Clinical Services Market POISED FOR GROWTH

In the next five years, almost three-quarters of clinical trials will be performed by CROs.

According to a recent report from JZ Med, the global clinical trial service market is expected to reach more than $64 billion by 2020, up from $38.4 billion at present, representing a CAGR of 9% between 2015 and 2020. By 2020 the average clinical trial outsourcing penetration will likely reach around 72%. In other words, by then close to three-quarters of clinical trials will likely be performed by professional CROs.

As sponsor companies — biopharmaceutical, biotechnology, drug device companies — continue to seek opportunities to increase efficiencies, reduce costs, and leverage resources, and enhance timelines, they are increasingly turning to outsourcing services offered by clinical trial service providers, both full-service CROs as well as providers of clinical trial technologies.

Analysts state that increased R&D by biopharmaceutical sponsors is one of the drivers toward increased outsourcing to CROs. Additionally, as sponsors are increasingly turning their attention to biologics and treatments for rare diseases, the complexity of clinical trials is also increasing. These factors are leading to increased pressures on the development continuum — from patient recruitment to analyzing big data to improving outcomes.

According to TechNavio's analysts, the global CRO market is forecast to grow at a CAGR of 9.83% from 2014 to 2019.

Emerging Markets

According to Nice Insight's 2015 pharmaceutical and biotechnology outsourcing survey, 63% of global sponsors outsource their drug R&D to global CROs in emerging markets, a remarkable 68% jump from the 2014 survey, when only 43% reported outsourcing to these markets. In addition, more sponsors (88%) today will consider working with a CRO in an emerging market, up from 84% in 2014.

The rising cost of drug development is one

EXECUTIVE VIEWPOINTS

MARK ENGELHART
Chief Commercial Officer
ACM Global
Central Laboratory

PROACTIVE SUPPORT OF OUTCOMES

It's become increasingly important for drug developers to take proactive measures to optimally position their clinical trials for success and gain a competitive advantage in introducing their new drugs to the market. We encourage the sponsors we work with to engage with our central lab scientific experts early in the protocol development process, first by characterizing the desired study outcomes, and then identifying the endpoints and selecting the lab tests that will ultimately support those outcomes.

CONDUCT A LABORATORY REVIEW

By conducting an expert laboratory review early in the protocol development process, the central lab is able to ensure critical milestones are achieved within the indicated time and cost parameters, as well as ensure optimal use of resources, without increasing risk. With the array of testing options available, test selection is more complex than ever. When the endpoints that will support desired outcomes have been clearly defined, appropriate testing options can be more easily identified.

MARC SIROCKMAN
Executive VP and
General Manager
Artcraft Health

INCENTIVIZING THERAPEUTIC INTERVENTION

Basic and applied analytical research suggests that there is a positive correlation to incentive-based treatment or therapeutic intervention. The incentive or reward should be correlated with the behavior and the individual, which should then be linked directly to the intended outcome. Understanding the impact of the incentive on the intended outcome will deliver an improved therapeutic intervention overall.

REPLENISHING THE PIPELINE

The historical schema within R&D and the continued apprehension from regulatory to push the envelope will continue to be barriers to refilling the diminished pipelines. The communication channels within the overall drug development process create bottlenecks. Current innovation trends provide the opportunity for more efficient and effective strategies to engage and enhance the ultimate scope of reach of solutions. But to use these current innovations for successful outcomes, leveraging a strategic communications and innovations partner early on can assist in removing challenges and barriers for success.

FRANK VAN DE WIJNGAERT
Strategic Development
Partner
Chiltern

INNOVATION IN BREAST CANCER TREATMENT

Personally, I consider the developments in the diagnosis, subtyping, and treatment of breast cancer the most significant clinical innovation in the past 50 years. The prevalence of breast cancer is high and despite significant developments, the mortality is still too high and women and families affected by it will suffer significantly from it both physically and emotionally. Over the past 50 years we have seen significant improvements in the development of identifying tumor subtypes.

of the trends driving movement to emerging markets. Biopharmaceutical companies are also challenged to improve productivity and efficiency, streamline clinical trials, and meet more rigorous regulatory and quality assurance requirements to sustain profitability — in essence, to achieve far more for less cost. To that end, many are implementing strategies to boost profit margins while reducing fixed and variable costs. As part of their strategy, they are looking to emerging market CROs to help them meet these challenges.

