

Defining GLOBAL

For more than 300 years, the word global has been used as an adjective to describe “pertaining to the whole world; worldwide; universal.”

Today, global is defined by markets, patient populations, corporate structures and models, and business opportunities. We asked thought leaders who represent a wide variety of company types and industry sectors to provide their world view on what global means to them and to their businesses.

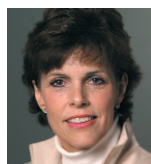
This overview of the different aspects of global is followed by in-depth analysis of what operating globally means in terms of business, development, regulations, as well as marketing.

We hope this first annual special issue provides you with a few perspectives on some of the trends and factors impacting the worldwide life-sciences industry.

global (adj.)

1. pertaining to the whole world; worldwide; universal.
2. comprehensive.
3. globular; globe-shaped.
4. of, pertaining to, or using a terrestrial or celestial globe.
5. (of a computer operation, linguistic rule, etc.) operating on a group of similar strings, commands, etc., in a single step.

Origin: 1670–80



KARLA ANDERSON
Managing Director, Life Sciences
BearingPoint

Global is a perspective of looking at the business in its totality, not just at a given market or a given country or a given set of rules and regulations, but at the business as a whole. It's always considering the interdependencies of multiple, diverse geographies — across all parts of the globe — and how each impacts the other.



LEONE ATKINSON, M.D.
Senior Director of Clinical Development
PTC Therapeutics

At PTC, we define global by the human impact of disease throughout the world. Because devastating diseases, such as nonsense mutation Duchenne and Becker muscular dystrophy, affect all populations, we take time to thoughtfully respond to patient inquiries from all over the world regarding our investigational treatments. In addition, we are committed to building a sustainable biopharmaceutical company through controlled growth and strategic collaborations to develop and commercialize breakthrough treatments for patients worldwide.



AJIT BAID
Managing Director
The Research Partnership (USA)

Being truly global means making a paradigm shift in the way pharma companies think about the world. When the United States accounted for more than 60% of the global healthcare market, companies could afford to primarily focus on this market, but with EU and U.S. markets now being squeezed and the growth in China, Latin America, India, and Eastern Europe, we can no longer define global as just the United States, Japan, and five EU countries. Being global

requires a re-evaluation of the U.S.-centric business model and redefining the priorities and practices of big pharma.

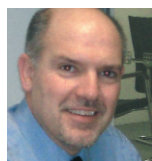


HANS BISHOP
President, Specialty Medicine
Bayer HealthCare Pharmaceuticals

The meteoric rise of the emerging economies represents a significant growth opportunity for us. Just as an example, in 2000, emerging markets accounted for only 7% of global growth, while the United States accounted for 42%; in 2009, emerging markets will account for 34% and the United States 9%.

We've got to adapt our business model to this changing landscape in a variety of ways, such as the way we structure our organization all the way to how we design the marketing mix for our products.

We're also going to have to deal with increased complexity across the board. Whether it's the challenges of dealing with dozens of different regulatory bodies or developing custom packaging for each major country, complexity will be a way of life.



GRAHAM BUNN
VP, Global Partnerships and Alliances
Medidata Solutions Worldwide

To a technology solutions provider, global means offering solutions designed to help biopharmaceutical customers and partners achieve their business goals anywhere in the world.

This calls for solutions that provide the flexibility to adapt to language, culture, location, and infrastructure with local support, while also offering the control, centralization, standardization, information flow, and regulatory sensitivity required by a global business within the biopharmaceutical industry.

We define global as it relates to clinical trials — the business of our customers and partners — and this means just about anywhere in the world since trials are run in every continent except Antarctica currently.



JASON BURKE
Worldwide Director, Health and Life Sciences
SAS

For SAS in life sciences, global describes organizations that are able to act locally with geographically and culturally diverse assets. It means that an organization's people, business processes, and information assets can be consistently applied in a locally relevant manner. It also means local assets and market drivers can reliably inform and improve nonlocal people and business processes. Insofar as these hold true, global describes organizations that consistently institutionalize learnings across geographies and markets.



