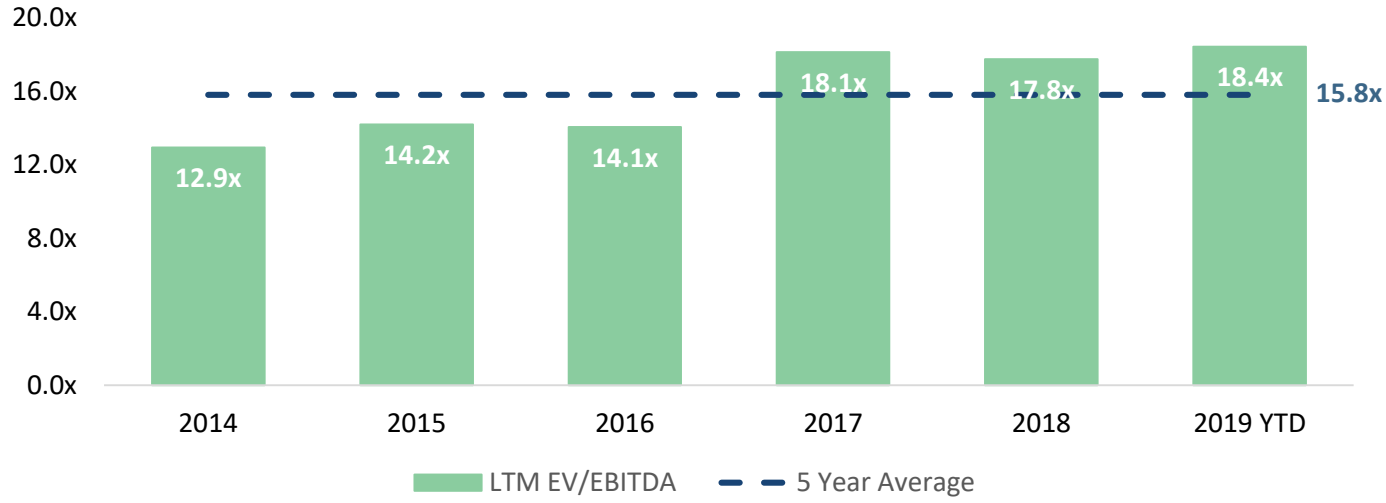
Announced Date	Target	Buyer	Geographic Location	Enterprise Value	LTM Revenue	LTM EBITDA	EV / LTM Revenue	EV / LTM EBITDA
Oct-19	Clinical Trial Centers Alliance	Apex Innovation Sciences	USA	NA	NA	NA	NA	NA
Feb-19	Citoxlab	Charles River Laboratories International	France	$510.0	NA	$36.7	NA	13.8x
Mar-18	Accelovance	Linical USA	USA	32.9	$26.8	NA	1.2x	NA
Feb-18	MPI Research	Charles River Laboratories International	USA	800.0	240.0	68.4	3.3x	11.7x
Sep-17	Optimal Research	Synexus	USA	NA	NA	NA	NA	NA
Jul-17	MAPI Development	ICON	France	139.5	NA	NA	NA	NA
Jul-17	Chiltern International	Covance	UK	1,200.0	NA	NA	NA	NA
Jun-17	PAREXEL International	Pamplona Capital Management	USA	5,007.4	2,097.0	342.8	2.4x	14.6x
May-17	inVentiv Health	INC Research Holdings	USA	4,513.7	2,177.4	292.7	2.1	15.4
Sep-16	ExecuPharm	PAREXEL International	USA	155.0	NA	NA	NA	NA
May-16	IMS Health Holdings	Quintiles Transnational Holdings	USA	13,266.8	3,063.0	743.0	4.3	17.9
May-16	Synexus	Pharmaceutical Product Development	UK	257.8	68.8	15.9	3.7x	16.2x
Median				$655.0	$1,168.5	$180.5	**2.9x**	**15.0x**
Mean				2,588.3	1,278.8	249.9	2.9x	14.9x