While there are valid concerns about globalizing clinical research, emerging markets such as China, Eastern Europe, Turkey, Argentina, and Brazil play a critical role in advancing medical science, analysts at Nice Insight report. Emerging markets offer a number of attractive features, such as the potential for reduced R&D costs and development time and the availability of a large, affordable talent pool with nearly comparable technical capabilities and skills.

Along with competition for clinical trial sites and an escalating number of clinical trials, sponsors and their CRO partners face strong competition for patients in certain therapeutic areas, increasingly complex trial protocols, and increased regulatory requirements. The cost and time to secure well-qualified sites and enroll patients have soared.

For clinical trials, emerging markets offer attractive features, with the potential for faster, less costly clinical trial enrollment, and more cost-effective trial conduct. Typically, these markets also have a larger, clinically naive patient population as potential trial subjects than established markets such as the United States and Western Europe, and offer a means of streamlining trial costs, NiceInsight's reports.

For the minority of sponsors (12%) that have not considered outsourcing projects to emerging market CROs and/or CMOs, more than half (57%) are primarily concerned that the quality level is too risky, and more than one-third (36%) say the logistics are too complicated. Other concerns were regulatory compliance (29%), intellectual property (14%), and communications challenges (14%). According to the NiceInsight's survey, global sponsors that outsourced clinical trials to CROs conducted considerably fewer of their outsourced trials in the United States and Canada in 2015 (19%) than in 2014 (31%). India and Western Europe also decreased as locations selected for clinical trial outsourcing (18% to 11% and 14% to 10% respectively). Clinical trial outsourcing continues to rise in China (15% in 2014 to 18% in 2015) and more than doubled in Argentina and Brazil (7% to 15%). Outsourcing trials also increased in Eastern Europe and Turkey (9% to 10%), the Middle East and Korea (both 2% to 6%), and

These developments made it possible to start targeting the disease individually with patient-specific treatment cocktails. In addition to these developments, we have seen the development of molecular subtyping assays giving us a more accurate picture of which patients may or may not respond to neoadjuvant chemotherapy by reclassifying up to 22% of tumors, which helps suggest the best course for therapy. Eventually, we will be able to evaluate and treat breast cancer patients differently, because we will rely on their functional molecular subtype rather than just IHC-FISH pathology results.

JOSEPH SGHERZA
Senior VP,
Global Operations
ClinicalRM

ADAPTIVE DESIGN — GROUND BREAKING

One of the most advanced clinical trial innovations is the adaptive design model. The ability to use several treatment arms, while using fewer subjects, and decreasing risk is a ground-breaking model for accelerating the clinical trials decision-tree process. By working with our partners to develop adaptive frameworks and targeted protocols, this model has proven to be both highly efficient and flexible, ultimately allowing pharmaceutical and biotechnology companies to test multiple compounds in a shorter period of time.

LARRY FLORIN
Clinical Leader, Life
Sciences R&D Practice
Cognizant

ANTI-INFECTIVES AND IMMUNOLOGY TOP INNOVATIONS

I believe that innovative anti-infective and immunology therapies have had the greatest impact on mankind, reducing suffering and saving tens of millions of lives. Pioneered by Dr. Edward Jennings, many have contributed to develop vaccines and drugs that have eradicated smallpox, prevented and/or reduced the frequency of polio, diphtheria, tetanus, measles, mumps, and rubella and essentially shortened the course of or effectively cured chickenpox and flu as well as hepatitis A and B.

PATENT-RELATED INITIATIVES

Beyond financial incentives including research funding, tax abatements, cost sharing, and more lucrative licensing and partnering agreements, many experts suggest implementing creative patent-related initiatives that balance social welfare attributes, including affordable pricing and improved patient well-being, with profit motives. Patent-related proposals range from extended exclusivity periods to forgoing exclusivity in exchange for future benefits. Flexible, tailored combinations of incentives and rewards most appropriate for a particular circumstance should be considered.

HUGO STEPHENSON
Executive Chairman
DrugDev

SPIRALING COSTS, TRIAL COMPLEXITY

The problem is not refilling pipelines as there are myriad exciting would-be treatments coming out of big pharma and biotech discovery organizations. No, the problem is that it costs too much to test them in clinical trials. These spiraling costs are due to rising complexity and targeting tougher diseases but the main reason is antiquated and disparate process — clinical trial organizations must adopt technology to streamline process and to drive industry standards.

