

# **Preclinical CRO Market Report by Service (Bioanalysis and DMPK Studies, Toxicology Testing, and Others), End Use (Biopharmaceutical Companies, Government and Academic Institutes, Medical Device Companies), and Region 2024-2032**

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## **Abstracts**

The global preclinical CRO market size reached US\$ 6.0 Billion in 2023. Looking forward, IMARC Group expects the market to reach US\$ 11.0 Billion by 2032, exhibiting a growth rate (CAGR) of 6.8% during 2024-2032. The growing expenditure on research and development (R&D) activities, the rising complexity of the regulatory environment, the increasing focus on core competencies among companies, and recent advancements in specialized treatments are some of the major factors propelling the market.

Global Preclinical CRO Market Analysis:

**Major Market Drivers:** The rising focus on personalized medicines is one of the key factors positively influencing the market growth. Some of the key preclinical CRO market recent developments include technological advancements, such as high-throughput screening in silico modeling and advanced imaging techniques.

**Key Market Trends:** The development in biotechnology, pharmaceutical, and medical device industries, along with regulatory support, are bolstering the preclinical CRO market growth. Moreover, the rising number of clinical trials has increased the need for CROs with a global presence and expertise in navigating international regulatory environments. This trend is further propelling the demand for preclinical CRO services.

**Geographical Trends:** According to the preclinical CRO market outlook, North America is acquiring a dominant share of the overall market. This can be attributed to the presence of leading pharmaceutical and biotech companies. Moreover, there has been a significant increase in R&D investments and preclinical studies, which is further acting as another growth-inducing factor across the region.

**Competitive Landscape:** Some of the leading players in the global preclinical CRO market include Charles River Laboratories Inc., Covance Inc. (Laboratory Corporation of America Holdings), Eurofins Scientific, ICON Plc, MD Biosciences Inc. (MLM Medical Labs), Medpace, Parexel International Corporation, PPD Inc., and Wuxi AppTec, among many others.

**Challenges and Opportunities:** According to the preclinical CRO market overview, rising regulatory compliance, surging competition, and cost pressures are some of the major challenges that the market is facing. However, continuous advances in preclinical testing technology are opening new opportunities for CROs to enhance their service offerings and improve efficiency.

## Global Preclinical CRO Market Trends:

### Rising Research and Development Activities

The escalating R&D activities in the pharmaceutical and biotechnology industries are driving the preclinical CRO market share. Additionally, the drug development process is becoming more complex, thereby requiring extensive preclinical testing to ensure the safety and efficacy of new drugs. According to the U.S. Food and Drug Administration (FDA), researchers are required to use Good Laboratory Practice (GLP) defined in regulations of medical product development for preclinical studies. Moreover, outsourcing preclinical R&D activities to CROs can be more cost-effective for pharmaceutical companies than conducting these studies in-house. CROs often have specialized expertise, infrastructures, and resources that can streamline the drug development process and reduce costs. For instance, in January 2024, the National Center of Advancing Translational Sciences developed a preclinical research toolbox in collaboration with other NIH institutes and centers. The resources include the Assay Guidance Manual, Compound Management, NCATS Pharmaceutical Collection, PubChem, Probes, Phenotypic Drug Discovery Resource, and BioPlanet.

## Complex Regulatory Environment

The complex regulatory environment in the pharmaceutical and biotechnology industries is a significant factor adding to the preclinical CRO market share. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), require extensive preclinical testing to demonstrate the safety and efficacy of new drugs. Moreover, for instance, the National Center for Advancing Translational Sciences partnered with academia, industry, and patient advocacy groups to enable more than 45 novel drugs to move into clinical trials. According to them, a new drug's journey from the lab to the medicine cabinet can take up to 15 years. This has led to an increased demand for preclinical CRO services to ensure compliance with regulatory requirements. Moreover, the globalization of clinical trials has made it necessary for pharmaceutical companies to navigate complex regulatory environments in multiple countries. Preclinical CROs with expertise in international regulatory requirements can help companies navigate these challenges. For instance, according to the Centers for Disease Control and Prevention, the development of a vaccine takes 10 to 15 years of laboratory research, and researchers need to submit an investigational new drug application to the FDA, which includes all the information about the vaccine. The FDA's Center for Biologics Evaluation and Research regulates the usage of vaccines in the United States.

## Increasing Cost of Drug Development

The escalating cost of drug development is bolstering the preclinical CRO market revenue. Drug development is a complex and lengthy process that requires extensive research and testing. This complexity can lead to higher costs associated with conducting preclinical studies. Furthermore, to prove the safety and effectiveness of new medications, organizations like the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) demand comprehensive preclinical testing. Meeting these regulatory requirements can be costly. Drug development is inherently risky, with many drugs failing to reach the market despite significant investments. According to Member Magazine of the American Society for Biochemistry and Molecular Biology, it takes 10 to 15 years to develop one successful drug. Researchers discovered that the drug's inability to have the desired impact in humans was between 40% and 50% of failures. About 10% to 15% were caused by inadequate pharmacokinetic properties. At the same time, around 30% were attributed to uncontrollably high toxicity or adverse effects. Preclinical CRO market companies can help to mitigate these risks by providing expertise in preclinical research, thereby aiding them in making informed decisions about which drugs to consider.

## Global Preclinical CRO Market Segmentation:

IMARC Group provides an analysis of the key trends in each segment of the global preclinical CRO market report, along with forecasts at the global, regional, and country levels from 2024-2032. Our report has categorized the market based on the service and end use.

