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eCLINICAL SOLUTIONS MARKET

(CDMS/EDC, CTMS, eCOA, Randomization & Trial Supply Management, Safety), **Services, Buyers** (Pharma/Biopharma, CROs, Healthcare providers), **Delivery Modes** (Web Hosted, On-premise, Cloud-based)

– Global Forecasts to 2018



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1 EXECUTIVE SUMMARY

eClinical solutions help in reducing project time, cost, and in enhancing the quality of clinical processes and data analysis. This in turn optimizes the drug development process. As regulatory compliance pressures are rising, pharmaceutical companies are actively seeking ways to decrease the cost and manage the risks associated with clinical trials, which in turn is increasing the demand for eClinical solutions.

The global eClinical solutions market was valued at \$XX million in 2013 and is expected to reach \$XX million by 2018, at a CAGR of XX% from 2013 to 2018. The growth of the eClinical solutions market is primarily triggered by the growth in the number of clinical trials, increasing government pressure to reduce the cost and time spent on clinical developments, government funding to support clinical trials, and significant clinical R&D investments by pharmaceutical and biopharmaceutical companies. Integration of various eClinical solutions on a single platform is the emerging trend in the clinical trials industry. However, factors such as the high cost of eClinical systems, and scarcity of a skilled workforce for conducting clinical trials are restraining the growth of this market.

TABLE 1

GLOBAL eCLINICAL SOLUTIONS MARKET, BY TYPE, 2011–2018 (\$MILLION)

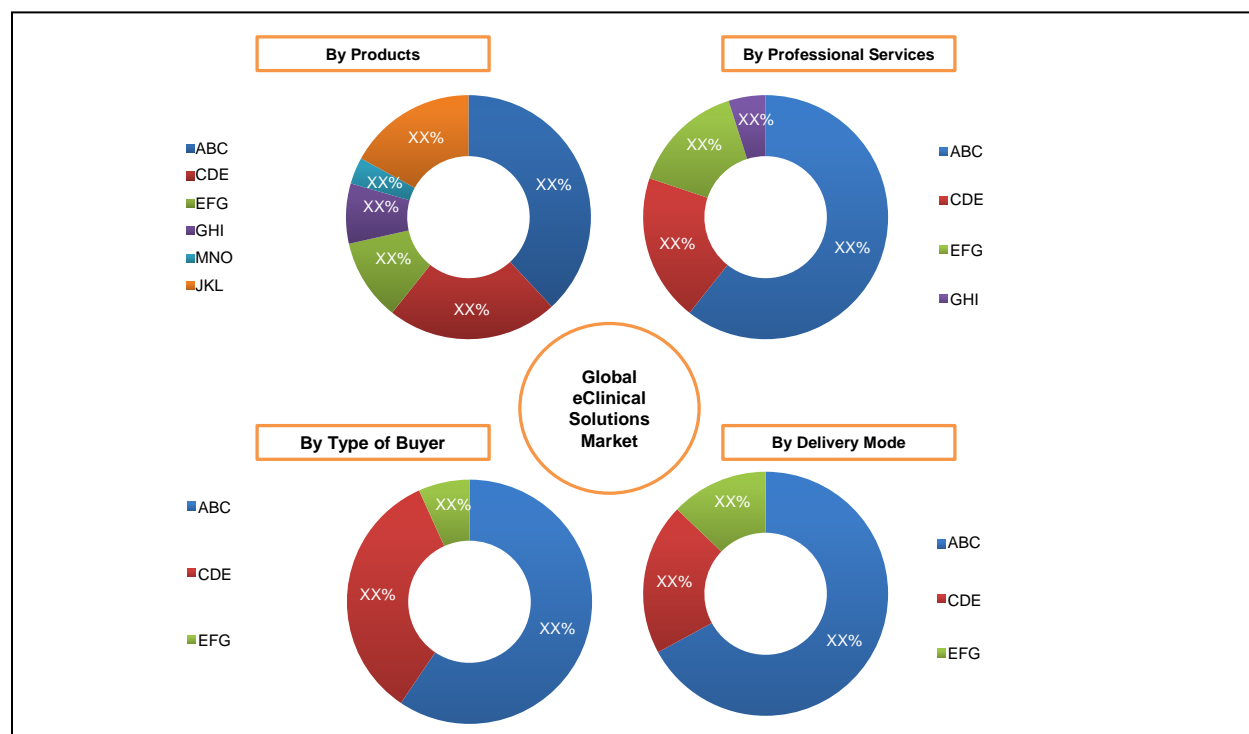
Type	2011	2012	2013	2018	CAGR
Products	XX	XX	XX	XX	XX
Professional Services	XX	XX	XX	XX	XX
Total	XX	XX	XX	XX	XX

Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal For Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

In this report, the global eClinical solutions market is broadly segmented into two categories, namely, products and professional services. The products market is further classified into clinical data management system/electronic data capture (CDMS/EDC), clinical trial management system (CTMS), electronic clinical outcome assessment (eCOA), randomization and trial supply management (RTSM), safety solutions, and others. The others segment consists of core lab integration systems, regulatory information management services, and coding systems. The CDMS/EDC segment accounted for the largest share of the global eClinical solutions market by products at an estimated \$XX million in 2013, while the eCOA market is expected to grow at the highest CAGR of XX% from 2013 to 2018. Increasing acceptance of ePRO (Electronic Patient Reported Outcomes) solutions due to better work efficacy, technological advancements, and increasing penetration of Internet are the key factors stimulating the growth of the eCOA solutions market.

FIGURE 1

GLOBAL eCLINICAL SOLUTIONS MARKET, BY SEGMENTS, 2013



Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal For Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

2 eCLINICAL SOLUTIONS MARKET, BY PRODUCT

2.1 INTRODUCTION

TABLE 2

eCLINICAL SOLUTIONS MARKET, BY PRODUCT, 2011–2018 (\$MILLION)

Product	2011	2012	2013	2018	CAGR% (2013–2018)
CDMS/EDC	XX	XX	XX	XX	XX
CTMS	XX	XX	XX	XX	XX
eCOA	XX	XX	XX	XX	XX
RTSM	XX	XX	XX	XX	XX
Safety Solutions	XX	XX	XX	XX	XX
Others	XX	XX	XX	XX	XX
Total	XX	XX	XX	XX	XX

Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal for Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

As of 2013, the Clinical Data Management System (CDMS)/Electronic Data Capture (EDC) segment accounted for the lion's share of ~XX% of the global eClinical trials products market, and is poised to grow at a CAGR of XX% from 2013 to 2018. The increasing need for improved data standardization to meet the regulatory requirements is the key factor propelling the growth of the CDMS/EDC market. The eCOA segment is estimated to witness the highest CAGR of XX% in the next five years. The high growth rate of the eCOA solutions market can be attributed to the growing acceptance of ePRO (Electronic Patient Reported Outcomes) solutions over data collection on paper due to better work efficacy and also due to the increasing penetration of the Internet.

