



By Carolyn Gretton

## ▶ Vision and Planning are Key to Efficient Real-World Data Use

**TREND:** Market forces are driving the need for real-world data in the life-sciences industry.

### RECOMMENDATIONS FOR REAL-WORLD DATA RESEARCH

- » Develop a shared vision for RWD research. An education program explaining why RWD is important and how it is used by researchers, regulators, and competitors, as well as the potential threats and new opportunities, will help leadership come to consensus on vision and goals.
- » Establish the baseline and build the plan. Based on the vision, the next step is to benchmark internal processes to determine how RWD is captured, stored, and what capabilities are used to analyze the data.
- » Break down internal barriers. Biostatisticians and programmers who understand RWD are in scarce supply, so companies should consider moving them into a single RWD research support organization. Also, CSC recommends replacing RWD research silos with a centralized organization for acquiring and managing data.
- » Develop an informatics platform. An informatics platform for RWD includes data acquisition, management services, and a wide range of analysis tools. Its benefits include the ability to rapidly implement the infrastructure and applications needed for RWD and to access shared services such as data management and statistical programming needed to jumpstart a RWD program.
- » Establish RWD partnerships. Partnerships will increase access to high-quality data while building trust with other stakeholders. Organizations should establish a cross-functional team focused on supporting the development of partnerships with payers and providers.

Source: Computer Sciences Corp.,  
Real World Data Research: A Case for Action.  
For more information, visit [csc.com](http://csc.com).



Dan Foltz

**R**eal-world data (RWD) research is now a high-priority of life-sciences companies.

A survey by Computer Sciences Corp. (CSC) found that most life-sciences executives understand the importance of RWD, yet believe there are many internal and external barriers to achieving effective use in their organizations. RWD is essential to measuring outcomes, assessing comparative effectiveness, and responding to research conducted by regulators, payers, and clinicians. Yet there are many questions about the effective use of RWD, according to the survey.

Dan Foltz, director of CSC Health Intelligence, says many life-sciences executives are concerned about how their customers and regulators are using real-world data to make decisions.

"I advise my clients to follow a five-step plan to improve the effectiveness and efficiency of their real-world data research capabilities," he says. "Start with a vision, benchmark your current capabilities, actively improve your internal processes, and build a long-term plan that includes external partnerships and in some cases pre-competitive collaboration with other pharmaceutical companies."

▼ For more information, visit [csc.com](http://csc.com).

### Pfizer Displaces Merck as No. 1 IN OB/GYN IMAGE STUDY

Pfizer has knocked Merck out of the top spot in terms of ob-gyns rankings in SDI Health's Pharmaceutical Company Image 2011 study.

Pfizer was ranked No. 1 in the 2011 study, up from second place in 2010. Both Pfizer and Bayer gained mentions by an estimated 40% of ob-gyn physicians participating in the SDI study as one of the three companies they held in highest esteem, but Bayer had one fewer mention than Pfizer. In 2010, Bayer ranked fourth, with 30% of ob-gyns considering it a top company.

Merck, last year's leader, dropped to third. In 2011, 38% of ob-gyns reported that Merck was a top company, down from 43% in 2010.

"Bayer's improved standing is impressive, particularly over only one year," observes Jason Fox, associate director of SDI's syndicated analytics group. "The company's reps have increased their presence among ob-gyns and must be making a positive impression."

As a whole, physicians' perception of the pharmaceutical industry improved in 2011, with 58% reporting a somewhat positive or extremely positive overall impression; up two percentage points from 2010.

▼ For more information, visit [sdihealth.com](http://sdihealth.com).



Jason Fox

### New Guidelines Make it Tougher TO GAIN PHARMA TRADEMARK APPROVALS

In recent years, both the FDA and European Medicines Agency (EMA) have set forth stricter governmental brand name standards to help prevent look-alike and sound-alike pharmaceutical brand names such as Losec/Lasix and Prozac/Prilosec, which could result in potentially harmful or fatal prescribing mix-ups.

As a result of the new guidelines, FDA and EMA drug rejection rates have increased, in turn leading to a domino effect, as pharmaceutical companies rapidly increase the number of trademarks they

file with every new drug. According to the Thomson Compumark report, Pharmaceutical Trademarks: How to Survive the Name Game — New Challenges and Opportunities for Pharmaceutical Companies, the long-term FDA trademark rejection rate has increased to 36% in recent years as a result of these more stringent approval guidelines, and combined, the FDA and EMA are rejecting 40% to 50% of pharmaceutical trademarks each year.