Advanced Clinical understands today's challenges and complexities for the successful management of clinical trials. We take pride in delivering the most customized solutions, grounded in quality, in order to ensure a better clinical experience for our clients.

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Thailand and Vietnam (1% to 5%). Countries in emerging markets are subject to the same global standards for clinical trials. Local governments have supported the trials, making efforts to improve their business environment and regulatory adherence.

Big Data

The McKinsey Global Institute estimates that applying big data strategies to better inform decision making could generate up to $100 billion in value annually across the U.S. healthcare system, by optimizing innovation; improving the efficiency of research and clinical trials; and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

In the healthcare and pharmaceutical industries, data growth is generated from several sources, including the R&D process itself, retailers, patients, and caregivers. Effectively using these data will help pharmaceutical companies better identify new potential drug candidates and develop them into effective, approved, and reimbursed medicines more quickly.

McKinsey outlines several scenarios in which big data and analytics can improve the future of clinical research:

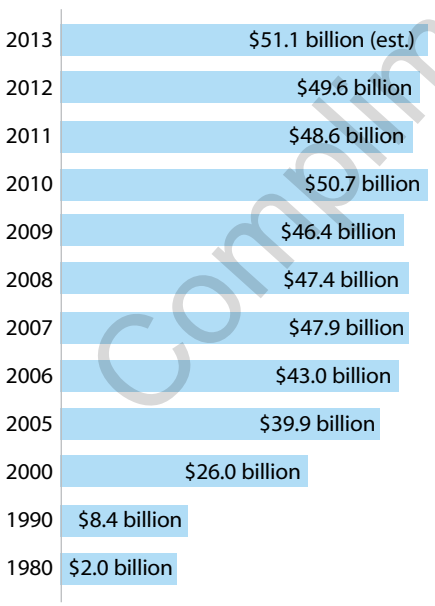
- Predictive modeling of biological processes and drugs becomes significantly more sophisticated and widespread. By leveraging the diversity of available molecular and clinical data, predictive modeling could help identify new potential-candidate molecules with a high probability of being successfully developed into drugs that act on biological targets safely and effectively.
- Patients are identified to enroll in clinical trials based on more sources — for example, social media — than doctors' visits. Furthermore, the criteria for including patients in a trial could take significantly more factors (for instance, genetic information) into account to target specific populations, thereby enabling trials that are smaller, shorter, less expensive, and more powerful.
- Trials are monitored in real time to rapidly identify safety or operational signals requiring action to avoid significant and potentially costly issues such as adverse events and unnecessary delays.
- Instead of rigid data silos that are difficult to exploit, data are captured electronically and flow easily between functions, for example, discovery and clinical development, as well as to external partners, for instance, physicians and CROs. This easy flow is essential for powering the real-time and predictive analytics that generate business value.

However, many pharmaceutical companies are wary about investing significantly in improving big data analytical capabilities, partly because there are few examples of peers creating a lot of value from it. Despite this initial hesitancy, McKinsey analysts believe investment and value creation will grow, stating that while the road ahead is indeed challenging, the big data opportunity in pharmaceutical R&D is real, and the rewards will be great for companies that succeed.

McKinsey research suggests that by implementing eight technology-enabled measures, pharmaceutical companies can expand the data they collect and improve their approach to managing and analyzing these data. The eight measures are: integrate all data, collaborate internally and externally, employ IT-enabled portfolio-decision support, leverage new discovery technologies, deploy sensors and devices, raise clinical-trial efficiency, improve safety and risk management, and sharpen focus on real-world evidence.

But for a big data transformation in pharmaceutical R&D to succeed, executives must overcome several challenges, including organizational, technology and analytics, and mindsets, McKinsey researchers say.

R&D SPENDING



Source: PhRMA

EXECUTIVE VIEWPOINTS

IBS MAHMOOD
President and CEO
DrugDev

THE INTERNET PROVES TRANSFORMATIVE

The biggest clinical innovation in the past 50 years is, without a doubt, the Internet. The Internet has transformed the way that sponsors, CROs, doctors, and patients work together, and created the opportunity for global studies to operate on the scale that we see today. That said, the potential of the Internet to transform clinical trial operations is only just being tapped, and we believe that improvements in quality and efficiency exist from streamlining the administrative challenges of global trial management with technology today.

