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Brocair Partners LLC, based in New York, was formed in 2004 to provide mergers & acquisitions advisory services, equity and debt placement services, and strategic advice to healthcare companies. Brocair Partners has advised a range of public and private companies across healthcare segments that include pharmaceuticals, medical devices, patient care, consumer health and nutrition, healthcare business services and information technology, and pharmaceutical ingredients and intermediates, both in the United States and worldwide. Outside North America, Brocair Partners collaborates on cross-border healthcare transactions with a constellation of key affiliates worldwide.

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# CRO Industry Perspective

**Data analytics and expanding post-marketing surveillance is driving growth.**

## CRO Industry Overview

Contract Research Organizations (CROs) provide R&D services to companies in the biotechnology, pharmaceutical and medical device industries, which outsource R&D activities to access capabilities not found in-house, manage R&D costs and improve efficiencies. According to Grand View Research, the global CRO market is expected to reach \$45.2 billion by 2022. Though CROs were initially niche players in clinical research services, full-service CROs today provide a wide range of services that include discovery and preclinical development, clinical trial services, post marketing surveillance, data management and analytics, consulting, and often other commercialization services.

CROs are involved with every step in the drug development process. In the discovery stage, a lead compound is found to have the potential of a new medicine. This lead compound is then tested in preclinical trials, mainly in forms of in-vitro and in-vivo experimentation. In-vitro testing is done in the lab using inanimate research tools, while in-vivo tests are conducted on animals. The discovery and preclinical development market was worth \$3.25 billion in 2016<sup>1</sup>, representing 16% of the CRO market today. It is expected to grow annually by 8.3% to 2016<sup>2</sup>.

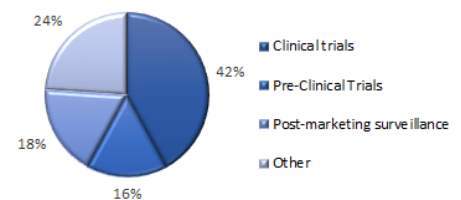
If the lead compound successfully completes its pre-clinical studies, it moves into the clinic and into human subjects. A Phase I clinical trial usually involves a small group of healthy participants and focuses primarily on drug safety and dosage determination. After products are tested for safety, a Phase II trial is conducted to test effectiveness in a slightly larger group of ill patients. After safety and effectiveness have been established, Phase III trials, which are typically much larger studies, compare the safety and effectiveness of

the new treatment to other available treatments. After successfully completing Phase III trials, the new product may receive FDA approval. Across the three phases, clinical trial services represent the largest component of the CRO market, worth \$25 billion in 2017 and growing 7% annually, according to Beroe, Inc.<sup>3</sup>

Post-marketing surveillance, which represents 18% of the market, often called Phase IV trials, occurs after the drug or device has reached the market. Often involving hundreds of thousands of people, outcome data from Phase IV helps researchers test a wider range of conditions than can be explored in a Phase III trial. In this way, post-marketing surveillance provides continuing assessments on safety and long-term side effects throughout the entire marketed lifespan of the product. According to Grand View Research<sup>4</sup>, the market was valued at just over \$2 billion in 2014, and will grow at 14.2% annually during the period to 2020<sup>5</sup>.

Other CRO services, representing 24% of the CRO market, include data management and consulting services, and commercialization services.

### Services Segmentation



BofAML CRO Industry Report 2017

<sup>1</sup>GrandView Research, November 2017

<sup>2</sup>GrandView Research, November 2017

<sup>3</sup>Clinical Leader, July 2017

<sup>4</sup>GrandView Research, November 2016

<sup>5</sup>Transparency Market Research, March 2015

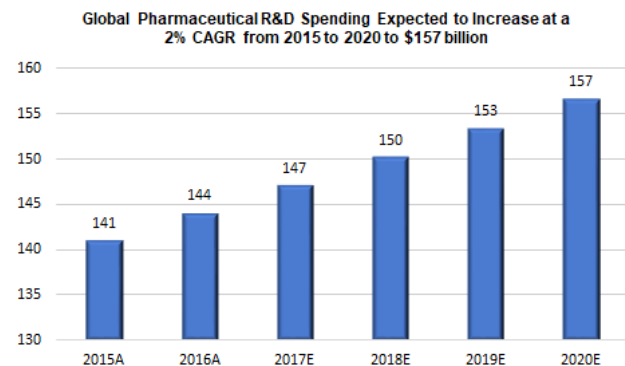
## Industry Leaders

Despite the ongoing consolidation effort outlined in our 2014 report, 46% of the CRO market is still fragmented, while the top five CROs only account for 36% of the market.

IQVIA Holdings, the merged entity of IMS Health and Quintiles, is the world's largest full-service CRO with a 11% market share. Covance, now a division of Laboratory Corporation (LabCorp), is the second largest global CRO with 8% of total market share. Like IQVIA, Covance also provides a wide range of services, but it focuses more on early and late stage product development services. PAREXEL, accounting for 6% market share, provides a broad range of clinical research, technology and consulting services. PAREXEL is followed by ICON plc and PRA Health Sciences, both with 4% of the market share. PRA Health specializes in clinical trials across all phases of clinical development, while ICON focuses on late-stage clinical development (mostly Phase III).