Knowing they will need to have a healthy reserve of backup names to contend with this rejection rate, pharmaceutical manufacturers are routinely filing for five to 10 different trademarks for each trial drug in their pipelines, the report says.

▼ For more information, visit [compumark.thomson.com](http://compumark.thomson.com).



Adam Bianchi

tion study, although executives view government-specific price cuts as the top risk in their pricing strategies, Europe's recent austerity economic policies are considered the next most significant threat among a list of recent trends impacting drug pricing.

The study, *Global Pricing Strategy: Maximize Revenue in an Evolving Economic Climate*, found that even a country as small as Greece can impact the pharmaceutical pricing strategies of companies across the industry.

"The reasoning behind Europe's new economic policies certainly resonates within drug pricing teams," says Adam Bianchi, chief operating officer at Cutting Edge Information. "With backgrounds in finance and economics, market access executives understand the budget crunch governments are under after bailing out their economies and industries."

Unfortunately for life-sciences companies, reimbursement for drug and device treatment has become a focal point for cost-cutting discussions.

Drug companies have already begun to feel the effects of the new economic landscape in Europe. Germany has enacted a 2% across-the-board price cut for pharmaceuticals, and each country and payer is eyeing how other countries and payers react, which could lead to price cuts in other European nations, the United States, and emerging markets.

▼ For more information, visit [cuttingedgeinfo.com](http://cuttingedgeinfo.com).

### Internal Communications Function SHIFTS TO ADDRESS PHARMA PRIORITIES

The structure of a biopharmaceutical company's internal communications group must evolve to reflect the changing goals and strategies, according to a Best Practices report. Realigning to support new corporate initiatives and establishing service levels to reflect priorities and resources are key improvement areas for internal communications executives in 2012.

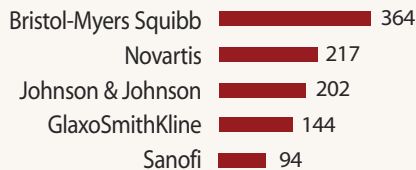
The Best Practices study, *Internal Communications Excellence: Optimizing Group Structure & Operations*, notes that about 50% of all internal communications budgets go to staff salaries and field travel. Key points of budget allocation variance lie in the relative amount of spend for non-

labor support systems; the pharma segment invests 20% here versus 7% at the multi-industry benchmark class.

In the pharma segment, 52% of internal communications executives surveyed by Best Practices noted their group has a business unit focus, while 48% have an enterprise-wide focus. Only 14% noted a product focus for the internal communications group.

▼ For more information, visit [best-in-class.com](http://best-in-class.com).

#### TOP COMPANIES IN NUMBER OF U.S. TRADEMARK FILINGS (2009)



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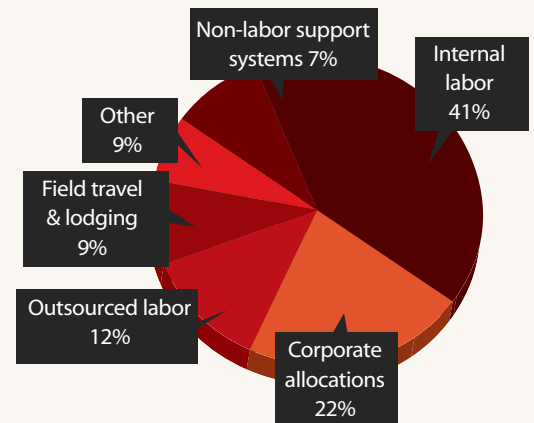
Source: Thomson Compumark, *Pharmaceutical Trademarks: How to Survive the Name Game – New Challenges and Opportunities for Pharmaceutical Companies*. For more information, visit [compumark.thomson.com](http://compumark.thomson.com).

### Pharmaceutical Pricing Strategies THREATENED BY AUSTERITY MEASURES

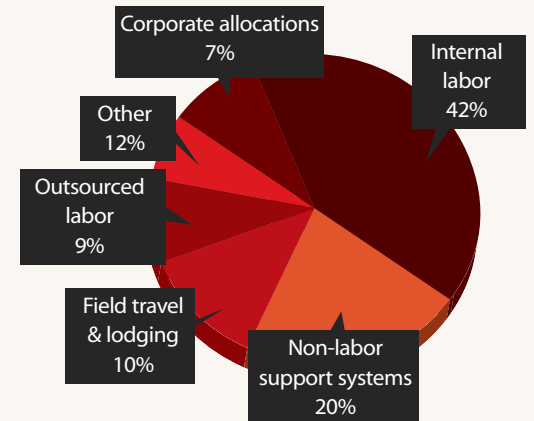
European governments' emerging economic policies and government-specific price cuts around the globe have drug companies' pricing teams on edge. According to a recent Cutting Edge Informa-

#### ALLOCATION OF THEORETICAL 10% MARKETING BUDGET INCREASE, BY ACTIVITY

##### Total Benchmark Class Field



##### Pharma Segment



Source: Best Practices, *Internal Communications Excellence: Optimizing Group Structure & Operations*. For more information, visit [best-in-class.com](http://best-in-class.com).