BRIAN DALEIDEN
Director of Marketing
SupplyScape

Global means not just imagining a global market but instead thinking in terms of a global operating environment. Supply, internal business operations, collaborative operating partnerships, and customer demand all play on a global basis through direct and indirect relationships. Thinking globally means finding integrated ways to weave these elements together.



TIM DIETLIN
VP, Clinical Development Practice
Campbell Alliance

As an industry, we need to think about how to serve people, and not just how to serve people in North America or people in countries that have favorable regulatory environments and reimbursement structures, but really about serving all people.



ARGELIO DUMENIGO
Senior Strategist
Razorfish

Global means understanding the needs of the audience within each country, understanding the unique selling proposition for a brand or product and finding ways to articulate and manifest that proposition in a way that is meaningful to different cultures. It means understanding the needs of employees and leadership in those markets, since they will likely vary from market to market and country to country. Trying to paint everything with the same broad strokes used successfully elsewhere might not necessarily apply across all markets.



JEAN-JACQUES GARAUD, M.D.
Global Head of Development and Chief Medical Officer
Roche

We are a global company, which means that we have a fully integrated network of research and development centers around the world. Our teams are global, as is our reach when it comes to collaborations with academic centers, health authorities, and scientific institutions. This is particularly important in clinical trials because we require many patients to ensure an adequate number to achieve our goals and clinical endpoints. This means that we conduct trials in a range of countries, including China, Africa, Brazil, the United Kingdom, Sweden, the United States, and Canada. This is a critical part of our plan as we are developing products for a global market.

And the last point is that we're global when it comes to running clinical trials because our clinical trials need many patients to be involved and our sampling of patients goes around the world. We involve a lot of coun-

tries, including China, South Africa, Brazil, the United Kingdom, Sweden, the U.S., and Canada; there are no limits. The world of global is very broad, and we are developing products on a global scale for a global market.



BRUCE GARRETT, M.D.
President and CEO
Global Research Services

Global means providing services 24 hours a day wherever clinical research is performed: services that are tailored to cross-cultural differences while maintaining standardized corporate processes and upholding international regulations. Global means having corporate staff at any geographic location accessible with Web-based technology.



MARK GOLDBERG, M.D.
Chief Operating Officer
Parexel International

Being global is not just about having a presence; it is about having a meaningful presence. A service provider should have the critical mass to effectively support global development programs, relationships with regulatory authorities, and importantly access to thought leaders and investigators throughout a wide array of geographies. It also means having globally standardized and integrated processes so that operations are seamless across geographies, ensuring consistency and quality.



HOWARD HASSMAN, M.D.
Chief Scientific Officer
CRI Worldwide

As we consider the question of going global, we think about recent industry trends to move clinical trials outside of the United States. This emerging trend seems to be driven by the fact that a more robust treatment effect can be observed in clinical trials conducted in other nations, particularly in Eastern Europe and Asia.

The implications of this trend are important for a variety of reasons. Sponsor organizations are making considerable investments in trials based outside the United States; thus, the market for U.S.-based clinical trials is shrinking. Some U.S.-based clinical-trial sites, and many CROs, are responding to this trend by adding infrastructure and clinical capabilities in these developing countries. This is one opportunistic approach. Another more scientific approach is to determine the cause for reduced drug signals in the United States.



GERRY HEPBURN
President, Clinical Operations
Aptuit

We take a holistic approach to doing business in today's global environment. This means not only serving customers worldwide as well as having state-of-the-art facilities in major markets globally, but also providing the expertise needed to achieve success in each market of importance to customers — understanding the regulatory and cultural nuances needed to navigate successfully to completion of key drug development milestones.

BILL HOOK
VP, Global Strategy, Healthcare Logistics
UPS

Global means exciting new growth opportunities for pharma companies.



It also means new competition, navigating a complex regulatory landscape, and changing customer demands.

To succeed in the global marketplace, it's critical that pharmaceutical companies closely examine and make changes to their supply chains to ensure that they have the reach, flexibility, and scalability to meet new market demands.



JONATHAN KAY

Head of Brand Management
TNS Healthcare

I took on the opportunity of my new role as head of brand management at TNS Healthcare because it is so critical to the success of a business to view the brand as a global asset.

