# EU CANDIDATE COUNTRIES OFFER RIPE FIELD for Clinical-Trial Recruitment

Conducting clinical trials in Europe is not a new concept for global pharmaceutical companies, but choosing the country in which to hold a particular trial can sometimes be the subject of much deliberation. According to analysis from Insight Pharma Reports, major changes in the political landscape in post-Soviet era Europe have opened many new clinical-trial options outside of the more mature Western European markets.

"Europe holds a unique position: it has the advantage of offering not only well-established clinical-trial markets in countries that have a long history of conducting clinical trials, but also many promising emerging markets that are new to the clinical trial arena," says Pavle Vukojevic, M.D., author of European Clinical Trial Site Options: An Insider's Analysis. "Within this spectrum, a majority of European countries fall under the European Union umbrella and adhere, with some variation, to its guidelines and legislation concerning the conduct of clinical trials."

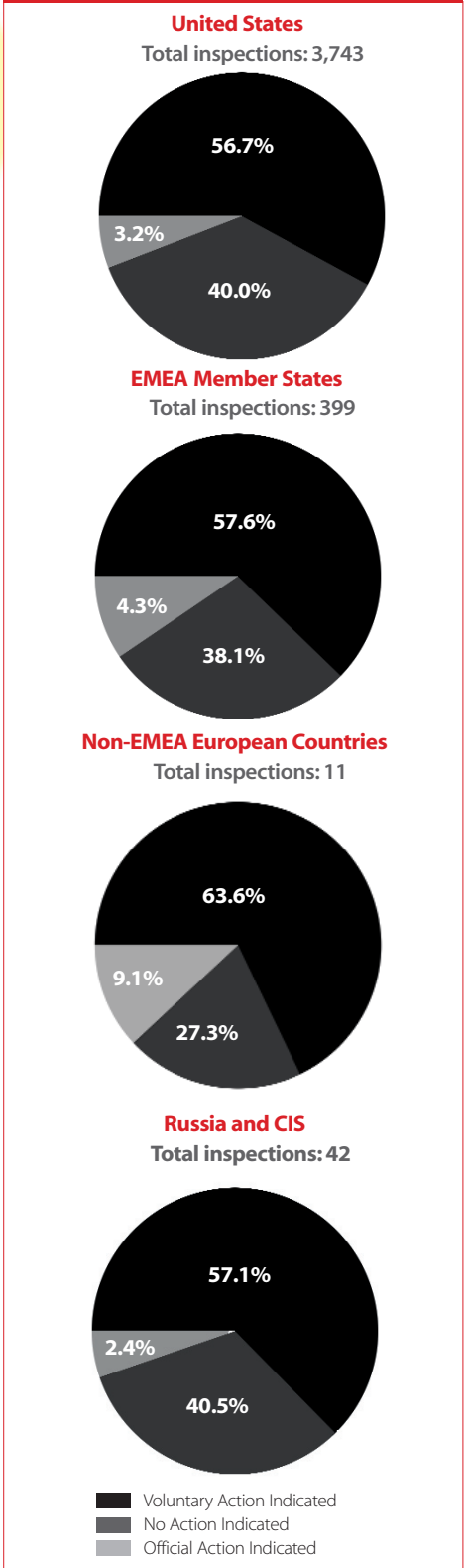
According to the report, as of April 2008, there were an estimated 5,126 ongoing clinical trials worldwide, an increase of more than 12% for each of the three categories (Phase I, II, and III) compared with the equivalent 2007 period and a 5.7% CAGR since 2001.

The clinical-trial industry in developed countries in Europe is a mature and expensive option. Most of these populations are treatment-savvy and, due to competition, patient recruiting can be difficult and time-consuming. These considerations have driven companies to consider India and China as sites for clinical trials. However, differences in medical practices and training, as well as problems with English language fluency, can make the trial process in these countries extremely difficult.

Advantages of holding clinical trials in EU candidate countries include: shorter study approval timelines, excellent recruitment rates, treatment-naïve patients, and lower costs. An analysis of recent FDA inspection outcomes provided in the Insights Pharma Reports indicates that the performance quality of clinical trials for these non-EU countries is equivalent to inspection outcomes reported for studies conducted in the U.S. and EU member countries.

*For more information, visit insightpharmareports.com.*

**OUTCOMES OF FDA INSPECTIONS SINCE 1994, BY REGION**




Note: Total inspections figure is the number of inspections recorded on the FDA's Clinical Investigators Inspection List (CLIIL) database from Jan. 1, 1994, to the April 14, 2008, update.
Source: Insight Pharma Reports, European Clinical Trial Site Options: An Insider's Analysis. For more information, visit insightpharmareports.com.

# MOLECULAR TESTING NEXT FRONTIER in Disease Management


***DNA assays will become part of the routine fabric of laboratory medicine by 2010.***

The field of molecular diagnostic medicine DNA testing has emerged fully from research into clinical practice and is becoming a dominant platform in clinical medicine. Molecular medicine will soon transform the entire spectrum of disease management, from assuring the early detection of disease to defining the prognosis of disease evolution and predicting a patient's response to specific therapies.

