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CRO Industry Perspective

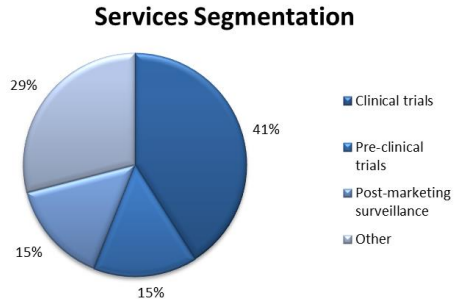
Demand to spur full-service model, strategic partnerships, and growth in preclinical services

CRO Industry Overview

Contract Research Organizations (CROs) provide outsourced research services to the biotechnology, pharmaceutical and medical device industries, allowing them to manage R&D costs and focus on their core competencies. These services include drug and device research and development, including drug discovery, preclinical and clinical trials, post-marketing surveillance, and related data management and consulting services.

Preclinical services, which include discovery services, represent 15% of the CRO market. These consist of drug safety testing and toxicity testing in the form of in-vivo and in-vitro experimentation. In-vitro experimentation, conducted using laboratory tools, is used to test the efficacy of a drug on microorganisms, such as extracted cell tissue or DNA molecules. In-vivo experimentation in preclinical trials and drug discovery involves testing on animal models, rather than isolated organisms.

Clinical trial services represent the largest component of the CRO market at 41%. Services include testing developmental-stage drugs or devices on human participants. A Phase 1 clinical trial is the first time human subjects are used in the product development process. Phase 1 usually involves a small group and focuses primarily on drug safely. After products are approved for safety, they enter Phase 2 trial for effectiveness testing and dosage determination. After safety and effectiveness have been established, products are further tested in Phase 3 for potential side effects and overall effectiveness compared to other available treatments. New products may receive FDA approval after Phase 3 has been successfully completed. Across the three phases, clinical trials usually involve hundreds or even thousands of participants, to help establish efficacy and safety evidence. Lastly, Phase 4, or post-marketing surveillance, occurs after the drug or device has reached the market and is available for use. Phase 4 primarily serves to provide continuing assessments on safety and side effects of new drugs. Outcome data from the general public in Phase 4 helps researchers test a wider range of conditions than can be explored in a Phase 3 trial. Other CRO services include data management and consulting services, among others.



IBISWorld Industry Report: Contract Research Organizations in the U.S.

Industry Leaders

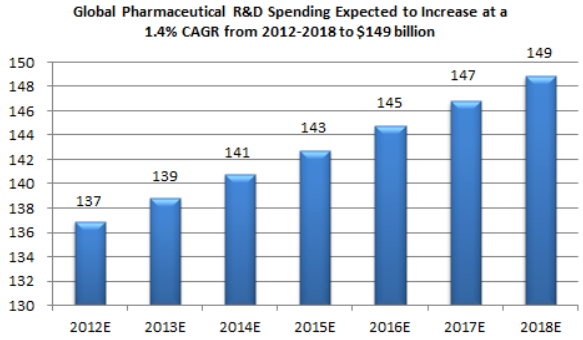
The CRO industry is highly fragmented. Low market share concentration can be attributed to the breadth of services and the existence of many small market leaders within each niche area.

The top four CROs only account for 35% of the market. Quintiles Transnational Corp, the world's largest CRO, currently holds a 17.8% market share and provides a comprehensive range of clinical trial services. Covance, the second largest global CRO, accounts for 7.9% of total market share. Like Quintiles, Covance also provides a wide range of services but focuses more on early and late stage product development services. PAREXEL International, accounting for 5.1% market share, provides a broad range of clinical

research, technology and consulting services to pharmaceutical, biotechnology and medical device companies. PAREXEL is followed by Charles River Laboratories with 3.9% of the market share. Charles River offers a long list of R&D services and research models to pharmaceutical, biotechnology and government agencies.