THERAPEUTIC MARKET FAST TRAX... 

## AUTOIMMUNE

Amgen/Pfizer's Enbrel was the most widely used tumor necrosis factor (TNF)-alpha inhibitor for recently treated psoriatic arthritis patients in the fourth quarter of 2010. But Abbott's Humira has superseded Enbrel as an early-line TNF-alpha inhibitor for newly diagnosed psoriatic arthritis patients, and Humira's early-line growth threatens Enbrel's future uptake in psoriatic arthritis.

About 28% of recently treated psoriatic arthritis patients were prescribed Enbrel, compared with 21.5% for Humira. Yet, among newly diagnosed psoriatic arthritis patients, Humira achieves a higher patient share than Enbrel in patients reaching the first and second line of disease-modifying antirheumatic drug (DMARD) therapy within one year of diagnosis.

Source: Decision Resources, Treatment Algorithms in Psoriatic Arthritis.

▼ For more information, visit [decisionresources.com](http://decisionresources.com).

An analysis of global pharmaceutical sales for the leading 15 therapy classes in 2009 found that autoimmune agents ranked eighth at \$18 billion, with global sales surging by 18%, the largest percentage increase among the top-selling drug therapy classes.

Source: Insight Pharma Reports, Autoimmune Diseases: Pipelines for Crohn's Disease, Multiple Sclerosis and Rheumatoid Arthritis.

▼ For more information, visit [insightpharmareports.com](http://insightpharmareports.com).

## CANCER

Two therapeutic classes currently dominate the cancer treatment sector: antineoplastics and cytostatic hormonal treatment. Expansion of target indications is a key factor in cancer therapy market growth; a number of very specific cancer treatments — particularly those that went on to become blockbuster drugs — have gone on to receive approval for treatment of other cancer types.

Source: Business Insights, The Cancer Market Outlook to 2016.

▼ For more information, visit [business-insights.com](http://business-insights.com).

China's gastric cancer drug market is forecast to grow from \$250 million in 2010 to \$469 million in 2015, driven by expansion of the diagnosed and drug treated population, greater access to chemotherapy agents used to treat gastric cancer, increased use of targeted therapies, and improved patient spending power.

Source: Decision Resources, Emerging Markets report, Gastric Cancer in China.

▼ For more information, visit [decisionresources.com](http://decisionresources.com).

## CENTRAL NERVOUS SYSTEM (CNS)

The global market value for CNS biomarkers was valued at an estimated \$1.4 billion in 2010. That value is projected to reach almost \$3.2 billion in 2015, increasing at a five-year compound annual growth rate (CAGR) of 17.1%. Of the three segments — discovery, drug development, and molecular diagnostics — the discovery segment is largest, valued at almost \$1.3 billion in 2010 and projected to increase at a CAGR of 14.6% to \$2.5 billion in 2015.

Source: BCC Research, Central Nervous System (CNS) Biomarkers: Technologies And Global Markets.

▼ For more information, visit [bccresearch.com](http://bccresearch.com).

While physician trials of Novartis' Gilenya, the first oral disease-modifying agent (DMA) for the treatment of multiple sclerosis (MS), have slowed down over the past quarter, market share continues to grow as a result of expanded uptake by prescribers.

Teva's Copaxone continues to be the market leader, capturing less than one-third of DMA-treated MS patients, with Biogen Idec's Avonex also strong among CIS and RRMS patients, and

Bayer's Betaseron and Pfizer/EMD Serono's Rebif strong among progressive MS patients.

Source: BioTrends Research Group, TreatmentTrends: Multiple Sclerosis, Q2 2011.

▼ For more information, visit [bio-trends.com](http://bio-trends.com).

The acetylcholinesterase inhibitor (AChEI) donepezil (Eisai/Pfizer's Aricept, generics) and Forest Laboratories' N-methyl-D-aspartate (NMDA) receptor antagonist Namenda lead all other therapies approved for Alzheimer's disease by a wide margin in the treatment of newly diagnosed Alzheimer's disease patients. AChEIs are the most frequently prescribed therapy for the treatment of Alzheimer's disease, with donepezil capturing the majority of patient share in the class. Meanwhile, Namenda, which is approved for the treatment of moderate to severe Alzheimer's disease in the United States, is most often prescribed in combination with AChEI therapy.

