# Around the WORLD in 3,650 DAYS

*Ten years ago, being global meant having a presence in the United States, Europe, and Japan. Times have changed. Today, emerging markets are having an impact on every aspect of the life-sciences industry from clinical trials to patient recruitment to marketing.*

Some experts say globalization will be the big story. As companies expand into new geographies to increase their revenue footprint and meet unmet healthcare needs, they will leverage talent wherever it is located to deliver solutions to markets everywhere.

"The current model of serving mature markets such as the United States, Europe, and Japan will change to a truly global mix of serving both mature and emerging markets," says Nagaraja Srivatsan, senior VP and head of life sciences, North America, for Cognizant, a global services partner for the life-sciences industry. "The cost models needed to support emerging markets are quite different. Companies will need a global eco-system of talent, systems, and processes to support all markets. It will be a more complex, globally networked model of local, regional, and global solutions to execute all processes."

While there have been many important innovations, particularly in the therapeutics/diagnostics arena over the past 10 years, according to Richard Minoff, managing partner of 1 Global Partners, a consultancy focused on commercialization, marketing and life-cycle management, the strong and fast-growing emergence of emerging markets — beyond just the BRIC nations — has been both a game changer and paradigm shifter.

"Very few organizations have been or are currently well-prepared to operate effectively or efficiently away from a United States and Western European centric-focus, let alone in emerging markets," he says. "A quick look shows that the healthcare systems are quite different and evolving. The mindsets of patients, family caregivers, physicians, insurance schemes, distribution networks, and governments are often quite different from Western thinking, and the pace of their evolution is often more than most companies can handle. Given the conventional wisdom and a lack of understanding and empathy concerning cultural issues, even working with colleagues in these emerging countries, have typical Western mindset organizations, executives, and staff befuddled. Hence some companies are either trying to immerse themselves rapidly and adroitly, while more recently others are either pulling away or are just testing the waters. The fact remains that the United States is no longer 50% to 70% of the business, and the United States and Western Europe have stunted, flat, or declining growth in many industry sectors, as well as a declining value to organizations in the future."

**"Globalization will continue to accelerate as social, economic, and technology forces create a new roadmap for multi-regional commercialization."**

**STEPHEN WRAY** / Cadient Group

**"The key challenge for global branding remains the alignment of the U.S. market versus the rest-of-world markets."**

**JED BEITLER** / Sudler & Hennessey

Over the past decade, biopharmaceutical development has experienced an intensive period of global expansion, migrating from a few core hubs to many diverse geographies


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> "The global brand model is working in terms of getting more brand recognition and consistency across geographies."
>
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> "Agencies have moved from national to regional and global marketing for most pharma brands as a means to be more cost-efficient and strategic."
>
> **PHIL DESCHAMPS** / GSW

around the globe, says Josef von Rickenbach, chairman and CEO of Parexel International, a global biopharmaceutical services organization. "As biopharmaceutical companies sought to develop and commercialize products for more regional and international markets, there has a growing need to conduct clinical trials throughout the world."

Mr. von Rickenbach also says over the past decade, research productivity has declined while pressure to reload the pipeline increased, creating enormous challenges for pharmaceutical companies. Smaller and mid-size biopharmaceutical companies retained their IP more often, taking compounds further into development before licensing them out. At the same time, the era of the single-minded quest for blockbuster drugs, with large bets on few drug candidates, waned during this period.

All of this has sponsors looking beyond their traditional borders to improve their bottom lines.

"There will continue to be an increasing focus on emerging geographies as biopharmaceutical end markets," Mr. von Rickenbach says. "The Asian pharmaceutical market, for instance, is forecasted to continue to grow rapidly in the coming decade, particularly in China. With the geographic shift of clinical development programs, most outsourced development will take place outside of the United States. As pharmaceutical companies focus on launching new products concurrently in several major healthcare markets to maximize rapid market penetration, they will need to conduct clinical trials in multiple jurisdictions to satisfy the regulatory requirements in those locations and take various market access considerations into account."

An important aspect of clinical development is patient recruitment, and many of the emerging markets not only offer naive patient populations in numbers beyond what the United States and Europe can provide, these regions have the technology infrastructure to manage the process.

"The global ubiquity of the various manifestations for social connectivity offer large-scale, cost-effective channels to match clinical trial participation with heretofore unaware

### BACK TO THE FUTURE

**PATIENT RECRUITMENT**

**JEFF ZUCKER**
Senior Director and Global Head, Patient Recruitment, Kendle

» **THEN: (2001):** Sponsors seldom make a change to a protocol based on feedback, and time and money are wasted.

» **NOW:** Sponsors have been more willing to involve the CRO earlier in the process to avoid the need for significant protocol changes. The prevalence of global partnerships and alliances between sponsors and CROs is a good indication of a more proactive, efficient, and cost-conscious approach.

### Emerging Clinical Trial Locations

» **The number of clinical trials** in **Brazil** has increased from nine in 2000 to 1,177 by 2008. In **Argentina**, the number of trials has risen from six to 801 over the same period, while **Mexico** has witnessed an increase from 63 to 2,014.