3 eCLINICAL SOLUTIONS MARKET, BY PROFESSIONAL SERVICES

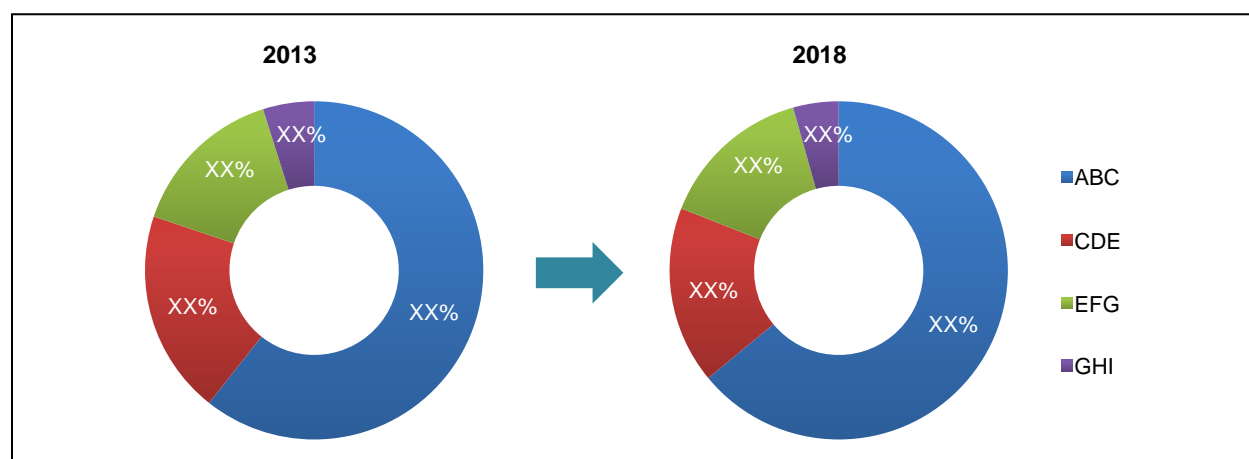
3.1 INTRODUCTION

In clinical trials, services form an important component of the market, primarily because the role of a service provider is indispensable when it comes to delivery of eClinical solutions. The healthcare industry relies heavily on service providers for setting up basic requirements, providing storage, maintenance, and regularly updating the technology.

In this report, eClinical professional services have been segmented into four major categories, namely, implementation services, training, support services (post sales and maintenance), and consulting.

FIGURE 2

GLOBAL eCLINICAL SOLUTIONS MARKET, BY PROFESSIONAL SERVICES, 2013 VS. 2018



Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal For Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

The implementation services segment accounted for the major share of ~XX% of the global eClinical services market in 2013; it is poised to grow at the highest CAGR of XX% from 2013 to 2018, to reach \$XX million by 2018. A number of factors such as the increase in the number of clinical trials, technological advancements for implementation of IT solutions, and stringent regulatory requirements for approval of clinical studies are driving the demand for the implementation of eClinical solutions in clinical studies.

4 GLOBAL eCLINICAL SOLUTIONS MARKET, BY TYPE OF BUYER

4.1 INTRODUCTION

TABLE 3
GLOBAL eCLINICAL SOLUTIONS MARKET, BY TYPE OF BUYER, 2011–2018 (\$MILLION)

Buyer	2011	2012	2013	2018	CAGR% (2013–2018)
Pharmaceutical/Biopharmaceutical/Medical Device Companies	XX	XX	XX	XX	XX
Clinical Research Organizations (CROs)	XX	XX	XX	XX	XX
Healthcare Providers	XX	XX	XX	XX	XX
Total	XX	XX	XX	XX	XX

Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal For Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

The CROs segment is estimated to grow at the highest CAGR of ~XX% in the next five years. Growth in the number of CROs in developed as well as developing countries, coupled with the growth in clinical trial outsourcing to specialized clinical research organizations, is the key factor responsible for the high growth rate of this segment. However, factors such as high implementation cost of eClinical solutions and budget limitations faced by small and medium-sized pharmaceutical companies and CROs are hampering the growth of the eClinical solutions buyers market.

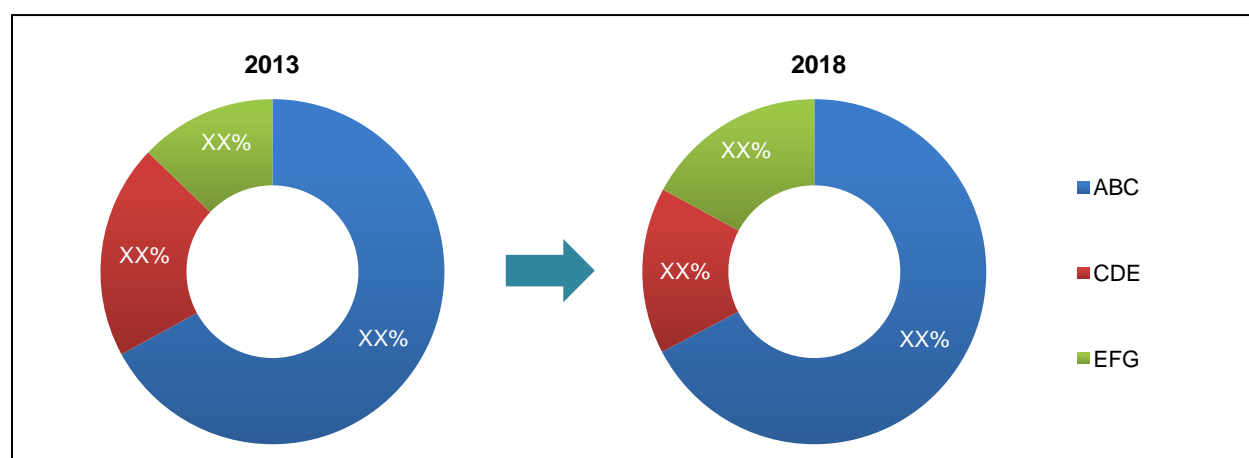
5 eCLINICAL SOLUTIONS MARKET, BY DELIVERY MODE