Source: Decision Resources, Treatment Algorithms in Alzheimer's Disease.

▼ For more information, visit [decisionresources.com](http://decisionresources.com).

Among recently treated multiple sclerosis (MS) patients in the fourth quarter of 2010, Teva's Copaxone garnered the highest patient share among key individual MS therapies, while the interferon beta products as a class captured the largest patient share. Copaxone was also the preferred therapy among newly diagnosed MS patients in both the first and second lines of therapy. Biogen Idec/Elan's Tysabri saw little use as a first-line therapy among newly diagnosed patients, consistent with its labeling, but experienced a considerable increase in patient share as a second-line therapy. In addition, Tysabri received al-

## Other market insights...

## Pfizer

## LIKELY TO REMAIN AT TOP IN 2016

According the EvaluatePharma report, World Preview 2016 — Beyond the Patent Cliff, the rheumatoid arthritis treatment Humira is expected to assume Lipitor's crown as the world's biggest-selling drug, while forecasted sales of the top 50 products in 2016 are expected to increase by \$21.7 billion, a 13% upgrade since April 2010.

Pfizer will hang on to its ranking as the largest seller of prescription medicines through to 2016, competing for the top spot with Novartis and Sanofi, while GlaxoSmithKline is expected to fall

out of the top five for the first time since the late 1980s.

▼ For more information, visit [evaluatepharma.com](http://evaluatepharma.com).

## Generic Injectables Market SET TO GROW

The global injectables market has value of around \$120 billion, according to the Espicom Business Intelligence report, Hospital Injectable Drugs: Future Prospects for Generics & Biosimilars. While the lion's share remains within the branded sector for the time being, the generic injectables sector already exceeds an estimated \$11.2 billion, and numerous high-value injectable products will face patent ex-

piry in major markets over the next decade. But many of the big sellers are biological products, and biosimilar approvals will only be possible for a few companies.

▼ For more information, visit [espicom.com](http://espicom.com).

## Physicians Want Smartphone, IPAD INFO ACCESS

There is significant physician demand for access to prescription drug information and online promotion programs on smartphones and iPads. Manhattan Research's ePharma Physician v11.0 study found that of responding e-pharma physicians — those who use digital channels for pharma resources and connecting with reps — 45% say they

most 10% patient share among recently treated patients in the last quarter of 2010.

Source: Decision Resources, Treatment Algorithms in Multiple Sclerosis.

▼ For more information, visit [decisionresources.com](http://decisionresources.com).

## DIABETES

Key opinion leaders believe that DPP-IV inhibitors will be the main class to benefit following the June 2011 suspension of pioglitazone use in France and Germany because of a link with bladder cancer. Pioglitazone use will continue to decrease, but most expect to increase their prescribing of DPP-IV inhibitors and GLP-1 agonists. Class use varies greatly among the seven major markets; pioglitazone is still highly used in the United States and Italy, but DPP-IV inhibitors have overtaken pioglitazone by share in the other major markets. GLP-1 agonists are most used in the large U.S. market, with 11% of patients on the drugs.

Source: Datamonitor, Hot Topics in Type 2 Diabetes: Physician Perceptions of Incretin Mimetics and TZDs - Physician Survey Provides Insights into TZD, DPP-IV, and GLP-1 Usage.

▼ For more information, visit [datamonitor.com](http://datamonitor.com).

Although Amylin/Lilly's Byetta currently commands a higher patient share than Novo Nordisk's Victoza, more patients were switched from Byetta to Victoza than vice versa (25.2% versus 2.8%) in the last quarter of 2010 among recently treated type 2 diabetes patients. The higher rate of switching suggests that Victoza use in the United States is increasing at the expense of Byetta.

Source: Decision Resources, Treatment Algorithms in Type 2 Diabetes.

▼ For more information, visit [decisionresources.com](http://decisionresources.com).

would like to access pharma product information on their smartphone or iPad. Manhattan Research estimates that 87% of U.S. physicians are e-pharma physicians.

▼ For more information, visit [manhattanresearch.com](http://manhattanresearch.com).

