

INSIGHT

# Contract Research Organizations: Segment Overview

## OVERVIEW

Contract Research Organizations (CROs) provide research services on a contract basis to the pharmaceutical, biotechnology and medical technology industries.

CROs provide biopharmaceutical development, preclinical research, clinical research and clinical trial management.

Many CROs specifically provide clinical study and clinical trial support for drugs or medical devices.

## SERVICES

Project Management

Patient Recruitment & Engagement

Site Management

Data Management

Data Transformation & Standardization

Safety Services

Biostatistics

Drug Supply Management

## CUSTOMERS

Biotechnology

Pharmaceutical

Medical Device Manufacturers

Universities

Research Institutions

## KEY TRENDS

### **Movement Toward Full-Service Model**

An increase in research & development (R&D) investment, higher costs and increased demand caused by a bump in patent expirations are driving companies to outsource clinical trials. And pharmaceutical organizations are seeing that product development can be accelerated by outsourcing entire clinical studies.

### **Rising Costs**

Increasing costs for R&D and clinical trials/studies are driving organizations to see CROs as an alternative – one that is less costly compared to retaining in-house staff.

### **Rapid Product Development**

A shorter development cycle and the rapid development of new treatments is driving an increase in the number of clinical trials/studies.

### **CRO Consolidation**

Larger CROs are purchasing newcomers and competitors to acquire more efficient research and trial management practices.

### **COVID-19 Lag**

Companies were unable to run normal clinical trials during COVID-19, creating a backlog.

### **Pandemic-Driven Changes**

COVID-19 restrictions spurred adoption of decentralized clinical trials that take place outside of a hospital, utilizing monitoring equipment, telemedicine and home visits.

### **New Normal?**

Mixed data from the pandemic years makes predictions difficult, but industry data points to increased demand for lower-cost outsourced, decentralized clinical trials – and CRO growth.

### **Increased Scrutiny on Price and Performance**

Trial sponsors increasingly are demanding cost certainty. Which is built on more accurate estimation and pricing, and which is delivered using advanced quoting toolsets. Also, on-time completion is expected – and achieved with better project data analysis, and improved planning and management.



**CRO revenue is projected to grow at a CAGR of 6.2% over the next five years.**

SOURCE: IBISWorld Inc.

## EXTERNAL DRIVERS

### Rising R&D Budgets

Organizations typically pay CROs from their R&D budgets. Industry R&D expenditures are rising in 2023, opening the door for additional opportunities for CROs.

### Aging Population

As the U.S. population ages, the rate of disease will rise – and likely spur the development of new medicines and treatments.

### Demand From Brand-Name Pharma

Pharmaceutical manufacturers must conduct clinical trials to test drug efficacy and discover any potential risks, and so brand-name pharmaceutical manufacturers constitute a significant market for CROs. Demand from major pharmaceutical companies will rise only marginally in 2023, potentially diminishing CRO revenue growth.

### Demand From Generic Pharma

Before a new generic version of a drug is marketed and distributed, generic pharmaceutical companies must ensure that it meets Food and Drug Administration (FDA) requirements. Generic drug makers frequently outsource drug research functions to CROs. Demand from generic pharmaceutical manufacturing will grow in 2023.

### Demand From Biotechnology

Biopharmaceutical products require vigorous clinical testing and FDA approval. Biotechnology companies, including small ones developing drugs too financially risky for larger competitors, contract with CROs to test newly developed medications. Demand from biotechnology will rise in 2023.

### Demand From Medical Device Makers

Medical device manufacturers test products with CROs for advanced devices like medical robots, pacemakers and neuroprosthetics. Demand from medical device manufacturing will rise in 2023.

### Increasing Adoption of Decentralized Trials

Decentralized and at-home trial adoption is growing. The practice can significantly reduce clinical trial cost and persuade patients to sign up – and likely will spur investment in CROs.

Improvements in at-home monitoring and treatment devices will drive decentralized trial growth in the next five years. These new technologies will make the trials more adaptable and cost-effective, and accelerate CRO revenue growth.

In 2021, a spike in outsourcing and decentralized trials drove a 17.6% increase in revenue growth for CROs – roughly three times the average growth from 2010 to 2020. Growth was weaker in 2022 and 2023, but technological improvements and the growing adoption of decentralized trials could make 18% growth the new normal.

### Remote Monitoring Technology

Improvements in medical monitoring devices have driven decentralized trial adoption. Today, virtually all clinical trials use various medical devices, depending on the disease and treatment method.