» **The Chinese Clinical Trial Register** (CHiCTR) and The Clinical Trials Registry in India (CTRI) have helped to encourage all clinical trials in these regions to be registered before the enrollment of the first participant and to disclose the mandatory 20 items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset.

» **The Chinese CRO market** was valued at $250 million in 2008. The market is expected to grow at a CAGR of 33% over the next four years to reach $791 million in 2012. By that time, Chinese CROs will account for an estimated 2.3% of the global CRO market.

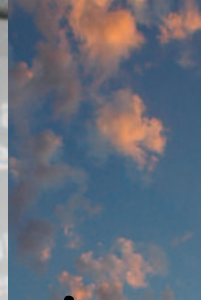
» By the end of May 2009, 895 clinical trials were registered in **India**. By comparison in 2006, 150 clinical trials had been approved by the Drug Controller of India (DCI). India is able to offer significant cost savings compared with conducting clinical trials in western countries. Phase I trials are about 50% cheaper than western equivalents, while Phase II and Phase III are 60% less expensive.

» The costs of conducting clinical trials in **Latin America** vary from substantially less expensive than the U.S. to slightly more expensive. In recent trials, the cost per patient for Latin America has varied from savings of 50% to relative cost increases against U.S. per-patient costs.

» The value of the **Polish clinical trial market** for Phase I to Phase IV clinical trials and bioequivalence studies has been estimated to be worth K167 million ($224 million) in 2008, having increased in value by 10% from the previous year.

» **Russia** is one of the world leaders in patient enrollment. The average patient recruitment rate in 2006 exceeded 4.7 patients per site per month. For some diseases, this figure is 10 times higher than in Western Europe and the United States.

Source: Business Insights.
For more information, visit globalbusinessinsights.com.



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## BACK TO THE FUTURE

### GLOBAL BRANDING: IS THE INDUSTRY READY FOR THE REAL THING?

**JOHN RACIK**
President and CEO, Stonefly Communications Group

» **THEN: (2001):** Global branding comes down to human nature, relationships, and personality. Clients haven't said, thou shall do this and do nothing else.

» **NOW:** Many clients still struggle with global branding especially from a "strategic vs. value" standpoint. If the global branding initiative is simply to cut costs then the client is truly missing out on the power and value global branding can have to activate individuals, groups, influencers, and even health policy within different countries.

patients," says Scott Ballenger, R.Ph., founder of the Trial Acceleration Institute, a consultancy that aims to improve study cycle times. "The biggest game changer during the last 10 years within clinical trial patient recruitment has been patient adoption and use of Web-based recruitment tools. Today, the majority of patients inquiring about clinical trials are coming through Web-based platforms vs. the old-school toll-free number as a first point of inquiry. These Web-based tools are global, cost-effective, afford privacy, and allow for new outreach tactics to be processed and tracked in real time. Looking to the future, I think social media will edge out mobile as the biggest market shaper in the area of clinical trial patient recruitment."

For others in the industry, the biggest market shaper in the next 10 years can be summarized in a single word: China.

"Pharmaceutical R&D will explode in China as a result of several initiatives and paradigms," says James Macdonell, VP of Patni Americas, a global IT services company. "The Chinese government is making massive focused investments in targeted research and in the development of life-sciences parks. Many U.S.-trained scientists are returning to China, which will drive innovation. The cost of labor will make drug discovery and development cheaper in China than virtually anywhere in the world.

"In addition, within five years, China will be the second-largest market for drugs in the world," he adds.

According to David Lacey, M.D., senior VP of discovery research at Amgen, a biotechnology company, the coming decade will reveal how effective the bio-pharmaceutical industry will be in China and India as innovative, home-grown medicines should enter clinical testing and perhaps reach registration.

The shift of industry revenue away from first-world countries and to the emerging markets in Asia, Latin America, and Eastern Europe will reshape the industry in the coming decade, says Matt Wallach, chief strategy officer of Veeva Systems, a provider of SaaS-based CRM solutions.

"Being a leader in the United States or Europe does not guarantee success in China, Brazil, or Turkey," Mr. Wallach says. "Life-sciences manufacturers will need to learn how to operate in these very different markets, most importantly, creating profitable cost and pricing structures that work in the different countries."

According to Stephen Wray, president and CEO of Cadient Group, an interactive marketing company, there is no doubt that globalization will continue to accelerate as social, economic, and technology forces create a new roadmap for multi-regional commercialization.

"Most healthcare companies have recognized that the BRIC countries will account for a major component of industry growth in the coming decade, and they have begun to realign resources to optimize their performance in a changing global landscape," he says. "With this shift comes the opportunity to establish globalized marketing methodologies, effectively introduce best practices in digital asset management, and to form global customer communities to reshape advocacy, encourage clinical collaboration, and transfer in-market best practices."

The ability of an organization to work within and among the emerging markets — and one-time small markets that have become critical such as Turkey — will be critical, Mr. Minoff of 1 Global Partners says.

