

Contract Research Organizations Global Market Including: CRO Market, Drug Discovery & Development Process, R&D Spend

A Contract Research Organization (CRO) is a service provider, which offers end-to-end solutions in conducting clinical trials for biopharmaceutical companies.

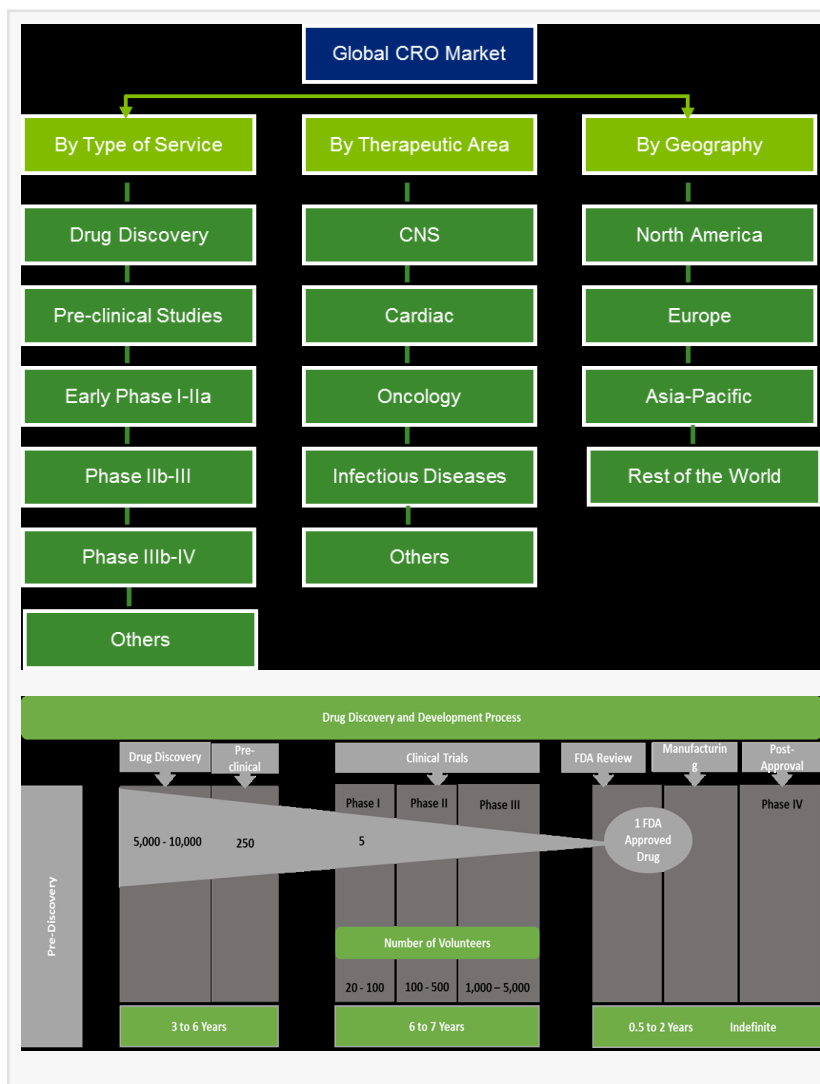
LONDON, GREATER LONDON, UK, November 18, 2016 /EINPresswire.com/ -- The CRO market is highly fragmented in nature and is shows intense competition amongst the players who are operating this market. The healthy growth of this market has led to the establishment of large number of players and these companies are now focusing on providing bundle of services to its clients. The contract research organizations and their one stop bundle service model are providing additional services of the clinical trials. These services include document preparation, liaison management, consultation, etc. In addition, most of the companies are involved in developing innovative new technologies and data base platforms that can improve the results of clinical trials and reduce the timelines required for the trials.

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1. Introduction

A Contract Research Organization (CRO) is a service provider, which offers end-to-end solutions in conducting clinical trials for biopharmaceutical and medical device companies. The core services



offered by CROs to biopharmaceutical companies include initial drug discovery solutions, toxicology studies, bio-analytical services, central laboratory, site monitoring, data management services, vigilance, bio-statistics, study and development program design and consulting, regulatory affairs and a variety of post-marketing surveillance services. At present, most of the pharmaceutical companies often outsource their R&D activities to CROs and is expected that these companies will increase their outsourcing activities for drug development process to CROs in future.