ROB ROBERTSON
President and CEO
MedNet Solutions

THE IMPACT OF SAAS-BASED ECLINICAL

Easy-to-use, build-it-yourself, and pay-as-you-go cloud-based eClinical solutions are among the most important technology innovations ever introduced to the clinical research community. Gone are the days when CROs and sponsors needed teams of programmers to develop studies, and large IT departments to install software and manage data centers. Today's state-of-the-art systems have made eClinical technology practical for virtually any research initiative, regardless of size, phase or duration.

ZAHER EL-ASSI
President
Merge eClinical

RISK MANAGEMENT KEY TO TRIALS

The challenges associated with conducting clinical trials in emerging

markets range from insufficient regulatory capacity to concerns about ethics to the limited healthcare infrastructure, all of which can impact patient safety and the quality of the generated data. That's why I believe risk management is a primary focus for sponsors and study managers. One way to mitigate this risk is through the many tools and functions available with advanced, modular cloud-based EDC systems.

GRADUAL IMPROVEMENTS POSSIBLE

While a complete overhaul of the clinical trial management process may be daunting, gradual implementation is relatively easy to achieve using modular EDC platforms and can provide measurable gains in productivity where you need them most. For instance, eclinicalOS or "eCOS" can be implemented at any given point in the clinical trial management process and configured precisely to the needs of studies — from randomization and inventory management to endpoint adjudication.

GREGORY MOODY
Executive Director,
Life Science Analytics
PerkinElmer Informatics

MAXIMIZING THE VALUE FROM DATA

Ensuring that companies maximize the value from data that has already been collected would greatly reduce the barrier to entry in many therapeutic areas. We have collected a ton of data, but not everyone has access to it in ways that are truly useful. Take a drug that wasn't successful; the data often disappears into the void. Making the data available and providing tools to visualize them in different ways can help to find correlations of significance.

TRIANGULATING THE TRUTH FROM DATA

Technology has enabled us to get more accurate, real-time feedback from patients in clinical trials, and more data. We capture diary data electronically, and potentially, if I wanted to know a patient's baseline activity, I could use FitBit or iPhone data. There is the potential for access to an unprecedented amount of prediagnosis data. But we need the tools to manage it. The ability to triangulate the truth from the diverse sources of data is huge.

KENT THOELKE
Executive VP, Scientific and Medical Affairs, Safety and Commercialization Services
PRA

OPEN-SOURCE MODELING

The current R&D model to bring new medicines to market is inefficient and costly. As drug pipelines continue to get smaller within pharma there has to be a robust solution to replenish those pipelines beyond the M&A route. The concept of an open-source type collaboration in the area of therapeutic innovation seems to be the next likely step to ensure that new therapeutics can be identified and brought to market in a more efficient, collaborative and lower cost model.

BIG DATA AND ANALYTICS

Certainly our ability today to leverage massive amounts of data has changed the drug development and clinical landscape forever. The ability to use artificial intelligence and machine learning can ensure that moving forward clinicians and scientists have every possible amount of previous intelligence available to them to analyze and utilize to drive new innovation. Big data, and the predictive analytics associated with big data, will continue to drive clinical innovation over the next 50 years.

LOU SHAPIRO
Senior VP
Tunstall Healthcare Group

CONNECTED HEALTH

The industry is making significant progress in changing how new treatments are developed. Progress has come from enhanced collaboration and leveraging key learnings from discoveries such as mapping the human genome. Barriers remain, but innovative uses of technology to collect and analyze trial data, and individual patient data through connected health sensors and mobile devices provide opportunities to learn and evaluate how well a patient is doing on a specific treatment early in its development.

NIH GUIDELINES AND TRIAL INCLUSION

The most impactful advancement for patients was when the NIH adopted inclusion guidelines to increase the number of women, minorities, and children included in clinical research. This was the first policy recognition that individuals may respond differently to a treatment. At the same time, our understanding of disease etiology increased. Also, diagnostics such as rapid antibody testing and viral load assays were playing a central role in developing the first treatments for HIV and AIDS.

SANDRA LOTTES, PHARM.D.
VP, Global Clinical Development & Operations
UBC

PATIENTS AT THE CENTER

Patients' care should always be the focus of any research program. Generally, patients are compensated appropriately for interventional studies. However, administration of patient-reported outcomes and surveys in trials and longitudinal studies can be overly burdensome, especially for very ill patients. For physicians and clinical staff, fair market value for procedures and additional requirements by study protocols may not truly measure the impact on the practice. Balancing efforts required and considering the potential influence on research outcomes should be a focused review of any clinical plan.

