Global Healthcare Regulatory Affairs Outsourcing - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts 2019 - 2029

Market Report | 2024-02-17 | 115 pages | Mordor Intelligence

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Report description:

The Global Healthcare Regulatory Affairs Outsourcing Market size is estimated at USD 8.35 billion in 2024, and is expected to reach USD 12.71 billion by 2029, growing at a CAGR of 8.74% during the forecast period (2024-2029).

During the pandemic, the massive influx of COVID-19 patients resulted in mass lockdowns, which disrupted clinical studies of various chronic diseases such as cancer. The reduction in the number of clinical trials amid the pandemic resulted in a decrease in the demand for healthcare regulatory affairs outsourcing services. For instance, a study published in the Frontiers in Medicine1 in December 2021 highlighted that clinical trial activities decreased during the pandemic as the number of COVID-19 patients increased. The source also stated that new drug submissions dropped in non-COVID-19 clinical developments amid the pandemic.

Therefore, disruptions in the global supply chain affected the manufacturing and distribution of pharmaceutical products during the pandemic's initial phase, significantly impacting the market growth. Regulatory affairs teams had to navigate challenges related to ensuring the availability and safety of essential drugs, necessitating regulatory adaptations.

Moreover, growing R&D expenditure, the increasing number of clinical trials, and the cost-effectiveness of outsourcing are expected to drive market growth. For instance, according to Global Observatory on Health R&D analysis published on February 2022, there was a constant rise in the number of newly recruiting trials registered on the WHO International Clinical Trials Registry Platform (ICTRP) for most WHO regions. Moreover, the number of trials registered in WHO's Europe, Americas, and Western Pacific regions increased at a higher rate than in other regions. For instance, in 2021, Western Pacific registered 16,860 clinical trials, around 20 times higher than that in Africa, which accounted for 851 clinical trials. Thus, an increasing number of clinical trial studies are expected to increase regulatory affairs outsourcing over the forecast period.

Furthermore, increasing research and development investment by pharmaceutical and biotechnology firms is anticipated to drive market growth. As per the PhRMA, the members of PhRMA invested about USD 102.3 billion in R&D activities in 2021. As per the data published by the European Federation of Pharmaceutical Industries and Associations in 2022, the research-based European pharmaceutical industry has increased from the past years and reached the value of EUR 300 billion (USD 323.7 billion) in 2021. The same source also stated that this industry received a significant R&D investment of EUR 41.5 billion (USD 44.77 billion) in 2021.

Additionally, various strategic activities by key market players, such as mergers and acquisitions, are anticipated to drive market growth. For instance, in July 2021, Covance acquired GlobalCare, a global leader in patient-centric decentralized clinical trials (DCTs), to expand Covance's DCT offerings into international markets and meet the growing demand for patient-centric trial designs.

Thus, the factors mentioned above are expected to increase the demand for healthcare regulatory services in the industry, thereby driving market growth over the forecast period. However, the risk associated with data security and lack of standardization is the major restraining factor for the studied market.

Healthcare Regulatory Affairs Outsourcing Market Trends

Product Registration & Clinical Trial Application Segment is Expected to Hold Significant Market Share Over the Forecast Period

Product Registration refers to the application for regulatory approval granted by the applicable authority in a given country or territory to allow a product to be marketed, distributed, sold, or imported into the country or region. The Clinical Trial Application refers to submission to the competent national regulatory authorities for getting authorization to conduct a clinical trial in the country. The clinical trial application contains detailed information about the investigational medicinal product and planned trial, allowing regulatory authorities to assess the study's feasibility.

The increase in outsourcing of clinical trial applications and product registrations in both developed and developing countries is driving the product registration and clinical trial application segment over the forecast period. Due to the complexity of the product registration process, lack of professionals in the industry, and lack of internal capability, most pharmaceutical and medical device companies outsource their product registration activities to third-party service providers. Furthermore, constant changes and updation in regulatory affairs also drive the outsourcing of such services. For instance, on 31 January 2022, the European Medicines Agency announced the regulatory harmonization of clinical trials in the EU. It also launched a new Clinical Trials Information System (CTIS). This is anticipated to propel the segment growth over the forecast period.

Thus, all factors mentioned above are expected to boost segment growth over the forecast period.

North America is Expected to Hold Major Market Share Over the Forecast Period

Pricing pressure due to the changing reimbursement scenario and generic competition is causing major pharmaceutical firms to outsource regulatory affairs activities expected to drive the growth of healthcare regulatory outsourcing services in North America. Additionally, growing research and development activity and rising clinical trials are anticipated to drive regional market growth. For instance, according to the Global Observatory on Health R&D, the United States registered 10,870 clinical trials in 2021, accounting for 18.1% of the total. According to the same source, Canada registered 2,099 clinical trials in 2021, accounting for 3.5% of the total. Thus, many clinical trials in the region are likely to drive the regulatory affairs outsourcing market.

Moreover, the presence of key regional players and strategic collaborations in the industry are driving the market's growth. For instance, in April 2021, Parexel and Veeva Systems announced a strategic partnership to speed up clinical trials by leveraging

technology and process innovation. Both businesses will benefit from each other's regulatory consulting services.

Thus, all factors above are expected to boost the market growth in the North America region over the forecast period.

Healthcare Regulatory Affairs Outsourcing Industry Overview

The Healthcare Regulatory Affairs Outsourcing Market is a slightly fragmented market owing to the presence of various market players. The competitive landscape includes an analysis of a few companies which hold significant market shares, including Charles River Laboratories, Syneos Health, Laboratory Corporation of America Holdings, ICON Plc., IQVIA, PAREXEL International Corporation, and Thermo Fisher Scientific Inc. (PPD), among others.

Additional Benefits:

- The market estimate (ME) sheet in Excel format
- 3 months of analyst support

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