Across markets, the brand maintains its fundamental characteristics and serves as an asset through which the company builds lasting and valuable relationships with physicians, patients, payers, and all other stakeholders. At the same time, those relationships take place in a local context, in the local market environment, with a local competitive set, and the channels and messages must ring true to the brand while fulfilling the potential of the local market. The beauty and the challenge of the tension between global consistency and local variation is that the brand as an asset may be adapted and leveraged locally to generate the most valuable experience and outcomes.



TIM KELLY

VP and Practice Leader, CIS, IMS Consulting
IMS Health

Global means a better way to collaborate and operate. Global methodologies and business networks are critical to achieving success. Having the flexibility to shift resources to higher growth countries/regions, such as emerging markets, enables our organization and our clients to optimize business performance.



CANDACE KENDLE, PHARM.D.

Chairman and CEO
Kendle

From a patient-access point of view, being global means reaching out worldwide to find the most efficient way to deliver a clinical trial and thinking in terms of how to globally deliver the right patients over the right time period to achieve trial success. From a geographic point of view, it certainly means touching Western worlds as well as emerging markets. From a very tactical point of view, it could mean how many countries are involved in a study, or from a commercial view, how many markets can be reached during the development process to have a successful market launch. There are many ways to think about and employ global strategies, but I don't think of it as simply counting up countries. Choices might be made based on infrastructure within countries where EDC can be used successfully. For example, if a trial is for an AIDS drug, the challenges involved in sub-Saharan Africa need to be considered. Tactical refers to executing a trial successfully on the ground, given the technology challenges.

WARREN LEVY, PH.D.

President and CEO
Unigene

When we talk about global in this business, the key thing to keep in mind is that most diseases are not geographically limited. In the pharmaceuticals business, for the most part, we need to have a global perspective

because that is the market we are trying to address. In today's market, there is more and more sourcing of pharmaceutical ingredients, pharmaceutical products, and performance of clinical studies in international locations outside the United States. Like other companies, not only are we talking about products that have a more universal demand, but more and more we are looking outside the United States to provide expertise, clinical sites, and even manufacturing on a global basis.

BOB MEROLD

General Manager
Symphony Metro Pharma

Global means the ability to fully optimize the value provided and the resources drawn against the largest possible opportunity set. A decade ago, pharmaceutical companies largely operated at the country level; there is a growing awareness of the synergies and efficiencies from embracing a view that spans the entire organization.



LIZ MOENCH

President and Founder
MediciGlobal

We define global as "glocal" a combination of global management and local implementation. For example, while we will develop a global strategy for patient recruitment, it is the local planning that customizes it for implementation. For patient recruitment and retention, we can be glocal in ways that were not possible before: through the integration of people, technology, and systems.



FRANCOIS NADER, M.D.

President and CEO
NPS Pharmaceuticals

For a small organization like NPS, being global simply means accessing all critical resources such as patients, experts, partners, and clinical trial sites, wherever they may be and in a cost-effective way. We are in the orphan drug space, so identifying the proper experts in their respective fields is crucial to our overall success. Our outsourcing business model helps us cast a wide net to optimize ex-U.S. patient availability, providing us with a more diverse pool of data from a small global patient population. From a financial point of view, certain ex-U.S. markets offer a cost-effective way of conducting research and development activities. So, by having an outsourcing and partnering development strategy, we are not only able to execute cost-effective trials through shared expenses, but we can also capitalize on the global experience our partners bring to the table. Additionally, we are able to effectively increase revenue opportunities through accessing global markets in partnership with companies that are present and strong in Asia, Europe, Latin America, or have a global presence. In the end, being global for NPS is about our reach — reaching the patients while also accessing global expertise, tapping into development resources, and increasing our revenue worldwide.



KAREN POLITIS-VIRK, M.S.

Director of Biotech and Pharmaceutical Research
Language Connections

As a result of many technological advances and current economic pressures, it is becoming increasingly common for companies to conduct their business in many parts of the world. Successful globalization, however, largely depends on overcoming language and cultural barriers, dealing successfully with different government policies, and redefining business management strategies. As industries become international, we are becoming more dependent on a global

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economy. Going global means having the ability to adapt to each environment easily and to operate effectively everywhere. In addition, going global is a vehicle for establishing a better understanding among people in different parts of the world.



