

Healthcare Regulatory Affairs Outsourcing Market- Growth, Trends, Covid-19 Impact, and Forecasts (2023 - 2028)

Market Report | 2023-01-23 | 135 pages | Mordor Intelligence

AVAILABLE LICENSES:

- Single User License \$4750.00
- Team License (1-7 Users) \$5250.00
- Site License \$6500.00
- Corporate License \$8750.00

Report description:

The Healthcare Regulatory Affairs Outsourcing Market is expected to register a CAGR of 8.5% during the forecast period of 2022-2027.

During pandemic a large number of clinical trials were postponed as well as canceled, this has impacted the regulatory outsourcing market, as clinical trials are the major driver for the industry. For instance, according to the study titled "COVID-19 Pandemic and Trends in Clinical Trials: A Multi-Region and Global Perspective" published in the Frontier in Medicine in December 2021, there is a decrease in clinical trials between each month in 2019 and the corresponding month in 2020, the average percentage change in newly started clinical trials for diseases other than COVID-19 was -7.5% &, with a maximum of -57.3% observed between April 2019 and April 2020. Similarly, in 2019 and 2020, the average percentage change in reported results for each month was -5.1% in 2020. This is expected to reduce the overall regulatory affairs services demand in the industry.

The market growth can be attributed to the growing R&D expenditure, increasing number of clinical trials, the cost-effectiveness of the outsourcing, and lack of internal skilled professionals. For instance, according to ClinicalTrials.gov March 2022, as of March 2021, 410,703 studies were listed in 220 countries out of which 318,134 interventional studies and 90,926 observational studies. Moreover, as per the same source, the number of clinical trial studies is expected to increase from 325,775 in 2020 to 399,532 by the year 2023. Thus, an increasing number of clinical trial studies is expected to increase the regulatory affairs outsourcing over the forecast period.

Furthermore, increasing research and development investment by pharmaceutical and biotechnology firms is anticipated to drive market growth. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the members of PhRinvested MA about USD 83 billion in R&D activities in 2019. Also, more than 260 vaccines are under development for various diseases,

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

including COVID-19, as per PhRMA, 2020.

Additionally, various strategic activities by key market players such as product launches, 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), in order to expand Covance's DCT offerings into international markets and meet the growing demand for patient-centric trial designs.

Thus, all the aforementioned factors are expected to boost the market over the forecast period. However, the risk associated with data security and lack of standardization are the major restraining factor for the studied market.

Healthcare Regulatory Affairs Outsourcing Market Trends

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

Product Registration refers to the application for regulatory approval granted by the applicable governmental authority in a given country or territory to allow a product to be marketed, distributed, sold, or imported in that country or territory. And a 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 expansion of the clinical trial applications and product registrations segment over the forecast period. Due to the complexity of the product registration process, lack of industry professions, and lack of internal capability, most pharmaceutical and medical device companies outsource their product registration activities to third-party service providers. This is anticipated to propel the segment growth over the forecast period.

Thus, all aforementioned factors are expected to boost the 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 which are supplementing the growth of healthcare regulatory outsourcing services in North America. Additionally, growing research and development activity rising in the number of clinical trials anticipated the market growth in the region.

Furthermore, as per November 2021 updated data by Clinicaltrials.gov, 32% of the trials were registered in the United States where the major number of trials are related to various types of drugs which is likely to drive the regulatory affairs outsourcing thereby anticipated the market growth.

Moreover, the presence of key players in the region and strategic collaborations by these companies 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 aforementioned factor expected to boost the market growth in the North America region over the forecast period.

Healthcare Regulatory Affairs Outsourcing Market Competitor Analysis

The market studied is a fragmented market owing to the presence of various market players. The market players are focusing on

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

R&D to develop new and efficient products in the market. Some of the market players are Accell Clinical Research, LLC., Charles River Laboratories International, Inc, Criterium Inc., Covance, Inc., ICON Plc., IQVIA, PAREXEL International Corporation, Pharmaceutical Product Development, (PPD) LLC.

