BY DENISE MYSHKO

GLOBAL MARKETS

GLOBAL R&D

Global development strategies can bring significant cost and time efficiencies to the entire clinical trial process, while also providing strong clinical data for faster regulatory approval of new therapies in growing markets.

The globalization of clinical studies has been driven by several factors, including the need to access larger patient populations for the larger Phase III, Phase IV, or safety trials, and the need to reduce the expense of conducting those trials by taking advantage of high-quality, lower-cost clinical resources available outside North America and Western Europe," says Mark Goldberg, M.D., chief operating officer at Parexel International.

Jay Bolling, CEO and president of Roska Healthcare, cautions that moving to a country that has a lower cost structure is not the answer.

"The most successful R&D in the emerging markets will be based on the talent available onsite," he says. "While outsourcing repetitive functions may be a cost-effective business strategy, the process of scientific discovery will always require great talent that is embedded onsite at the parent company to achieve the best outcomes."

John Vann

Chiltern

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Dr. Goldberg says another driver is the increasing importance of serving new markets in emerging regions, such as Latin America and the Asia-Pacific region, and particular countries within these regions such as Brazil and India, as well as China and South Korea.

He says the Asia-Pacific region in particular comprises some of the world's fastest-growing pharmaceutical markets.

"While located within the emerging Asia-Pacific region, Japan continues to maintain its position as the second largest pharmaceutical market globally and is among the most mature markets within the Asia-Pacific region," he

INCREASING PHYSICIAN PARTICIPATION IN TRIALS

Over the past decade, the number of physicians participating in clinical research has continued to decrease in the United States and countries in Western Europe while participation increased at double-digit rates in Asia, Latin America, and Central/Eastern Europe.

In partnership with the Academy of Pharmaceutical Physicians and Investigators, the Association of Clinical Research Organizations (ACRO) conducted a survey of investigators, non-investigators, and former investigators in the United States and Western Europe to uncover factors deterring physician participation in clinical research and to determine opportunities for improved involvement.

The survey found that 70% of all respondents in both the United States and Western Europe believe that the current regulatory environment makes clinical trials difficult to manage. Based on the research findings, ACRO has made several policy recommendations that could boost physician participation in clinical research, including:

- Harmonize regulations governing clinical research across global markets, including expansion of industry standards to cover academic and federally funded research.
- Address current, former, and non-investigators' concerns and misconceptions about liability issues surrounding clinical research.
- Balance and standardize approach around conflict of interest and financial disclosure issues.
- Expand and improve online access to information about clinical research opportunities for current and potential investigators.
- Guarantee health insurance for clinical trial participants to increase enrollment of eligible subjects.

Source: Association of Clinical Research Organizations. For more information, visit acrohealth.org.

THE GLOBAL MARKETS

Argentina

- Approval of generics law — patients choose between branded and generic drugs
- Marketing strategy focused on patients, moving away from physicians
- Emerging market with huge potential for R&D outsourcing

Brazil

- Latin American hub for direct investment and exports to neighboring nations
- Government policies favor generics use — branded drugs' revenues are low
- Recognized potential for CRO and CMO growth — still in development phase

Central and Eastern Europe

- High unmet needs for cardiovascular and respiratory disease treatments
- Increasing private healthcare expenditure — copayments on the rise
- Markets are dependent on parallel imports for innovative medicines
- Russia, Poland, Czech, and Hungary demonstrating healthy R&D climate
- Turkey: Ability to produce active ingredients and finished products

China

- API manufacturing hub
- Increasing competency in R&D outsourcing
- Anti-infectives and cardiovascular drugs – fastest growing markets
- Improved IP laws — potentially attractive climate for foreign direct investment

India

- Highly skilled labor and low costs — attractive market for partnerships (CRO, CMO) (active pharmaceutical ingredients)
- Pharmaceutical companies with global presence
- US FDA approved labs — preferred destination for R&D outsourcing
- Weak IP protection — a concern

Korea

- Innovative capability and well-developed industry

Singapore

- US-Singapore Free Trade Agreement– Asia-Pacific manufacturing hub
- Highly competent facilities for clinical trials and drug development
- Favorable investment policies — Asia-Pacific headquarters of major foreign pharmaceutical companies

Source: Frost & Sullivan. For more information, visit frost.com.

says. "Japan is attractive for inclusion in global studies not only for its market potential but also for its high-quality data, advanced technologies, and large pool of well-trained professionals. Biopharmaceutical companies are seeking greater opportunities to include China in their global development strategies and obtain market registration in China."

Ken Kramer, Ph.D., senior VP, medical director, Alpha & Omega Worldwide, a part of The Core Nation, agrees Asia provides R&D with opportunities to make significant strides.

"Taking advantage of a more homogenous population compared with Europe or North America, Asia could provide patient pools for clinical trials with fewer confounding variables," he says. "For example, the largest increase in the prevalence of Alzheimer's disease (AD) will occur in Asia, where 48% of the world's Alzheimer's cases currently reside. The number of people with Alzheimer's disease is expected to grow in Asia to almost 63 million by 2050, which will represent 59% of the world's AD cases. Despite the large number of patients in need, access to them for clinical studies will remain a challenge."

John Vann, executive VP, corporate development at Chiltern, says Latin America will also be important for R&D.

"While there is tremendous emphasis on growth in Asia-Pacific, the scientific and technological expansion in Brazil and Argentina tells me that the region is on the move in R&D," he says.

The pharmaceutical markets in Latin America are worth $50 billion and growing fast, according to a recent report by Espicom Business Intelligence. Governments are using their bargaining power to negotiate and centralize drug purchases in an effort to contain costs. Overall, public drug expenditure in the region will continue to rise.

Private pharmacy sales are surging, as countries such as Brazil, Mexico, and Venezuela have higher disposable incomes, according to Espicom. Innovative drug prices have risen, but governments have started to control them, either directly or indirectly. Contrary to what has happened in developed markets, generics consumption in Latin America is low, with the exception of Brazil. Local protectionism, very low prices, and high production capabilities have helped the country to develop a sizeable bioequivalent generics market. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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