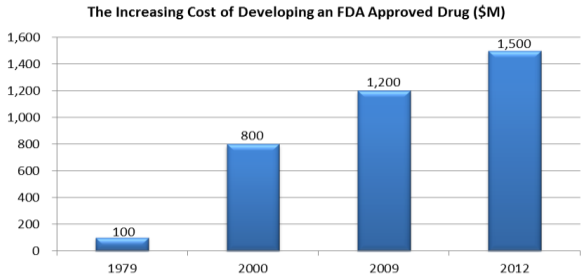
Growth Drivers

Growth in the CRO industry is closely related to R&D spending from pharmaceutical, biotech and medical device companies. R&D spending is rising at an annualized rate of 1.4%, reaching $149 billion in 2018 due to the costs related to high regulation and increased need to build strong pipelines.[1] Outsourcing allows these companies to manage R&D expenses and focus on their core competencies.



[1]EvaluatePharma's coverage of the world-leading 4,000 pharmaceutical and biotech companies, 2012

At the same time, the average cost of developing an FDA approved drug has nearly doubled since 2000, reaching an average cost of $1.5 billion in 2012. As these costs continue to rise, biopharmaceutical and medical device companies increasingly look towards CROs to manage R&D costs.

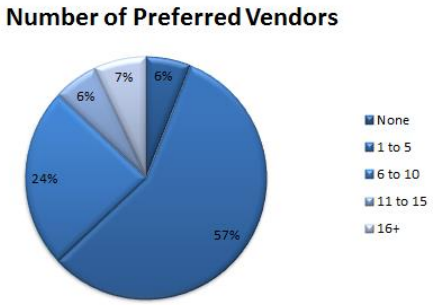


[2]PhRMA and The Burrill Report 2012, Cowen and Company

Biopharmaceutical companies are expected to drive growth in the next few years as they begin to take up a larger proportion of the CRO end-markets. These companies often outsource a greater proportion of their development due to more limited financial resources than traditional pharmaceutical companies. Demand from biopharmaceutical companies is expected to rise at an annualized rate of 8.7% from 2013 to 2018.[3]

Recent Trends

The fragmented nature of the CRO industry has led to an effort to further consolidate. Some major developments driving CRO industry consolidation include a push towards a full-service model, strategic partnerships with pharmaceutical companies, and strong performance from preclinical services. Pharmaceutical companies are streamlining vendor management by working with fewer CROs that can provide integrated support. As such, major trends that have driven recent consolidation reflect the need to extend services and geographic coverage. Acquiring smaller players that serve niche markets has enabled large CROs to provide a wider scope of services in response to the growing demand of large and globalizing pharmaceutical companies.



The move towards a full service model is paired with the growing attractiveness of strategic partnerships. Strategic Partnerships are multi-year, highly-integrated engagements between biopharmaceutical companies and CROs. Over the past five years, top players in the CRO industry have established strategic partnerships with leading pharmaceutical companies. Strategic partnerships benefits for both parties, as the CRO can secure a more stable revenue stream, and the pharmaceutical companies can outsource their services to one integrated CRO thereby reducing their level of oversight, decreasing fixed costs, and improving speed and flexibility. A PAREXEL study reported 85% of biopharmaceutical industry executives interviewed who were engaged in strategic partnerships believed the relationship to be mutually beneficial.[4] An example of this type of arrangement is Covance's 10-year, $1.6 billion services agreement with Eli Lilly and Company. This partnership helps bring Eli Lilly a more flexible R&D cost infrastructure.

Consolidation and growth in the CRO industry has also been partially driven by development of the preclinical services market. Demand for outsourced preclinical services is expected to grow at a faster rate than that of clinical services as pharmaceutical companies rely on drug discovery services to help refill pipelines and meet the demand for advanced new treatments. From 2009 to 2013, preclinical development services and drug discovery services is estimated to grow at an annualized rate of 15.3% and 14.5% respectively vs. 11.7% growth of clinical phases I-IV.[5] Recent scientific innovation in areas such as genomics, toxicology, bioinformatics and imaging technologies is also contributing to the demand for preclinical services.