## MARKET CONCENTRATION

### California

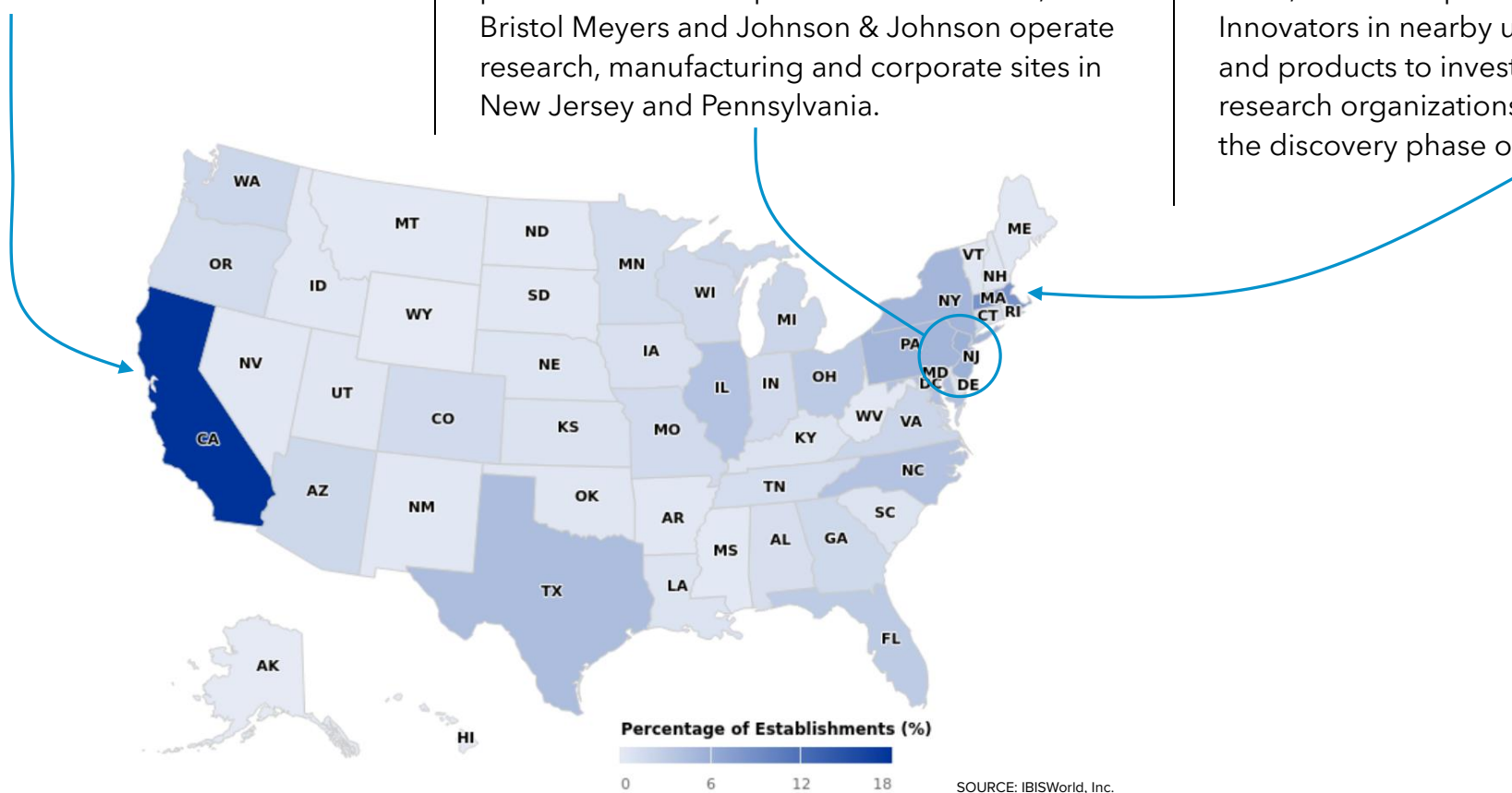
California's venture capital base is a magnet for pharmaceutical and biotechnology companies. And the state's large population makes it an outstanding location for clinical trials. Many companies test drugs in research hospitals throughout California and the West.

### Mid-Atlantic Region

The Mid-Atlantic's large, concentrated population makes it an excellent area for running clinical trials. And there are number of large hospitals that service New York, New Jersey and Pennsylvania. What's more, major pharmaceutical companies such as Merck, Bristol Meyers and Johnson & Johnson operate research, manufacturing and corporate sites in New Jersey and Pennsylvania.

### Boston

Boston is home for a large number of top-notch biotechnology companies and research hospitals. Major pharmaceutical companies also have research facilities in the area, and work with the renowned universities nearby. What's more, venture capital has exploded in Boston. Innovators in nearby universities take research and products to investors, offering contract research organizations opportunities to work on the discovery phase of drug development.



## COMPETITION

### Other CROs

Competition is fierce among CROs. There are thousands of CRO companies, and they range from small, limited-service providers to full-service, global organizations.

CROs primarily compete on on-time/quality performance, breadth of services, price, specific expertise and geographic markets.

To close deals, CROs must present a mix of technical knowledge, skills and expertise in line with the client's budget and desired outcome.

Looking closer, CROs must quickly adopt new technologies because pharmaceutical, biotechnology and medical device companies are subject to increasingly rapid technological changes.

Ultimately, CROs need to offer superior technologies, products and services that are more effective and commercially attractive than those offered by their competitors. And they must offer a proven ability to manage large-scale clinical trials.

### In-House Capabilities

CROs also compete with the in-house departments of pharmaceutical, biotechnology and medical device companies, as well as universities, teaching hospitals and other organizations.

In the next five years, IBISWorld estimates that outsourcing of research and development to CROs will increase, as more pharmaceutical and biotechnology companies seek ways to replace their inefficient and costly internal functions with a more efficient and cost-effective alternative.



**Major CROs and medium/small CROs each hold a 50% market share**

SOURCE: IBISWorld Inc.

## SUCCESS FACTORS

### Appropriate Pricing & Focus

A CRO's price structure should concentrate on services that offer a competitive advantage, and on services that are profitable.

### Good Reputation

A good reputation for high quality is key, as is the ability to build strong, positive relationships with clients to generate repeat business.

### Economies of Scale

Growth creates cost efficiencies and, in the process, creates access to nationally based customers.

### Access to Highly Skilled Workforce

CROs employees are highly skilled and educated. Research and development require a workforce that is comfortable with innovation, offers technical expertise and intelligence, and is strong in creative problem-solving.

### Ability to Quickly Adopt New Technologies

Efficient laboratory equipment, and the ability to invest in new equipment, is necessary to keep up with advances in the field and maintain competitiveness.

### Understanding Policies & Regulation

The healthcare sector is highly regulated. CROs must comply with stringent regulations to maintain smooth operations and take advantage of potential government incentives.

### About ForeFront

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