5.1 INTRODUCTION

Based on the mode of delivery, the eClinical solutions market is divided into three segments, namely, licensed enterprise/on-premise model, web-hosted model, and cloud-based model.

FIGURE 3

GLOBAL eCLINICAL SOLUTIONS MARKET, BY DELIVERY MODE, 2013 VS. 2018



Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal For Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

The on-premise model is the traditional mode of software implementation, and was the most preferred and common mode of delivery in the past. In this model, end-users purchase the software licensing based on their organizational needs and determine how it will be implemented and maintained. This model demands certain infrastructural requirements at the customer location or premise, and the applications are installed in such a way that they can be accessed at the specific premise only.

Web-based eClinical solutions are available to CROs, healthcare providers, and pharmaceutical companies. This hosted model offers improved performance and reliability, by avoiding long deployment cycles. It also minimizes upfront investment, eliminating the need to incur high infrastructure costs.

Cloud/software-as-a-service (SaaS) is a recently evolved delivery mode. In this mode, the cloud vendor offers a separate cloud-based server to customers in a subscription-based or pay-as-you-go pricing model. Cloud offerings by these service vendors are mainly in the form of three deployment models, namely, public cloud, private cloud, and hybrid cloud. A recently emerging trend in the cloud industry is community clouds, which caters to the specific needs of large communities (such as research communities) and can share data and store data on a dedicated research cloud.