[3] IBISWorld Industry Report: Contract Research Organizations in the U.S.
[4] Strategic Partnerships 2013 by PAREXEL International
[5] Global CRO Market: Quantitative Assessment by Frost & Sullivan

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
United States									
Accelovance, Inc.					■	■	■	■	
Advantar Laboratories, Inc.	■	■	■				■	■	
Bioanalytical Systems, Inc.	■		■				■	■	
Charles River Laboratories International, Inc.	■			■		■	■	■	
Clinipace Worldwide, Inc.		■	■	■	■	■		■	■
ClinTech Research LLC	■	■	■				■	■	
Covance Inc.	■	■	■	■	■	■	■	■	■
CRI Worldwide		■			■		■	■	
inVentiv Health, Inc.		■		■		■	■	■	■
MPI Research, Inc.	■		■				■	■	■
Nanosyn, Inc.	■						■	■	
Parexel International Corporation		■	■	■	■	■	■	■	■
Pharmaceutical Product Development, Inc.	■	■	■	■	■		■	■	■
Phillips-Medisize Corporation			■						■
PRA International, Inc.		■		■			■	■	
Quintiles Transnational Corp.	■	■			■	■	■		
SYNARC, Inc.		■				■	■	■	■
SynteractHCR		■			■		■	■	■
Worldwide Clinical Trials, Inc.		■	■		■		■	■	
Non - U.S.									
Advinus Therapeutics Private Limited	■	■	■	■			■	■	
Bilcare Limited		■			■		■	■	
Biocon Ltd.	■		■				■		
bioMérieux SA (Institut Mérieux)		■			■			■	
Cerep SA	■				■		■	■	
CMIC Holdings Co., Ltd.	■	■	■	■	■			■	
Cyprotex plc	■						■		
EPS Co., Ltd.	■	■	■	■	■	■		■	■
Eurofins Scientific S.A.	■	■	■				■	■	■
ICON plc		■	■	■	■	■	■	■	■
INC Research, Inc.		■		■	■		■	■	
JCL Bioassay Corporation	■	■	■	■				■	
Pierrel S.p.A.		■	■	■		■		■	
Qol Co. Ltd.		■	■		■	■		■	
SGS SA		■				■			
Shanghai Medicilon, Inc.	■		■				■	■	
ShangPharma Corporation	■						■	■	
WuXi PharmaTech Co. Ltd.	■	■	■	■			■	■	■
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
BASi	Bioanalytical Systems, Inc. provides contract research services and niche instrumentation for the life sciences industries and acedemic 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.	24.7	2.8
Cerep	Cerep SA provides in vitro pharmacology, in vitro ADME-Tox and in vivo PK services, as well as solutions for drug discovery to 500 pharmaceutical and biotechnological companies worldwide. The company also offers assay development services as well as BioPrint profiles and services.	27.3	2.6
charles river 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).	1,143.0	249.9
CMIC 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	512.8	64.4
COVANCE	Covance Inc., a drug development services company, provides various product development services to the pharmaceutical, biotechnology, and medical device industries primarily in the United States and Europe. Its Early Development segment offers preclinical services, such as toxicology; pharmaceutical and nutritional chemistry, and food safety. Late-Stage Development segment provides full management of Phase II through IV clinical trials.	2,279.5	329.9
cyprotex	Cyprotex PLC provides in vitro and in silico absorption, distribution, metabolism, excretion, toxicity, and pharmacokinetics (ADMET and PK) information to the pharmaceutical industry primarily in North America, Mainland Europe, and the United Kingdom.	13.5	1.5
EPS Corporation	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.	365.7	38.3
eurofins	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	1,376.4	226.8
ICON 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.	1,236.7	147.8
PAREXEL	PAREXEL International Corporation, provides clinical research, medical communications, consulting, commercialization, and advanced technology products and services to the pharmaceutical, biotechnology, and medical device industries worldwide.	1,734.4	208.3
QUINTILES	Quintiles Transnational Corp. 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.	3,731.0	498.8
药明康德 WuXi AppTec	Wuxi PharmaTech (Cayman) Inc. operates as a pharmaceutical, biotechnology, and medical device research and development outsourcing company in China and the United States. It operates in two segments, Laboratory Services and Manufacturing Services.	525.7	139.2

*Source: CapIQ, Latest Twelve Months as of 7/31/2013