Source: CapIQ as of October 1, 2019

CRO INDUSTRY – TRADING & TRANSACTION COMPS

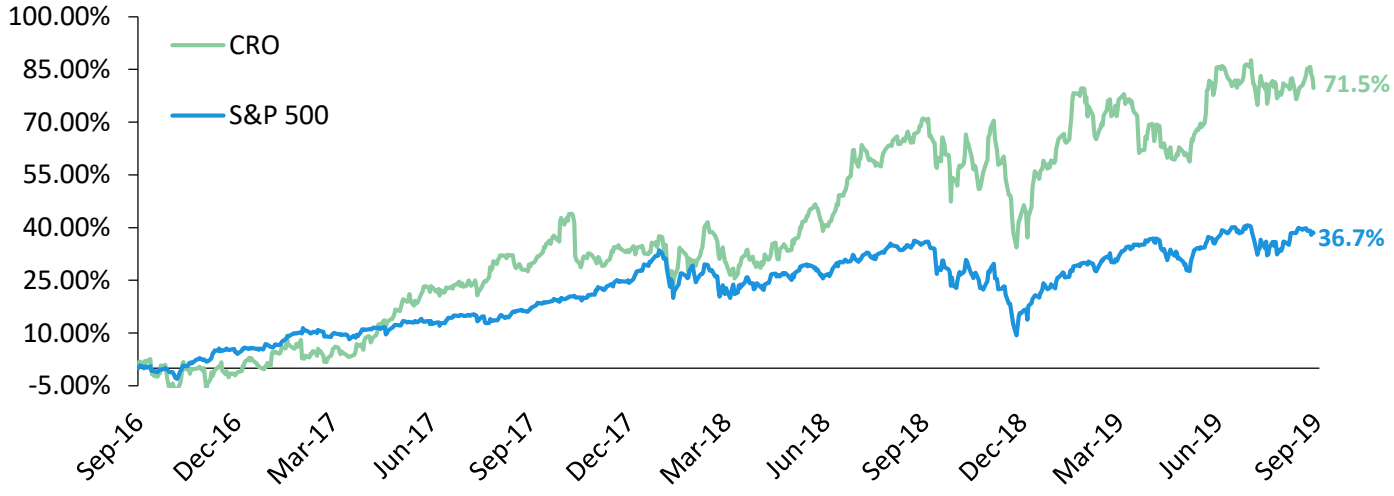
Since 2017, there has been a strong trend of consolidation in the CRO space. Strategic acquirers and Private Equity investors continue to show robust interest in the space. This trend has continued through 2019, with a YTD average EV/EBITDA multiple of 18.4x – a new high within the last 5 years

CRO LTM Average EV/EBITDA Multiples[1]



Over the last 3 years, the CRO industry has **outpaced the S&P 500 by 34.8%** in terms of equity performance. On an EV/EBITDA basis, CROs are **trading at a premium of 43.4%**. Strong clinical trial services demand, industry specialization, and improved client offerings through implementing technologies has led the sector to a substantial premium over the S&P 500.

CRO Equity Value Performance – Last 3 Years



CRO basket constituents: *Charles River (NYSE:CRL), ICON (NasdaqGS:ICLR), IQVIA (NYSE:IQV), Medpace (NasdaqGS:MEDP), PRA Health Sciences (NasdaqGS:PRAH), Syneos Health, Inc. (NasdawGS:SYNH)*

Source: CapIQ as of October 1, 2019; Equity Performance weighted by Market Capitalization
1) EV/EBITDA multiples are averages for each respective year

Bourne Partners is a healthcare-focused investment banking and private equity firm focused exclusively in the healthcare space, covering pharma, pharma services, and consumer health. We help companies execute both sell-side and buy-side M&A in addition to facilitating capital raises to finance growth or a recapitalization, with some examples below.

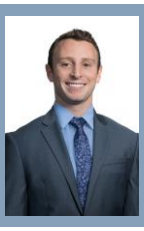
Objective: Bourne Partners worked to advise Accelovance on the carve out of Optimal Research, Accelovance's site network business.
Result: As advisors to Accelovance, Inc., Bourne Partners assisted with the carve out of its wholly-owned, independently operated subsidiary Optimal Research, to Synexus Limited.

Objective: Accelovance engaged Bourne Partners to identify an acquirer for the remaining clinical CRO business after the successful carve-out of Accelovance's SMO segment, Optimal Research, in late 2017.
Result: With the advice of Bourne Partners, Accelovance signed a merger agreement with the Japanese CRO, Linical, to sell all remaining assets for $32mm. The combined companies will now boast a strong international CRO presence reaching through North America, Europe, and Asia Pacific.

Objective: Avista, a CDMO that offers differentiated services ranging from API and drug product development to analytical testing, engaged Bourne Partners to serve as its exclusive advisor in the sale of the company.
Result: Avista was acquired by Cambrex at a value of $252 million.

OTHER RELATED EXPERIENCE

Since 2001, Bourne Partners has been a thought leader in the healthcare investment banking space. Our team is a trusted resource for clients and our track record of success includes raising over $2 billion in equity and debt capital and executing more than $6 billion in M&A transactions.



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