6 GEOGRAPHIC ANALYSIS

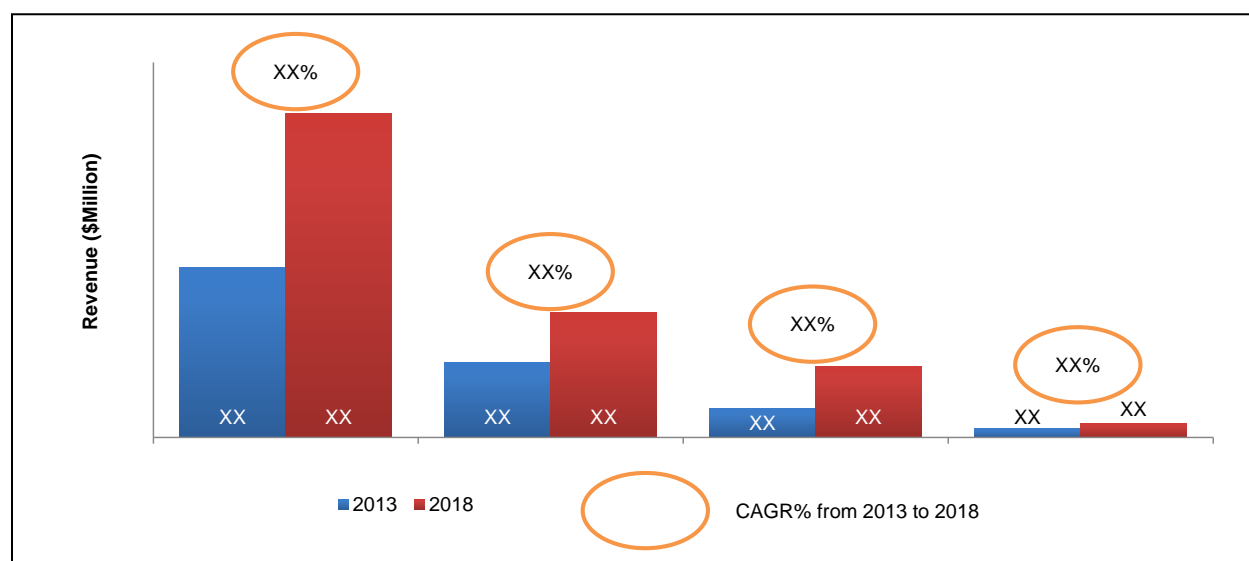
6.1 INTRODUCTION

Globally, there is a growing demand for decreasing the overall cost and time consumed during clinical trials; this, coupled with the technological advancements in eClinical solutions, is the major factor contributing to the growth of the eClinical solutions market. Other factors that are driving this market are the growth in the number of clinical trials and the increasing applications of cloud computing technology in the healthcare industry.

In this report, the global eClinical solutions market is divided into four major regions, namely, North America, Europe, Asia-Pacific, and Rest of the World (RoW).

FIGURE 4

GLOBAL eCLINICAL SOLUTIONS MARKET, BY GEOGRAPHY, 2013–2018 (\$MILLION)



Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, clinicaltrial.gov, National Center for Biotechnology Information, The EU Industrial R&D Investment Scoreboard, Tennessee Chinese Chamber of Commerce, Journal For Clinical Studies, Expert Interviews, and MarketsandMarkets Analysis