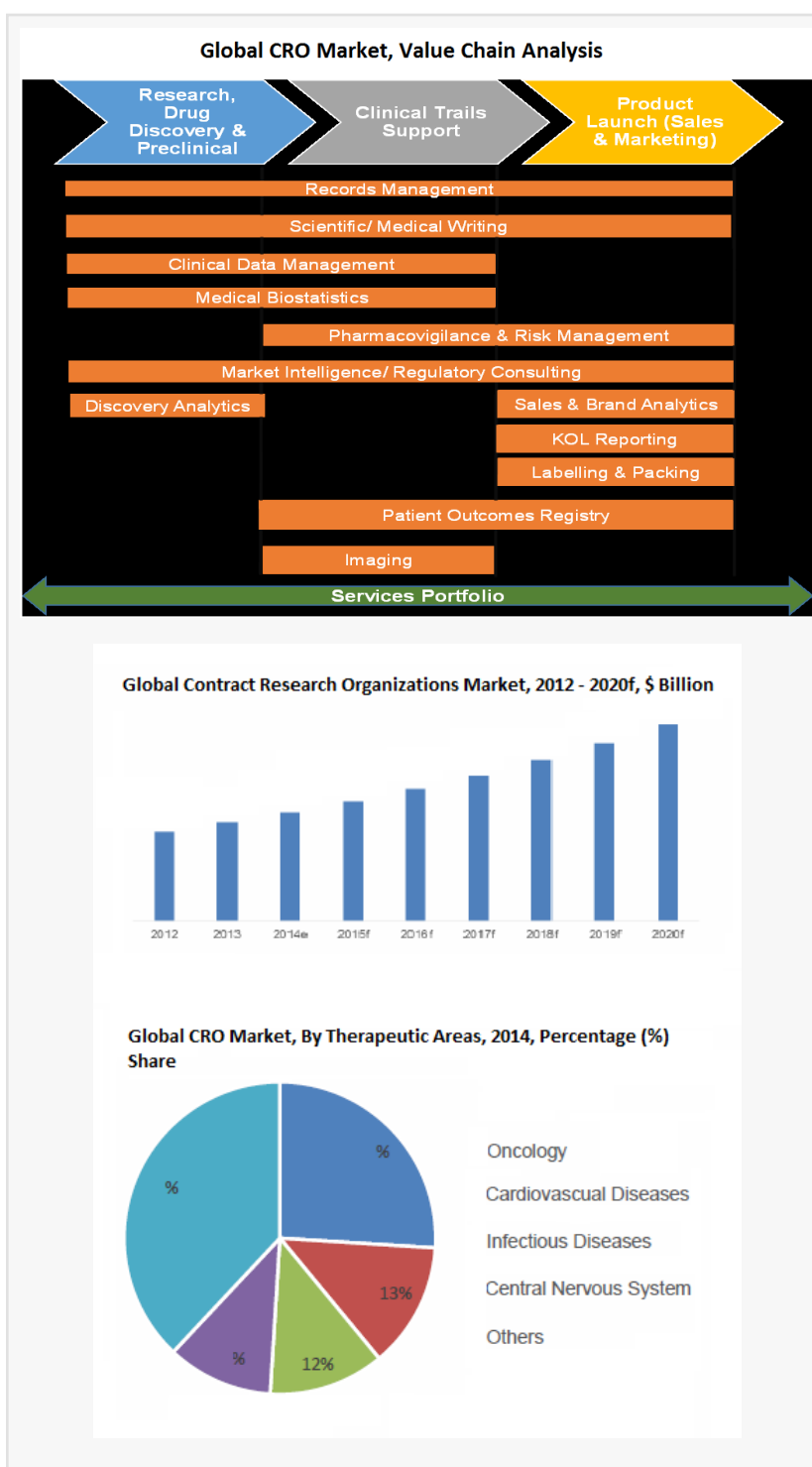
The report delivers a strategic analysis of the global market for CROs, and growth forecast for the period from 2012 – 2020. The scope of the report includes competitive analysis of various market players who are operating in the market, segmental analysis based on type of clinical trial phases and therapeutic areas. It also covers geographical analysis of the market with growth forecast for the period of 2012 – 2020. The Porter's Five Forces analysis and value chain analysis included in the report provides an insight into market dynamics and industry competition.

2. Drug Discovery And Development Process

Discovery and development of an

effective and safe pharmaceuticals is a challenging task that can take 10 to 15 years of time and incur cost of approximately USD 1.0b to 1.5b. The drug discovery and development process required sophisticated technology and a broad array of medical and laboratory expertise, which include: target identification, pre-clinical evaluation, toxicology and safety testing, and clinical trials design and implementation. A typical drug discovery and development process can be described as shown in figure.