### Breakup by Service:

Bioanalysis and DMPK Studies

Toxicology Testing

Others

### Toxicology testing dominates the market

The report has provided a detailed breakup and analysis of the market based on the service. This includes bioanalysis and DMPK studies, toxicology testing, and others. According to the report, toxicology testing represented the largest market segment.

According to the preclinical CRO market recent developments, the growth of toxicology testing is driven by stringent regulatory requirements set by healthcare authorities worldwide to identify the potential adverse effects on human health. Moreover, as pharmaceuticals become more complex, understanding potential toxic interactions with biological systems becomes even more critical. Toxicology testing in the preclinical stage helps in saving companies significant time and financial resources by preventing the progression of unsuitable candidates. For instance, the U.S. Food and Drug Administration states that it is crucial to screen new molecules for pharmacological activity and toxicity potential.

### Breakup by End Use:

Biopharmaceutical Companies

Government and Academic Institutes

## Medical Device Companies

Biopharmaceutical companies dominate the market

The report has provided a detailed breakup and analysis of the market based on the end use. This includes biopharmaceutical companies, government and academic institutes, and medical device companies. According to the report, biopharmaceutical companies represented the largest market segment.

According to the preclinical CRO market statistics, biopharmaceutical companies are dominating the market due to the increasing development of biologics, including monoclonal antibodies, recombinant proteins, and gene therapies, which require thorough preclinical evaluation, often necessitating specialized expertise that CROs provide. Furthermore, biopharmaceutical entities are investing heavily in preclinical activities, many of which are outsourced to CROs for efficiency and expertise.

### Breakup by Region:

North America

United States

Canada

Asia-Pacific

China

Japan

India

South Korea

Australia

Indonesia

Others

Europe

Germany

France

United Kingdom

Italy

Spain

Russia

Others

Latin America

Brazil

Mexico

Others

Middle East and Africa

North America exhibits a clear dominance in the market, accounting for the largest preclinical CRO market share

The report has also provided a comprehensive analysis of all the major regional markets, which includes North America (the United States and Canada); Asia Pacific (China, Japan, India, South Korea, Australia, Indonesia, and others); Europe (Germany, France, the United Kingdom, Italy, Spain, and others); Latin America (Brazil, Mexico, and others); and the Middle East and Africa. According to the report, North America represented the largest market segment.

North America is dominating the preclinical CRO market, owing to the presence of many leading pharmaceutical and biotech companies, which directly correlates with heightened demand for preclinical research services across the region. Additionally, firms in North America consistently lead in investments in terms of R&D activities. Moreover, this commitment to innovation drives a considerable need for preclinical studies and specialized CRO services. This, in turn, is positively influencing the regional market. For instance, in February 2022, the European life sciences company InSilicoTrials and the Canadian CRO IonsGatePreclinical Services Inc. (IonsGate), which specialize in preclinical research services, collaborated to take advantage of cutting-edge technologies like simulation. Besides this, the implementation of regulatory requirements by government bodies in North America regarding drug safety is escalating the demand for preclinical CROs to meet requirements and navigate the intricate approval process. Furthermore, the wide presence of established CROs specializing in early drug discovery, such as LabCorp and Charles River Laboratories, is expected to augment the market growth in North America over the forecasted period.

#### Competitive Landscape:

The top companies in the preclinical CRO market are broadening their portfolio to provide end-to-end solutions, encompassing everything from early-stage discovery to preclinical development, which ensures clients can access a full suite of services under one roof. Additionally, companies are investing in technologies, such as in vitro toxicology, high-throughput screening, and computational modeling, to enhance their preclinical study capabilities. Furthermore, they are expanding their operations globally by setting up new facilities, upgrading existing ones, or acquiring regional players. Apart from this, several market players are attracting top talent and focusing on ongoing training to ensure their teams stay updated on the latest scientific advances and regulatory changes. Moreover, they are entering into long-term collaborations with pharmaceutical companies to streamline the drug development process, reduce redundancies, and foster deeper understanding between parties.

The market research report has provided a comprehensive analysis of the competitive landscape in the market. Detailed profiles of all major companies have also been provided. Some of the key players in the market include:

Charles River Laboratories Inc.

Covance Inc. (Laboratory Corporation of America Holdings)

Eurofins Scientific

ICON Plc

MD Biosciences Inc. (MLM Medical Labs)

Medpace

Parexel International Corporation

PPD Inc.

Wuxi AppTec

(Please note that this is only a partial list of the key players, and the complete list is provided in the report.)

#### Global Preclinical CRO Market News:

April 2024: Labcorp, a leading player in innovative and comprehensive laboratory services, expanded its precision oncology portfolio to improve patient care and cancer research globally. Labcorp is investing in scientific, diagnostic, and laboratory innovations to support its pharmaceutical, biotechnology, and clinical research to bring cutting-edge therapies.

March 2024: Veeda Clinical Research Limited, a full-service contract research organization acquired Heads, a European CRO that specializes in clinical trials in oncology.

January 2024: The National Center of Advancing Translational Sciences developed a preclinical research toolbox in collaboration with other NIH institutes and centers. The resources include the Assay Guidance Manual, Compound Management, NCATS Pharmaceutical Collection, PubChem, Probes, Phenotypic Drug Discovery Resource, and BioPlanet.

#### Key Questions Answered in This Report



1. How big is the global preclinical CRO market?
2. What is the expected growth rate of the global preclinical CRO market during 2024-2032?
3. What are the key factors driving the global preclinical CRO market?
4. What has been the impact of COVID-19 on the global preclinical CRO market?
5. What is the breakup of the global preclinical CRO market based on the service?
6. What is the breakup of the global preclinical CRO market based on the end use?
7. What are the key regions in the global preclinical CRO market?
8. Who are the key players/companies in the global preclinical CRO market?

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