## India Biotech Market GROWTH

India is the third-largest biotechnology market in Asia, after Japan and South Korea, and accounts for around 2% of the global market. The Global Industry Analysts (GIA) report, Biotechnology In India: A Market Report, predicts the Indian biotechnology market is set to exceed \$11 billion by 2017, driven by foreign investment, growing R&D and infrastructure investment, an emerging contract re-

## GASTROINTESTINAL

Global sales of antiemetics came in at an estimated \$2.5 billion in 2010 and are projected to reach \$3.6 billion in 2015, for a five-year CAGR of 7.4%.

The market segment made up of NK1 receptor and dopamine antagonist and anticholinergics, worth about \$582 million in 2010, is expected to post the strongest growth over the period, with a CAGR of 13.3% propelling it to an estimated value of \$1.1 billion in 2015.

Source: BCC Research, Antiemetics: Technologies and Global Markets.

▼ For more information, visit [bccresearch.com](http://bccresearch.com).

## INFECTIOUS DISEASE

The combined world market for testing and treatment products for hospital-acquired infection (HAI) is expected to reach \$10.3 billion in 2015, up from \$9 billion in 2010, with higher growth experienced in the testing segment as a result of efforts to decrease the rate of fatality through rapid discovery and treatment of nosocomial infections.

Source: Kalorama Information, Hospital-Acquired Infections: Diagnostic Markets and Testing Developments, Treatments, Key Competitors and Trends.

▼ For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

## OPHTHALMIC

The market for age-related macular degeneration (AMD) and diabetic retinopathy (DR) drugs generated an estimated \$3.17 billion in 2010 and the market is predicted to exceed \$5.08 billion in 2014. If analysts' estimates hold true, this would make retinal diseases the most lucrative sector of

the ophthalmic drugs market, surpassing glaucoma treatments.

Source: visiongain, Macular Degeneration (AMD) and Diabetic Retinopathy (DR): World Drug Market 2011-2021.

▼ For more information, visit [visiongain.com](http://visiongain.com).

## PAIN MANAGEMENT

In 2010, combined U.S. sales of pain management products — pharmaceuticals and devices — totaled about \$33.1 billion. Since pain is the single most common reason patients seek medical care, this market is expected to increase at a CAGR of 3.7%, reaching \$38.2 billion in the year 2014.

Source: Medtech Insight, U.S. Markets for Pharmacologic & Device-Based Therapeutic Approaches to Pain Management.

▼ For more information, visit [medtechinsight.com](http://medtechinsight.com).

## VACCINES

The global market for vaccines was worth an estimated \$28.1 billion in 2010. That value is projected to be \$64.2 billion in 2015, after increasing at a five-year CAGR of 17.9%.

Source: BCC Research, Vaccine Technologies and Global Markets.

▼ For more information, visit [bccresearch.com](http://bccresearch.com).

## WOUND CARE

The U.S. market for wound biologic products is forecast to reach an estimated \$554 million in 2011 and will grow at a rate of 18.8% to almost \$1.06 billion in 2015.

Source: BioMedGPS, SmartTRAK Wound Biologics.

▼ For more information, visit [biomedgps.com](http://biomedgps.com).

The world market for products that treat wounds grew 6.2% to an estimated \$14.9 billion in 2010 and is expected to grow by almost 7% in 2011, driven by an aging population, increased diabetes incidence, and a host of new approaches and recent innovations.

Source: Kalorama Information, World Wound Care Markets 2011.


▼ For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

## Strong BRIC Market FOR IN VITRO DIAGNOSTICS

The growing economies of the BRIC nations — Brazil, Russia, India, and China — are expected to experience an increased demand for healthcare services led by testing.

Kalorama analysts report in a recent report, Emerging Markets for In Vitro Diagnostics (IVD in Brazil, Russia, India, China and Other Nations), that projected IVD sales in the BRIC nations are likely to increase from \$2.9 billion in 2009 to \$5 billion in 2014.

This increase represents a compound annual growth rate (CAGR) of 12%.

▼ For more information, visit [kaloramainformation.com](http://kaloramainformation.com). 

search market, drug discovery, and growth in manufacturing outsourcing to India.

▼ For more information, visit [strategyr.com](http://strategyr.com).

## Russian CRO Market EXPANDS

Russia is set to emerge as a distinct competitor in the global CRO market, with GBI Research forecasting yearly growth of 9.5% between 2009 and 2017, for an estimated market value of \$309 million by 2017. The GBI Research study, Emerging Market for Clinical Trials in Russia, notes that growth is being driven by Russian legislation put in place during September 2010, which requires drug manufacturers to conduct trials within Russia before a product can be launched there.

▼ For more information, visit [gbiresearch.com](http://gbiresearch.com).