Additional Benefits:

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

Table of Contents:

1 INTRODUCTION

1.1 Study Assumptions and Market Definition

1.2 Scope of the Study

2 RESEARCH METHODOLOGY

3 EXECUTIVE SUMMARY

4 MARKET DYNAMICS

4.1 Market Overview

4.2 Market Drivers

4.2.1 Increasing Number of Clinical Trials

4.2.2 Life Science Companies Focusing on Their Core Competencies

4.3 Market Restraints

4.3.1 Risk Associated with the Data Security

4.4 Porter's Five Force Analysis

4.4.1 Threat of New Entrants

4.4.2 Bargaining Power of Buyers/Consumers

4.4.3 Bargaining Power of Suppliers

4.4.4 Threat of Substitute Products

4.4.5 Intensity of Competitive Rivalry

5 MARKET SEGMENTATION (Market Size by Value - USD million)

5.1 by Services

5.1.1 Regulatory Consulting

5.1.2 Legal Representation

5.1.3 Regulatory Writing & Publishing

5.1.4 Product Registration & Clinical Trial Applications

5.1.5 Other Services

5.2 by End User

5.2.1 Pharmaceutical and Biotechnology Companies

5.2.2 Medical Device Companies

5.3 Geography

5.3.1 North America

5.3.1.1 United States

5.3.1.2 Canada

5.3.1.3 Mexico

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

- 5.3.2 Europe
 - 5.3.2.1 Germany
 - 5.3.2.2 United Kingdom
 - 5.3.2.3 France
 - 5.3.2.4 Italy
 - 5.3.2.5 Spain
 - 5.3.2.6 Rest of Europe
- 5.3.3 Asia-Pacific
 - 5.3.3.1 China
 - 5.3.3.2 Japan
 - 5.3.3.3 India
 - 5.3.3.4 Australia
 - 5.3.3.5 South Korea
 - 5.3.3.6 Rest of Asia-Pacific
- 5.3.4 Middle-East
 - 5.3.4.1 GCC
 - 5.3.4.2 South Africa
 - 5.3.4.3 Rest of Middle-East
- 5.3.5 South America
 - 5.3.5.1 Brazil
 - 5.3.5.2 Argentina
 - 5.3.5.3 Rest of South America

6 COMPETITIVE LANDSCAPE

- 6.1 Company Profiles
 - 6.1.1 Accell Clinical Research, LLC.
 - 6.1.2 Charles River Laboratories International, Inc.
 - 6.1.3 Criterium Inc.
 - 6.1.4 Covance, Inc.
 - 6.1.5 ICON PLC.
 - 6.1.6 IQVIA
 - 6.1.7 Medpace, Inc.
 - 6.1.8 PAREXEL International Corporation
 - 6.1.9 Pharmaceutical Product Development, (PPD) LLC.
 - 6.1.10 Promedica International
 - 6.1.11 WuXi App Tec

7 MARKET OPPORTUNITIES AND FUTURE TRENDS

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Healthcare Regulatory Affairs Outsourcing Market- Growth, Trends, Covid-19 Impact, and Forecasts (2023 - 2028)

Market Report | 2023-01-23 | 135 pages | Mordor Intelligence

To place an Order with Scotts International:

- Print this form
- Complete the relevant blank fields and sign
- Send as a scanned email to support@scotts-international.com

ORDER FORM:

Select license	License	Price
	Single User License	\$4750.00
	Team License (1-7 Users)	\$5250.00
	Site License	\$6500.00
	Corporate License	\$8750.00
		VAT
		Total

*Please circle the relevant license option. For any questions please contact support@scotts-international.com or 0048 603 394 346.

** VAT will be added at 23% for Polish based companies, individuals and EU based companies who are unable to provide a valid EU Vat Numbers.

Email*	<input type="text"/>	Phone*	<input type="text"/>
First Name*	<input type="text"/>	Last Name*	<input type="text"/>
Job title*	<input type="text"/>		
Company Name*	<input type="text"/>	EU Vat / Tax ID / NIP number*	<input type="text"/>
Address*	<input type="text"/>	City*	<input type="text"/>
Zip Code*	<input type="text"/>	Country*	<input type="text"/>
		Date	<input type="text" value="2026-02-27"/>
		Signature	

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