ERIC RAMBEAUX
VP, Business Strategy and Portfolio
Solvay

In the context of the pharmaceutical industry, globalization is a dream that has been built on the hope of leveraging globalization to generate synergies and, therefore, cost savings. Looking at facts, the opportunities remain dreamy. The FDA and EMEA are moving apart, killing the dream of global registrations (or indications); healthcare economies are different in each part of the world, making the cost benefits of a given therapy impossible to globalize; and doctors are communicating, but medical practices vary by country to the extent that certain dosages are different between Europe and the United States.

The only things that are really global are the threats: registrations differ but pharmacovigilance bodies exchange information; media are global and can send the bad news of a dead patient around the globe in a minute; inappropriate behaviors of an affiliate from one unit in one country can damage the whole company's reputation; talent is located around the world and can move to another company or to the other side of the world quickly; competitors can emerge tomorrow in China or India, penetrating Western markets far quicker than we can penetrate their markets. I believe the industry has suffered more from globalization than it has gained.



ADAM SERODY
Senior Director, Business Development
PharmaNet

True global capability means a fully functional team of resources in the country of interest, immersed in the local culture and language, with expertise in the local regulatory requirements. It's equally important that global teams with wide geographic spread have the latest technologies to bring communication, data, and study-related issues back through a central point of management to ensure proper oversight and quality.



AIZE SMINK
Executive VP, Project Management
Chiltern

Global is defined as all countries with clinical research capabilities, either well-established or new players. Considerations, for example, are excellent patient access or cost benefits. For postmarketing studies, the definition is usually constrained to only those countries with reasonably established markets. These studies are, therefore, more focused on the European Union, North America, some Latin American countries, and certain Asian countries.

BRUCE THOMAS
Senior VP
MeadWestvaco

Being global is about global knowledge transfer and the global integration of regional best practices. And it's about being able to contribute positively to the communities in which we or our customers operate. To be an essential resource, we must possess a deep understanding of the local marketplace, we have to have profound knowledge of consumers and consumer behaviors in the fastest-growing regions of the world, and we have to create truly global supply chains for speed and efficiency.



BRAD THOMPSON, PH.D.
Chairman, President, and CEO
Oncolytics Biotech

For us, global entails looking at the trends that impact oncology. We need to develop an oncology product in the major markets globally. The major markets in oncology are the United States, which covers more than half of the world's oncology market in terms of dollar value, and Europe and Japan. And then there are the emerging markets, which include the upper middle class and middle class populations in China and India. What we need to do in those areas is different. The challenge with developing a product in different markets is staying on top of what's required in the different jurisdictions with respect to product development.



SCOTT TREIBER
Senior VP, Clinical Operations
inVentiv Clinical

Being global does not only mean the actual physical presence of members scattered around the globe but also the conviction and commitment to integrate, communicate, and develop each individual employee to be part of a team. Global also means using the most appropriate location/country and employees, regardless of boundaries, languages, and cultures to provide the services required.



ALFONSO UGARTE
Senior VP, Global Marketing
Stiefel Laboratories

Global means universally inclusive — as in every customer around the world, every culture, every view, every need, and every solution, as well as how all of these relate to each other. In that sense, global does not mean standard, but rather, cohesively diverse and integrated, or intrinsically interconnected and interdependent.



DEREK WINSTANLY, MB CHB
Executive VP, Strategic Business Partnerships
Quintiles Transnational

Global means being on the ground with local experts and resources, linked by a globally integrated infrastructure and working to international standards. A truly global company can conduct business anywhere that it's needed, adapt to local circumstances, and deliver consistent high-quality and ethical services on a global basis.



RAY WODAR
Director of Life Sciences and Industry Strategy
Enovia, Dassault Systèmes

Global means being able to react on a global and regional basis — connecting multiple cultures and across multiple time zones — while adhering to different regulations on a local level. ♦

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



To access a FREE Podcast featuring John Doyle and Geoff Garabedian from Quintiles Consulting, go to pharmavoice.com/podcasts.