"The ability to harness and access the billions of potential new patients will be a tremendous market shaper over the next decade," he continues. "The critical cultural skills necessary to adapt to and manage this opportunity is not found in most organizations today at the middle and senior levels. It's not business as usual. Organizations will have to mold a different type of work force, a seemingly divergent culture but one that will become increasingly convergent over time. The smarter organizations will embrace the obvious differences and develop an orientation toward adaptability and flexibility, rather than the current dogmatic state and status quo mentality. Perhaps over time companies will come to realize that their mission of driving toward company and brand globalization might be better served by morphing into a 'glocal' tour de force."

With outsourcing driving overseas development, experts are seeing the rise of middle- class living standards among very large populations, and this has attracted companies into ex-U.S. markets that are now more lucrative than ever before, says Luis Gutierrez, senior VP of phar-

> **"Life-sciences manufacturers will need to learn how to operate in these very different markets, most importantly, creating profitable cost and pricing structures."**
>
> **MATT WALLACH /** Veeva Systems


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>
> **SCOTT BALLENGER** / Trial Acceleration Institute

maceutical and life-sciences operations at MedAssurant, a medical informatics solutions provider.

"Specifically, the BRIC market offers companies the ability to generate profits through volume rather than relying on U.S. prices," he explains. "This trend toward volume-driven pharmaceutical marketing will likely overshadow price-driven models in the coming 10 years as millions of new customers rise into the middle class and enter the pharmaceutical market."

## Global Branding: Know Thy Customer

Matt Giegerich, chairman and CEO of Ogilvy CommonHealth Worldwide, a healthcare communications network, says the industry is now at a crossroads with regard to globalizing its branding and marketing activities.

"All companies now realize that centralizing these activities promises far greater operating efficiencies," Mr. Giegerich says. "Not all manufacturers, however, agree that fully centralized global branding yields greater brand sales. Most are finding a productive middle ground, with global brand teams striving for at least regional controls, operating efficiencies and branding consistency."

One of the biggest game changers in the last 10 years is the loss of blockbuster — $2 billion plus — products and the relative trickle of newly approved medicines from the big pharmaceutical manufacturers, says Phil Deschamps, president and CEO of GSW Worldwide, a healthcare advertising agency.

"The top 15 pharma companies are only getting 10% of their sales from products launched in the last five years," he says. "Companies have recognized that they need to become smaller and considerably more efficient and effective in the marketing of their products. Advertising agencies have had to adapt to this profoundly changing environment and, as a result, have moved from national to regional and global marketing for most pharma brands as a means to be more cost-efficient and strategic."

According to John Racik, president and CEO of Stonefly Communications Group, a patient-focused advertising agency, the real value of global branding is internal.

"Global branding can be a catalyst to help marketers embrace how their customers want to receive and exchange information versus just pushing information at them," he says. "Externally, global branding can help us rally our clients to think it's not just about the pill, but about listening and suggesting how the client/brand can provide information and services that fit into their customers' life. The pill may very well be the catalyst or the reminder, but the results of every interaction have to support the everyday needs and wants of their customers. Companies need to decide that they are going to organize around their customers' needs versus the company's wants. They need to think globally and act locally. It all starts with a conversation, and then they need to keep it going and be relevant 24/7."

The key challenge for global branding remains the alignment of the U.S. market versus the rest-of-world markets, says Jed Beitler, chairman and CEO Worldwide of Sudler & Hennessey, a global healthcare marketing and communications organization.

"The alignment of the brand across geographies with one network is often an attempt by pharma companies to bridge that gap between both markets to bring them closer together," he says. "Agency networks have increasing responsibility to act as an 'early warning system' where there is deviation away from the central brand philosophy."

Mr. Beitler's colleague Max Jackson, CEO, EMEA/Asia Pacific, at Sudler & Hennessey, agrees that the global brand model is certainly working in terms of getting more brand recognition and consistency across geographies.

"Where it works best is when local markets are given a certain degree of latitude to meet local market conditions and challenges, but still within the spirit of the global brand," Mr. Jackson says.

From Scott Cotherman's perspective, pharmaceutical companies are taking different approaches to launching global brands, including centralized, regional, and/or local campaign adaptation strategies.

> **"The strong and fast-growing emergence of emerging markets — beyond just the BRIC nations — has been both a game changer and paradigm shifter."**
>
> **RICHARD MINOFF** / 1 Global Partners

"They are often reluctant to dictate a single approach for all markets, often resulting in regional/local affiliates making their own marketing decisions based upon available budgets," says Mr. Cotherman, CEO of CAHG, an integrated marketing communications network.

"It is incumbent upon the contemporary healthcare advertising agency to have a thorough understanding of market dynamics and market access, including regulatory, legal, pricing, and reimbursement, in every country where the brand is to be launched," he adds. "We have found that great efficiencies can arise when automated, self-serve, global campaign management solutions are implemented systemwide within our clients' operations. The biggest challenge preventing faster uptake of this approach is the legacy technology systems and internal-operation reporting structures that hinder the necessary effort to effect lasting change." PV