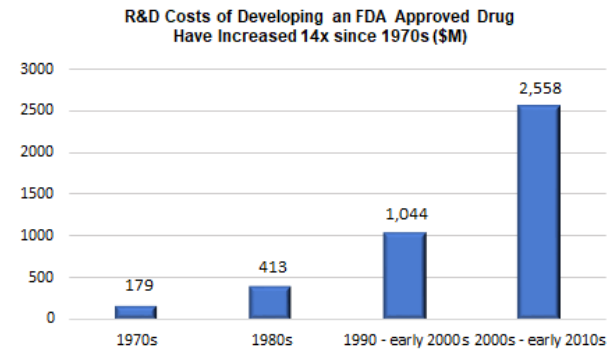
## Growth Drivers

R&D spending from pharmaceutical, biotech and medical device companies directly drives the CRO industry. R&D spending has accelerated since our last Industry Perspective in 2014 and is now expected to rise at an annualized rate of 2%, reaching \$157 billion in 2020. This is largely due to the costs related to high regulation and increased need to replenish revenue from the series of patent cliffs that have impacted big pharma's revenue from several lucrative blockbuster drugs. As these patents have expired, pharmaceutical companies have had to lower prices dramatically to respond to generic competition.<sup>6</sup>



EvaluatePharma's coverage of the world-leading 4,000 pharmaceutical and biotech companies, 2016

As complexities of R&D grow, the average cost of developing an FDA approved drug has increased 14x since 1970, reaching an average cost of \$2.6 billion in 2012<sup>7</sup>. Pharmaceutical companies have turned to CROs as a way of reducing costs. Thus, the CRO market is growing at a CAGR of over 7%<sup>7</sup>, which is faster than the growth rate of R&D spending.



Tufts CSDD, Credit Suisse, April 2016

Biopharmaceutical companies are expected to drive growth in the next few years. These companies often lack the financial resources and infrastructure to extensively conduct clinical trials. In 2016, 41% of clinical development is outsourced, a metric that is expected to reach 50% by 2020 driven by the increasing demand from biopharmaceutical companies.<sup>6</sup>

## Recent Trends

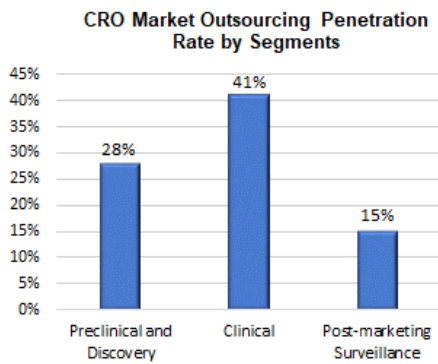
The CRO industry has continued its consolidation of recent years, for many of the same reasons we discussed in 2014. There continues to be a movement towards a full-service model, and an imperative to expand companies' commercial portfolio to replace products coming off patent. As pharmaceutical companies increasingly seek approvals in multiple markets worldwide, global CROs are better positioned than geographically-focused CROs, reflecting a need to extend services and geographic coverage.

But as CROs continue to expand their offerings, more value-added services are needed to differentiate themselves. This has increased the importance of data analytics in clinical development, which is exemplified by growing investment in big data, such as PRA Health Sciences' acquisition of Symphony Health Solutions and Quintiles' (now known as IQVIA) acquisition of IMS Health. Capitalizing on technology solutions such as proprietary platforms and data analytics, leading CROs can derive more valuable insights from existing and expanding sources of information. In this way, they continue to lower costs and increase efficiency in clinical trials.

<sup>6</sup> Credit Suisse CRO Industry Primer, 2016

<sup>7</sup> Tufts CSDD, Credit Suisse, April 2016

Growth in the CRO industry is also partially reflected in the expansion of post-approval and commercialization offerings. As seen in the graph above, post-marketing surveillance and commercialization are two less penetrated segments, compared to preclinical services and clinical development. With a total addressable market of approximately \$50 billion, they have the potential to drive industry growth in the next few years. As post-approval surveillance and commercialization are characterized by data warehousing, digital solutions, sale force management, patient engagement, and technology consulting, the efforts to bolster portfolio offerings are also consistent with CROs' strategic investment in big data.



Penetration rate is the percentage of these activities that are outsourced to 3rd party CROs.











## Competitive Matrix

Below is a matrix of selected Contract Research Organizations by market segment. Companies in bold are profiled on the next page.