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Company Executives — What global means to their businesses and to them

GERRY HEPBURN

President, Clinical Operations

Aptuit

Aptuit's ability to deliver a global solution for clients is exemplified by our presence in North America, Europe, and Asia along with our Depot networks around the globe, allowing us to get clinical trial materials anywhere in the world in three to four days. This global infrastructure also allows us to provide solutions across all time zones with teams comprising U.S., Europe, and India resources.

BILL HOOK

VP, Global Strategy, Healthcare Logistics

UPS

UPS has long been a global company with operations in virtually every corner of the world. Nearly 35 years ago, we understood the need to move where our customers needed us to go. We have made numerous investments in our global network, infrastructure, and local talent, including healthcare expertise, to serve the needs of our global customer base. Our healthcare logistics group gives manufacturers access to these global networks and our experts in areas such as regulatory compliance and supplier management help build supply-chain strategies and solutions. As trends change and emerging markets evolve, we're helping pharma companies realize the opportunities.

JONATHAN KAY

Head of Brand Management

TNS Healthcare

TNS Healthcare is truly a global organization. We are not just a loose net-

work of offices and partners in countries around the world. We are managed globally as one seamless organization under one CEO, board, and leadership team, with consistent metrics, structures, and solutions that enable clients to measure, monitor, and manage their businesses effectively across countries. At the same time, we have on-the-ground healthcare experts across the Americas, Europe, Asia-Pacific, and the Middle East, providing the local insights needed to ensure success in every target country. We really do epitomize the "glocal" concept — the best of both global reach and local knowledge.

TIM KELLY

VP and Practice Leader, CIS, IMS Consulting

IMS Health

Our company operates under a global model. Our sales, consulting, and service teams are structured globally so that we can provide the best business insights possible to our clients. We operate in more than 100 countries, and we leverage that local market knowledge to build global strategies and partnerships with clients.

BOB MEROLD

General Manager

Symphony Metro Pharma

As a technology vendor, global specifically means that we've learned to operate around the clock to get solutions to market faster. There is no reason many pharmaceutical processes couldn't scale similarly.

LIZ MOENCH

President and Founder

MediciGlobal

GLOBAL OUTLOOK FOR 2009



With many markets braced for the effects of economic recession, cost-containment will be a priority for countries that have already racked up heavy debts in the healthcare sector. The treatment of chronic and serious illnesses will be prioritized, leaving less reimbursement scope for

more "minor" treatments. Even for innovative chronic-illness drugs, payers and producers will increasingly turn to cost-sharing agreements to finance the use of new medicines. Drugmakers will be squeezed from increased pharmacovigilance on the part of regulatory authorities, particularly the FDA.

The United States will witness major changes in its healthcare system, at least in terms of policy direction in 2009 as the government of President Barack Obama takes charge. Among the legislation that will affect pharma firms will be the FDA's increasing scrutiny of drugs, both during the approval process and postmarketing; widening coverage of Medicaid and Medicare services; pre-emption of federal law over state law affecting product liability lawsuits, and the potential implementation of the biosimilars bill.

In terms of corporate strategy in 2009, major global pharmaceutical companies will continue to keep a tight leash on expenditures while seeking to exploit every avenue possible to sustain growth. Major impediments will be the steady rise in the number of products approaching patent expiration; competition from generic producers on a wider scale, particularly in niche therapeutic areas, and increasingly malnourished late-stage drug pipelines and diminishing potential product launches.

The patent cliff affecting blockbuster products will be increasingly steep as some 13 major products go off patent in 2009, directly affecting top-line growth. Furthermore, new product launches will be comprised mostly of drug lifecycle management measures such as additional indications and coverage for certain patient populations. On drug discovery research, the focus will be on chronic ailments such as oncology and neurodegenerative disease.

While the effects of the global economic downturn are not expected to have too great an impact on the largest pharma players, financial considerations from generic competition and failed R&D projects will nonetheless see

It sounds like an oxymoron, but global means expansion and shrinking at the same time, reaching out beyond traditional boundaries and shrinking in terms of connecting with one another. Social networks are a good example of this definition. They offer new market opportunities while bringing people closer together.