Organizational silos result in data silos. Functions typically have responsibility for their systems and the data they contain. Adopting a data-centric view, with a clear owner for each data type across functional silos and through the data lifecycle, will greatly facilitate the ability to use and share data. The expertise gained by the data owner will be invaluable when developing ways to use existing information or to integrate internal and external data. Furthermore, having a single owner will enhance accountability for data quality. These organizational changes will be possible only if a company's leadership understands the potential long-term value that can be unlocked through better use of internal and external data.

Pharmaceutical companies are now saddled

EXECUTIVE VIEWPOINTS

CALCULATED RISKS

While it may sound counterintuitive, disappointing outcomes can often lead to more fundamental shifts in development. We have had great successes in managing the complex process of developing new molecules, as well as navigating regulatory demands. Yet, too often, we work to improve treatment incrementally, when what may be needed is a completely new approach. We have become reluctant to taking risks in order to maintain what we perceive as the ultimate pathway for success.

JENNIFER GOLDSMITH
VP, Veeva Vault
Veeva Systems

THE PROMISE OF INTEGRATED PROCESSES

We are truly beginning to realize the promise of integrated processes. We have talked about it as an industry for a long time, but with clinical systems moving to cloud platforms we can now fully manage vital processes, such as site activation, that have typically cut across siloed technologies. With this comes a host of operational data that can help streamline processes and allocate resources where they are needed most. And that translates to safer drugs and faster time to market.

GOING PAPERLESS

The industry has made good progress recently toward achieving the paperless trial. Electronic data capture is common. Many organizations have adopted electronic forms for monitoring visit reports and other documents. Industry-led standards organizations, such as the DIA, are creating common ground. The biggest remaining barrier is the use of paper processes, not just paper documents. This is the difference between scanning a paper document once it has been approved or creating and managing electronic documents throughout the process. From an efficiency and compliance perspective, this difference is critical.

LINDSAY MCNAIR, M.D.
Chief Medical Officer
WIRB-Copernicus Group

RECOMBINANT DNA

The ability to make recombinant DNA, first reported by Cohen and Boyer in 1972, may not have seemed like a clinical innovation at the time, but that scientific method has led to the field of human gene transfer research, which has tremendous potential as an innovative therapeutic technology. We're now seeing an increasing number of these really exciting products entering late-stage development.

MOBILE HEALTH: THE NEXT FRONTIER

mHealth is creating significant changes in the way that we practice medical care and conduct clinical research. We've moved so quickly from basic electronic study drug adherence diaries a few years ago, to eConsent and entire studies being conducted through smartphone apps. This expanding technology creates some exciting possibilities for change. But we must ensure that the protection of human subjects and their personal health information keeps abreast of these technological advances.

MICHAEL MURPHY, M.D., PH.D.
Chief Medical and
Scientific Officer
Worldwide Clinical Trials

PATIENT ACCESS: A DIFFERENTIATOR

Incentivizing discovery, development, and commercialization of innovative therapeutics is predicated upon the convergence of multiple variables: access to funding for enabling nonclinical data for human trials, an ability to exploit increasingly permissive regulatory innovation for entry into clinical testing, predictable development pathways for registration in which regulatory and clinical risks are known and minimized, and an environment for commercialization that differentially rewards innovation in decisions for formulary placement and reimbursement. Given that rewards must be commensurate with risk from product inception, early creation of a predictable, development pathway to assure patient access becomes a differentiator.

METHODS IN MEDICINE

The evolution of trial methodology has enabled brisk, unencumbered confirmation of mechanisms of action, provided innumerable insights regarding clinically meaningful product attributes, and, through its many permutations, has facilitated addressing requirements for data posed by diverse stakeholders. In aggregate, "the trialists," and the requisite mastery of methodology under this professional umbrella have made seminal contributions to all phases of research, in every therapeutic area, providing techniques that are fungible across interventions. Mastery of research methodology — "methods in medicine" — has accelerated evaluation, approval, and access to innovative therapeutics.

with legacy systems containing heterogeneous and disparate data. Increasing the ability to share data requires rationalizing and connecting these systems. There's also a shortage of people equipped to develop the technology and analytics needed to extract maximum value from the existing data.