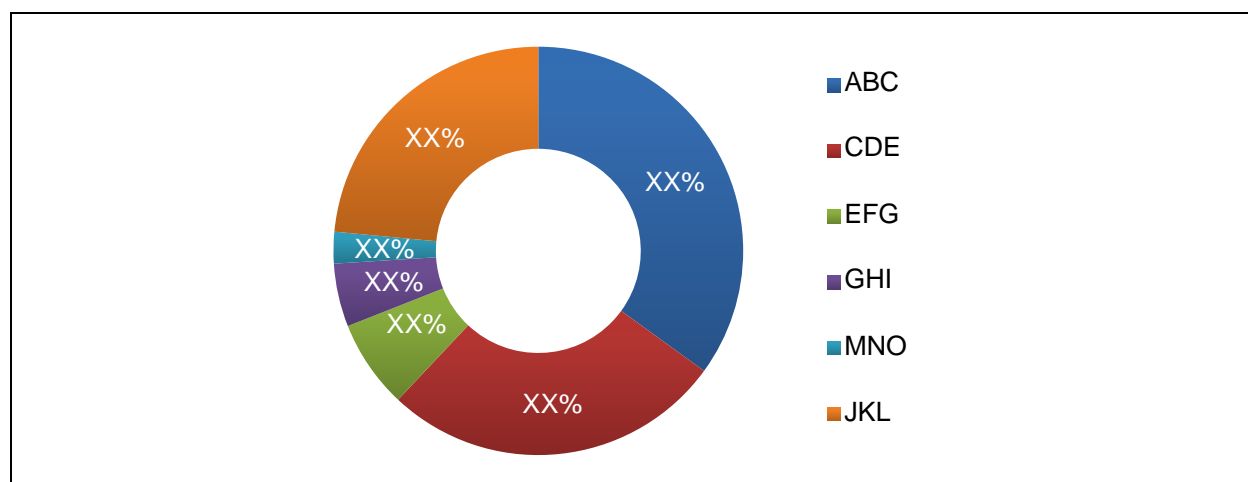
7 COMPETITIVE LANDSCAPE

7.1 MARKET SHARE ANALYSIS, BY SEGMENT AND KEY PLAYERS

7.1.1 KEY PLAYERS IN THE CLINICAL DATA MANAGEMENT SYSTEM (CDMS)/ELECTRONIC DATA CAPTURE (EDC) SOLUTIONS MARKET

FIGURE 5

GLOBAL CDMS/EDC SOLUTIONS MARKET SHARE, BY KEY PLAYERS, 2012



Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis

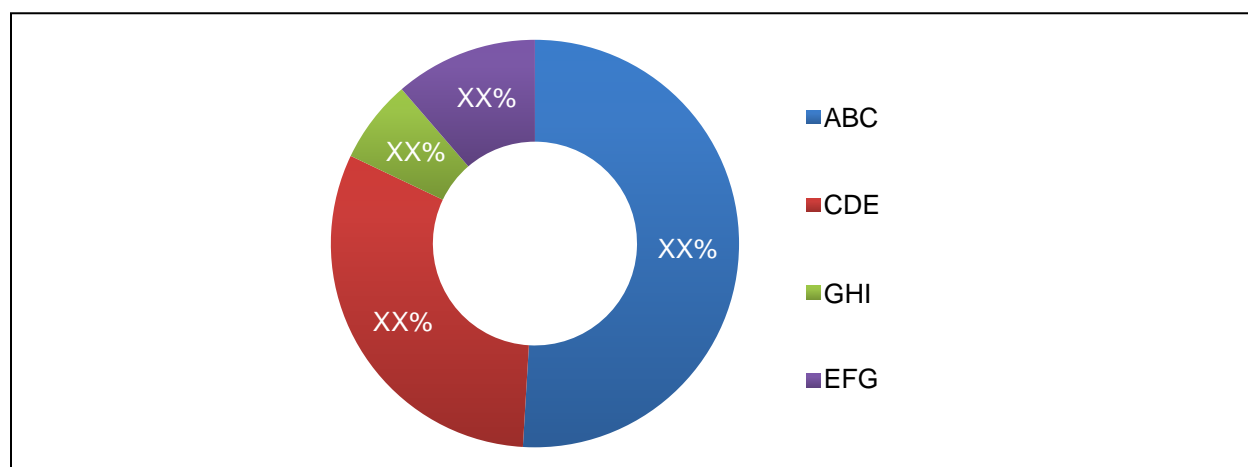
Oracle Corporation held the leadership position in the global CDMS/EDC solutions market, with a share of ~XX% in 2012. Oracle's Clintrial is considered as the most preferred EDC solution among end users. Clintrial is an incorporated software solution that offers CDMS, together with CTMS, to manage the entire clinical development process right from study initiation and FDA submission to post-marketing studies. The company has a strong geographic presence with ~XX customers, which include top pharmaceutical companies and clinical research

organizations, in 145 countries all over the world. The company has been focusing on acquisitions and new product launches as its key business strategies, to maintain its market leader position and ensure its business growth in the global CDMS/EDC solutions market. This is evident from the acquisition of Phase Forward, in April 2010, which enabled Oracle to strengthen its position and share in the global CDMS/EDC market.

7.2 COMPETITIVE SITUATION AND TRENDS

FIGURE 6

KEY GROWTH STRATEGIES, 2011–2013



Source: Annual Reports, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis

Partnerships, agreements, collaborations, and joint ventures was the key strategy adopted by industry players to achieve growth in this market. This strategy accounted for a share of XX% of the overall growth strategies adopted by market players. The rising demand for eClinical trial solutions and the high growth opportunities offered by emerging markets are the factors that have encouraged market players to adopt this strategy. Market players are focusing on the development of their existing eClinical products and services by integrating them with the solutions offered by other market vendors.

BioClinica, Inc. (U.S.), DATATRAK International (U.S.), PAREXEL International Corporation (U.S.), Merge Healthcare Incorporated (U.S.), OmniComm Systems, Inc. (U.S.), and Oracle Corporation (U.S.) are the major players that adopted this strategy to develop their business in the global eClinical solutions market.

Besides partnership agreements, companies adopted the strategy of new product launch and product development, in order to strengthen their product portfolio. The strategy of new product launch and product development accounted for a share of ~XX% of the total number of growth strategies adopted by players in the eClinical solutions market between 2011 and 2013. PAREXEL International Corporation (U.S.), CRF Health (U.S.), BioClinica, Inc. (U.S.), DATATRAK International (U.S.), Medidata Solutions, Inc. (U.S.), Oracle Corporation (U.S.), and PHT Corporation (U.S.) are some of the leading players that adopted this strategy to ensure their business growth.

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