DAVID MOSKOWITZ, M.D., M.A., FACP

Chairman, CEO, and Chief Medical Officer
GenoMed

Global means operating in all countries in the world, including the poorest.

AIZE SMINK

Executive VP, Project Management
Chiltern

Global means not being bound to any region or country. In a business context, this translates into looking objectively where certain activities can be best executed. In our business sector — contract research — there are key constraints that have to be taken into account. Examples of constraints are: experienced staff and investigators, patient access, and an appropriate regulatory environment.

BRUCE THOMAS

Senior VP
MeadWestvaco

We build global expertise by transferring knowledge and leveraging best practices to meet local needs or leverage local capabilities. For example, last year we partnered with an Indian pharmaceutical packaging company, Bilcare, in a joint acquisition of Florida's International Labs. The partnership combines MWV's packaging formats that enhance medication

a continuation of M&A activity in 2009. In this economically charged environment, firms are increasingly aware of their market value and are becoming more confident in holding out for a price that they feel reflects their true value. The most strategic acquisitions of 2009 will occur within the increasingly competitive biotech and generics sectors, with buyouts in the first sector prioritizing innovation and those in the second opting for geographic, regional control of rapidly developing markets.

Emerging markets such as the BRIC countries (Brazil, Russia, India, and China) are swiftly developing into investment hotspots for R&D outsourcing, with China and India leading the way. Yet there is also a reverse stream of activity from these countries — and India in particular — toward Western markets. Indian drugmakers are increasingly active in their European M&A ambitions, targeting local players in both growing markets such as Romania and well-developed ones such as Germany. A key challenge for many emerging markets in 2009 will be to strengthen their intellectual property rules a major stumbling block in convincing more brand-name companies to mar-

adherence, Bilcare's research and expertise in materials, products, processes, and services that enable the safe and effective integration of pharmaceuticals and packaging; and International Labs' contract packaging services for retail pharmacies and large pharmaceutical manufacturers.

Providing innovative adherence packaging, such as calendared blister packs, helps patients to take their medication correctly and on time, improving their health outcomes. Poor adherence is a widespread issue and has a significant financial impact for the global healthcare industry, especially when the results of nonadherence, such as increased hospitalizations and missed work days, are considered. In the United States alone, only about half of all drugs prescribed are taken correctly, costing the healthcare industry \$150 billion each year.



MANDI WALTERS

Senior Director, Business Development
PharmaNet

Being global in 2009 requires the proper balance. On one end, companies need to be able to deliver seamlessly in countries that have demonstrated prior performance and with proven processes. On the other end, service providers must be pioneers in the emerging markets. Approached strategically, innovation in these geographic locations can often provide the most value for the client.

LORI WEBBER

Senior VP and Chief Marketing Officer
SupplyScope

Today, global is a reality, not a vague strategy. Even when companies focus on local demand, they must take care to "think global, act local." Not doing so means losing the benefits of proven best practices that are derived from cross-market and cross-business collaboration. Today's innovators know business doesn't sleep. ♦

ket new treatments in these countries. That said, countries such as Thailand and Mexico have shown clear preferences for compulsory licensing of HIV drugs and other life-prolonging treatments for incurable diseases, and this does not look set to change.

Big pharma players will be looking to narrow their therapeutic focus in 2009, slimming down their R&D operations to concentrate on areas with the highest likelihood of returns. In this sense, the most successful pharmaceutical companies will emulate their counterparts in the biotech industry, working in smaller groups toward a defined program of specific goals. With progressively less money from blockbuster drugs expected to come in over the next five years, the traditional big pharma model of the past decade will be forcibly reduced, and companies are already beginning to prepare.

Source: IHS Global Insight, Pharmaceutical Growth in an Economic Downturn: Wrap-Up for 2008, Outlook for 2009; this report was prepared by Aparna Krishnan and Mitra Thompson with contributions from Anupama Bharath, Shuang Lewis, Gaelle Marinoni, and Maria Tamayo.