Many pharmaceutical companies believe that unless they identify an ideal future state, there is little value to investing in improving big-data analytical capabilities. Indeed, they seem to fear being the first mover, since there are few examples of pharmaceutical companies creating a lot of value from the improved use of big data. Compounding their hesitation is concern about increasing interactions with regulators if they pursue a big-data change program. Pharmaceutical companies should learn from smaller, more entrepreneurial enterprises that see value in the incremental improvements that might emerge from small-scale pilots. The experience so obtained might yield long-term benefits and accelerate the path to the future state.

Pharmaceutical companies desperately need to bolster R&D innovation and efficiency. McKinsey analysts say by implementing technology-enabled ways to benefit from big data, they could gradually turn the tide of declining success rates and stagnant pipelines.

In the last few years, we've seen many companies forming the beginnings of a mobile clinical trial platform. In 2011, Pfizer ran its first online clinical trial for an overactive bladder treatment, in conjunction with its traditional process, to test the waters of the online medium. Lack of consumer participation stopped the effort after a year, however. While social media sites such as Craigslist, Facebook, and Twitter were successful in leading consumers to the information of the trial, sign-up for the trial was too low. It was surmised that consumer trust in online sources was to blame.

Research Goes Mobile

Mobile, aka mHealth, and wearables are poised to disrupt the clinical trial landscape. Apple's ResearchKit, an open-source framework, allows researchers and developers to create powerful apps for medical research as well as create visual consent flows, real-time dynamic active tasks, and surveys using a variety of customizable modules that users can build upon and share with the community.

Apple's ResearchKit is already addressing one of the major hurdles in clinical research: patient recruitment. For one of its trials, Stanford University was able to recruit 11,000 participants for a heart disease study in just 24 hours using a first-of-its-kind iPhone app as an easy-to-use research tool that enables users to help advance the understanding of the health of the human heart, a feat that would normally take 50 medical centers an entire year to accomplish using traditional approaches. The MyHeart Counts app collects data about physical activity and cardiac risk factors for Stanford scientists studying the prevention and treatment of heart disease.

The free app uses the new ResearchKit framework, which gives users a simple way to participate in the study, complete tasks, and answer surveys from their iPhones. The app delivers a comprehensive assessment of each user's heart health and provides information on how to improve it.

In the future, it will also be used to study various methods — designed to be both easy and fun — for using smartphones and other wearable devices to enhance heart-healthy habits. (See the related article in this issue: Wearables in Clinical Trials.)

According to Gartner, by 2017 mobile apps will be downloaded more than 268 billion times, generating revenue of more than $77 billion and making apps one of the most popular computing tools for users across the globe. As a result, Gartner predicts that mobile users will provide personalized data streams to more than 100 apps and services every day.

In the next three to four years, apps will no longer be simply confined to smartphones and tablets, but will impact a wider set of devices, from home appliances to cars and wearable devices. By 2017, Gartner predicts that wearable devices will drive 50% of total app interactions.

Experts predict that it's only a matter of time before there is a complete digitalization of clinical trials, some say this won't happen until 2030, while others say the advancement of technology is happening so rapidly that the industry will see more immediate results. With the FDA now officially accepting electronic sourcing of trial data, clinical trial digitialization just might be closer than we think. PV

Clinical Trial Trends

- It is commonly agreed that clinical trials have become increasingly complicated and take more effort to manage.
- The current global environment is also forcing drug companies to come up with better drugs that are developed at lower cost.
- Challenged by the situation, a new model of virtually integrated drug development has evolved.
- At present the developed countries still dominate the global clinical trial market.
- Today, those major CROs in the developed countries that have sufficiently large facilities, globe-wide capacity, networked investigators, patient database and effective recruiting tools, etc. are increasingly approached by drug companies for close partnership collaboration. It thus results in more consolidations through M&As in the CRO industry.
- On the other hand, because of the increasing complexity of clinical trials, those small- to medium-sized CROs that possess niche technical capability are still needed for functional services.
- In parallel to the two CRO sectors, the global clinical trial service market is also split between the developed countries and the emerging markets.
- Among the emerging regions, Asia has become a prominent location for clinical trials.
- As clinical trial cost is still a concern to all drug companies, the CRO model in the low-cost regions is considered a right model as long as they are able to deliver the desired quality of service.
- In the forecasted global market, the developed countries will likely account for about 66.8% by 2020, down from 76% at present; whereas the emerging countries combined together will likely account for 25.2%, up from 15.7% at present.

Source: Business Wire

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