3. Market Drivers and Challenges



3.1 Drivers

Increased R&D Expenditure And Decline In Productivity

All the leading [pharmaceutical and biotechnology companies](#) have readjusted their R&D expenditure owing to a decline in productive outcomes clinical trials and increasing cost containment pressures. These pharmaceutical companies no longer conduct clinical drug development alone and are highly focused on reducing their R&D expenditure through globalization and collaborative research efforts with



the contract research organizations. Large investments in clinical trials are associated with huge financial risks, in order to alleviate these risks and to achieve high return on investment, companies are now tying up with CROs to outsource their drug development work. Contract research organizations help in reducing the operational expenditure of pharmaceutical companies and also the time required to conduct drug discovery and clinical trials of pharmaceutical and biotechnology products.

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3.2 Challenges

Data Safety Concerns And Clinical Trial Failures

[Overall drug development process comprise of three phases.](#) Among these, phase I is to evaluate the drug safety, phase II trials assess the drug efficacy and phase III is to monitor the side effects of the drug and also to compare with the other similar compounds which are already present in the market.

Drug clinical trial failure can occur at any stage, including the pre-clinical stage. Nonetheless, most of the drug failures takes place either in phase II or phase III trials. In the entire drug development process, 51% of drugs fail due to insufficient efficacy, 30% fail because of safety concern and remaining only 19% is due to poor strategic reasons in the market.

Stringent Government Regulations

Majority of the clinical trials and other research processes are outsourced to various countries simultaneously. These destination countries have different guidelines and regulatory processes related to drugs, filing and clinical trials. The conduction of multi-location trials of a single drug in different procedures in different countries poses a challenge to pharmaceutical companies as they have to follow a completely different procedure in each country. This is observed as one of the major challenges for research outsourcing in different countries and therefore, a company prefers to restrict outsourcing to one destination country.

4. Value Chain Analysis

The life sciences industry is revolutionizing as the companies face unprecedented challenges owing to pricing pressures caused by healthcare reforms and austerity measures. Moreover, this industry is facing tremendous pressure and increased competition to introduce new drugs in the market. To combat these challenges the pharmaceutical companies are now adopting strategies that focus on growth opportunities in emerging markets. In addition to this companies are pursuing breakthrough innovation through collaboration with academics and industry partners. These companies are now looking for introducing disruptive technologies that would aid in rapid results of clinical trials and would provide cost-arbitrage for the investments done. The pharmaceutical industry is undergoing sweeping changes as companies now prefer outsourcing their R&D, sales and marketing, legal services and compliance activities with more focus given on operational efficiencies.

5. Global Contract Research Organizations Market, 2012 – 2020f

The various type of services provided by contract research organizations to biopharmaceutical companies in drug development process includes initial drug discovery studies, pre-clinical studies, early clinical trial phase I-IIa, phase IIb-III, phase IIIb-IV and others. The others segment include various support services such as pharmacovigilance, bio-statistics, clinical data management, site management, monitoring, regulatory services, protocol development and medical writing. Clinical trials typically differ by phase and type, but it involves rigorous scientific testing and labor work. Clinical trials primarily aimed to develop new strategies or products to prevent, detect, and treat and to improve overall quality of life of people who are suffering with various diseases.

Over the last 15 years, the process of drug development become increasingly laborious and complex, requiring pharmaceutical companies to submit complex data to the regulatory bodies for its approval. As a result, these companies are able to launch only very limited number of drugs into the market due to stringent regulatory requirements. Hence, these biopharmaceutical companies are focusing on outsourcing these activities to contract research organizations to save the time required to bring the drug into the market and also to focus on their key business activities such as sales, marketing and R&D initiatives.

6. Global Contract Research Organizations Market Segmentation

6.1 Segment by Therapeutic Areas, 2014

The global CRO market based on the therapeutic areas is segmented into five segments, which includes CNS, cardiac diseases, oncology, infectious diseases and others. The others segment comprise various metabolic, dermatology, diabetes, respiratory diseases, etc. Among these above mentioned therapeutic areas, the oncology segment accounted for nearly 30% of total R&D pipeline in 2014 and is followed by infectious disease segment, which is accounted for 18% share of overall clinical trial pipeline. The infectious disease segment is followed by CNS and cardiovascular segments accounted for 7% and 10% respectively in 2014. The others segment that comprise various respiratory, dermatology, diabetes and metabolic diseases held 40% share of overall clinical trial

pipeline in 2014.

6.2 Segmentation by Geography, 2012 - 2014

The market for global contract research organizations is segmented into four major regions that includes North America, Europe, Asia-Pacific and Rest of the World. Among these, currently the market is primarily dominated by North America however, the Asia-Pacific region is growing at an impressive CAGR compared to other regions.

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