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Preclinical CRO Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2023-2028

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Abstracts

The global preclinical CRO market size reached US$ 5.6 Billion in 2022. Looking forward, IMARC Group expects the market to reach US$ 8.7 Billion by 2028, exhibiting a growth rate (CAGR) of 7.6% during 2022-2028. The growing expenditure on research and development (R&D) activities, rising complexity of regulatory environment, increasing focus on core competencies among companies, and recent advancements in specialized treatments are some of the major factors propelling the market.
A preclinical contract research organization (CRO) refers to a company that provides various research and development (R&D) services to the biotechnology, pharmaceutical, and medical device industries. It offers a range of services, such as toxicology studies, pharmacokinetics, formulation development, regulatory support, and pharmacodynamics studies. Preclinical CRO finds extensive applications in drug discovery, medical device testing, biocompatibility, disease modeling, safety pharmacology, and dosage form selection. It aids in expediting product development, enhancing regulatory compliance, leveraging specialized expertise, optimizing resource management, and offering scalable research solutions.
The increasing focus on core competencies among companies is facilitating the demand for preclinical CROs to offload specialized preclinical tasks and dedicate more resources to their primary areas, such as late-phase clinical trials or marketing. Additionally, the rising demand for preclinical CRO due to the rapid expansion of the pharmaceutical sector in developing countries to address unique healthcare challenges and the growing patient population is supporting the market growth. Furthermore, the recent advancements in specialized treatments, such as personalized medicine, biologics, and gene therapies, which require nuanced preclinical testing, are acting as another growth-inducing factor. Apart from this, the widespread adoption of preclinical CROs to provide companies with a risk-balanced approach owing to the high failure rate

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of drug development is contributing to the market growth. Besides this, the introduction of cutting-edge technologies that play a pivotal role in successful preclinical studies is supporting the market growth.

Preclinical CRO Market Trends/Drivers:

The growing expenditure on research and development (R&D) activities

The growth and vitality of the pharmaceutical and biopharmaceutical sectors are inextricably linked to their commitment to R&D. The quest for novel therapeutics, more efficacious treatments, and groundbreaking medical solutions has propelled companies to invest heavily in R&D activities. As diseases mutate and new health concerns emerge, there's a perpetual need for innovative medications and medical devices. This continuous drive for innovation necessitates extensive preclinical studies, which are generally outsourced to CROs to harness their specialized expertise and facilities. Additionally, the competition to be first-to-market further intensifies R&D endeavours. In line with this, outsourcing preclinical research allows companies to swiftly navigate the initial stages of drug development, thus ensuring a timely and efficient path from the lab to the patient.

The rising complexity of regulatory environment

The global pharmaceutical landscape is under the scrutiny of multifaceted and rigorous regulatory frameworks. These regulatory bodies mandate stringent standards to ensure the quality, safety, and efficacy of various products. Meeting these comprehensive requirements demands expertise, precision, and extensive documentation, often overwhelming for many companies. This is where the specialized knowledge of preclinical CROs becomes invaluable. These organizations are adept at understanding, navigating, and ensuring compliance with such intricate regulations. Their dedicated focus on preclinical research ensures they remain updated with the latest regulatory changes, employ best practices, and maintain state-of-the-art facilities that adhere to global standards. Additionally, this helps pharmaceutical companies adhere to regulatory mandates and also minimizes potential setbacks, saving both time and resources.

The increasing cost of drug development process

Drug development is a capital-intensive endeavor, with companies investing heavily in the lifecycle of a drug. The initial stages, including preclinical studies, are especially critical as they set the foundation for subsequent clinical phases. However, establishing and maintaining in-house facilities, technologies, and expertise for these early stages can be expensive. By outsourcing to preclinical CROs, companies can achieve significant cost efficiencies. CROs offer scalable solutions, allowing companies to pay for the specific services they need. Additionally, CROs often have economies of scale due to their focused nature, passing on the cost benefits to their clients. In a world where financial prudence is paramount, outsourcing preclinical research provides an

avenue to balance quality research with economic considerations.

Preclinical CRO Industry 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 2023-2028. Our report has categorized the market based on 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. Toxicology testing is dominating the market due to the stringent regulatory requirements set by health authorities across the globe to ensure that potential adverse effects on human health are identified. Furthermore, as pharmaceuticals become more complex, understanding potential toxic interactions with biological systems becomes even more critical. Modern drugs, especially those based on novel mechanisms of action or biologics, require thorough toxicological evaluations. Additionally, many drug candidates fail during the development process due to safety concerns. Toxicology testing in the preclinical stage helps identify potential red flags early on, saving companies significant time and financial resources by preventing the progression of unsuitable candidates. Besides this, the advent of advanced technologies, such as in vitro toxicology, computational modeling, and high-throughput screening, which are enhancing the capabilities of toxicological studies and providing more detailed and rapid insights, is boosting the market growth.

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.

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

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specialized expertise that CROs provide. Furthermore, biopharmaceutical entities are investing heavily in R&D, which translates to a multitude of preclinical activities, many of which are outsourced to CROs for efficiency and expertise. Apart from this, the development of biologics involves intricate production processes using living cells. The complexity warrants specialized preclinical studies, including assessments of potential impurities or contaminants. Moreover, biopharmaceutical drugs are under intense regulatory scrutiny due to their potential immunogenicity and unique mechanisms of action, which often demand the detailed and specialized services of preclinical CROs.
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,

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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. Additionally, the regional firms consistently lead in terms of research and development (R&D) investments. This commitment to innovation drives a considerable need for preclinical studies, pushing the demand for specialized CRO services. Furthermore, leading universities and research institutions in North America provide state-of-the-art infrastructure and generate cutting-edge research. This sophisticated ecosystem often collaborates with and complements the services of CROs. Apart from this, the imposition of stringent regulatory requirements by regional governments regarding drug safety is facilitating the demand for preclinical CROs to meet rigorous requirements and navigate the intricate approval process.

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 report has provided a comprehensive analysis of the competitive landscape in the global preclinical CRO 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

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Recent Developments:
In March 2021, Charles River Laboratories Inc. acquired Retrogenix, an early-stage CRO providing specialized bioanalytical services.
In October 2020, Covance Inc. (Laboratory Corporation of America Holdings) announced it is transforming into a decentralized CRO.
In February 2021, ICON Plc announced that it is acquiring PRA Health Sciences to consolidate itself as a CRO.
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 2023-2028?
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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