Company	Services Provided						Industries Served		
	Pre-clinical Development	Clinical Development	Formulation & Product Development	Post-marketing Surveillance	Data Management	Consultancy	Biotechnology	Pharmaceutical	Medical Device
<b>United States</b>									
<b>Bioanalytical Systems, Inc.</b>									
<b>Charles River Laboratories International, Inc.</b>									
Clinipace Worldwide, Inc.									
ClinTech Research LLC									
Enwigo International Holdings, Inc.									
LabCorp (Covance)									
<b>Medpace Holdings, Inc.</b>									
Nanosyn, Inc.									
Parexel International Corporation									
Pharmaceutical Product Development, LLC									
<b>PRA Health Sciences, Inc</b>									
Quest Diagnostics Incorporated									
<b>IQVIA Holdings Inc.</b>									
<b>Syneos Health, Inc.</b>									
SynteractHCR									
Worldwide Clinical Trials, Inc.									
<b>Non - U.S.</b>									
Bilcare Limited									
Biocon Ltd.									
bioMérieux SA (Institut Mérieux)									
<b>CMIC Holdings Co., Ltd.</b>									
<b>EPS Co., Ltd.</b>									
<b>Eurofins Scientific S.A.</b>									
Hangzhou Tigermed Consulting Co.,Ltd									
<b>ICON plc</b>									
Linical Co., Ltd.									
PSI CRO AG									
Pierrel S.p.A.									
Qol Co. Ltd.									
SGS SA									
Shanghai Medicilon, Inc.									
ShangPharma Corporation									
WuXi PharmaTech (Cayman) Inc.									
NextPharma Technologies (Holding), Ltd.									

## Profiles of Selected Participants

Below are profiles of selected publicly-listed contract research organizations.

Company	Brief Description	LTM* (USD \$M)	
		Sales	EBITDA
 <b>BASi</b>	Bioanalytical Systems, Inc. provides contract research services and niche instrumentation for the life sciences industries and academic organizations, primarily in North America and Europe. The contract research segment provides drug research and development services. The instrumentation segment designs, develops, manufactures, and markets in vivo sampling systems and accessories.	23.0	2.2
 <b>charles river</b> accelerating drug development. exactly.	Charles River Laboratories International, Inc. provides research models and associated services, and outsourced preclinical services to accelerate the drug discovery and development process. It operates in two segments, Research Models and Services (RMS), and Preclinical Services (PCS).	1,905.8	449.4
 <b>cmic</b> Pharmaceutical Value Creator	CMIC HOLDINGS Co., Ltd. provides various services related to the research, development, manufacture, and sale of pharmaceuticals in Japan. Its services include monitoring the progress of a clinical trial; data management that consists of saving case report forms of clinical trials and conducting statistical analyses; clinical research co-ordination services	632.5	73.0
 <b>EPS Corporation</b>	EPS Co., Ltd. provides a range of services in clinical trials to support drug development in Japan, China, southeast Asia, and Oceania. The company offers services in new drug development, generic drug development, global clinical development, data center, and offshore data management. It also engages in site management and software development activities.	590.8	81.8
 <b>eurofins</b>	Eurofins Scientific SE provides a range of analytical testing services including food and feed testing, pre clinical and clinical research, cosmetics and medical device testing, genomic and sequencing services, and environmental laboratory testing to the food, pharmaceutical, chemical, biotechnology, medical device, cosmetic industries industries as well as to government and legal services organizations	3,568.0	656.3
 <b>ICON</b> A Symbol of Excellence	ICON Public Limited Company provides outsourced clinical research and laboratory research services to the pharmaceutical, biotechnology, and medical device industries primarily in Ireland, the United States, and rest of Europe. The Clinical Research segment supports all stages of the clinical development process from compound selection to Phase I to IV clinical studies. The Central Laboratory segment offers various laboratory services.	1,946.6	413.4
 <b>IQVIA™</b>	IQVIA Holdings Inc. is the merged entity of Quintiles and IMS Health. It provides clinical, commercial, consulting, and capital solutions to biopharmaceutical industry. The company's clinical development services cover trial types, such as phase I/IIa, phase II/III and late phase.	8,475.0	1,786.0
 <b>MEDPACE</b>	Medpace Holdings, Inc. provides scientifically-driven outsourced clinical development services to the biotechnology, pharmaceutical, and medical device industries worldwide. The company offers a suite of services supporting the clinical development process from Phase I to Phase IV in a range of therapeutic areas.	455.8	113.6
 <b>PRAHEALTHSCIENCES</b>	PRA Health Sciences, Inc. provides outsourced clinical development services to the biotechnology and pharmaceutical industries worldwide. The company operates in two segments. The Clinical Research segment provides pharmaceutical development services, including clinical trial management. The Data Solutions segment offers data, analytics, technology, and consulting solutions to the life sciences market.	2,162.5	361.5
 <b>Syneos Health</b>	Syneos Health, Inc. operates through two segments, Clinical Solutions and Commercial Solutions. The Clinical Solutions segment offers various clinical development services spanning Phase I to Phase IV, including full-service global studies, as well as unbundled service offerings. The Commercial Solutions segment provides commercialization services. The company was formerly known as INC Research Holdings, Inc.	2,658.0	370.0

\*Latest Twelve Months as of 7/25/2018