According to the Kalorama Information report, The World Market for Molecular Diagnostics, as DNA-based diagnostic and therapeutic interventions come to market and payers start to cover those therapeutics that offer an attractive cost/benefit ratio, physicians will begin to depend on them for treating their patients — propelling the molecular testing market, valued at $3.7 billion in 2007, into double-digit annual growth through 2012.

The molecular testing market has been dominated by Roche's PCR (polymerase chain reaction) technology since the mid-1980s. However, the Kalorama report notes, many new technologies are poised to take over from PCR, including bead arrays, electrochemical arrays, microarrays, SNP-it, and WAVE. These innovations incorporate the need for products that can be easily miniaturized and simplified for use in routine laboratories that have not yet invested in molecular methods. New products also will respond to the demand for faster turnaround of test results and for standardization of a large menu of tests on a single platform, thus speeding the adoption of molecular assays in routine patient care.

"By the time DNA assays become part of the routine fabric of laboratory medicine in 2010 or so, it is expected that physicians around the world will rely on molecular assays in the treatment of their patients," says Shara Rosen, lead Kalorama diagnostic analyst.

*For more information, visit kaloramainformation.com.*

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## MARKET FOR BIOLOGIC IMAGING REAGENTS to Surge Past $9.5 Billion in 2013

Biologic imaging reagents play a fundamental role in today's medical, pharmaceutical, and biotechnology industries. Optical imaging reagents allow life-sciences researchers and drug developers to visualize and detect biological processes at the molecular level and to perform key genomics, proteomics, and cellular analysis assays. Nuclear and contrast reagents provide important diagnostic information to physicians, enabling the early detection and treatment of disease conditions in cardiology, neurology, and oncology.

According to BCC Research's technical market research report, Biologic Imaging Reagents: Technologies and Global Markets, the global market for biologic imaging reagent technology is expected to increase from an estimated value of $5.8 billion in 2008 to more than $9.4 billion in 2013 — a compound annual growth rate (CAGR) of 10.2%.

Technology and market forces are creating a key shift in biologic imaging reagents toward highly specific, multifunctional reagents.

This shift is creating opportunities for reagent manufacturers to address strategic market opportunities in genomics, proteomics, live cell imaging, early detection of cancers and neurological disorders, drug development, and hybrid imaging/therapeutic reagents.

According to the report, a main competitive strategy for achieving success in biologic imaging reagents businesses has been acquiring unique technology in fluorescent proteins, fluorescence dyes and probes, quantum dots, and nanotechnology. A second route to gaining technological competitive advantage is through strategic industry alliances.

*For more information, visit bccresearch.com.*

**GLOBAL VALUE OF BIOLOGIC IMAGING REAGENTS, BY TYPE, THROUGH 2013 ($ MILLIONS)**

| Reagent Type | 2006 | 2007 | 2008 | 2013 | CAGR% 2008–2013 |
|---|---|---|---|---|---|
| Contrast reagents | $2,338.9 | $2,496.2 | $2,590.5 | $3,662.2 | 7.2% |
| Nuclear reagents | $1,911.0 | $2,048.8 | $2,063.5 | $3,714.8 | 12.5% |
| Optical reagents | $964.0 | $1,079.8 | $1,184.1 | $2,100.2 | 12.1% |
| **Total** | **$5,213.9** | **$5,624.8** | **$5,838.1** | **$9,477.2** | **10.2%** |

Source: BCC Research, Biologic Imaging Reagents: Technologies and Global Markets.
For more information, visit bccresearch.com.

## BIOMARKERS CAN IMPROVE DRUG CANDIDATE'S CHANCE of Making It to Market

Biomarkers — a measure of a normal biological process in the body, a pathological process, or the response of the body to a therapy — are becoming an essential part of the clinical-development process, with researchers employing them as evaluative tools to improve decision making, accelerate drug development, and reduce development costs.

In its Pharma Matters white paper, Biomarkers: An Indispensable Addition to the Drug Development Toolkit, Thomson Reuters notes that success rates in conventional drug development have steadily declined in recent years, with less than 10% of tested products entering Phase I clinical trials. With increasing costs and fewer drugs making it through the clinical development process to the marketplace each year, the pharmaceutical industry is embracing biomarkers as a way to predict a drug candidate's performance earlier and with a greater degree of certainty.

The FDA estimates that an improvement of just 10% in the ability to predict drug failures before clinical trials could save $100 million in development costs per drug.

The field of oncology is leading the way in the use of biomarkers in drug development.

Today's clinical researchers "would not even conceive" of developing a new drug without simultaneously looking for biomarkers for efficacy, safety, and to measure the pharmacodynamics of the drug, says Jeffrey Ross, M.D., head of pathology at the Albany Medical Center in New York and one of the researchers involved in the original work on the HER-2 breast cancer gene and receptor.

"Trials are designed upon biomarker assays," Dr. Ross says. "So many abstracts of Phase II and III cancer trials talk about what biomarkers were selected, such as *in vivo* biomarkers, imaging biomarkers, blood and tissue based biomarkers, on and on and on."

One example of a biomarker in use in oncology is circulating tumor cells (CTCs), a biomarker present in the blood of cancer patients.

At the moment, CTCs are used in the development of anticancer drugs as an objective and direct measurement of the response of the cancer to a novel agent.

Although still in development, this biomarker holds further promise: the number of CTCs in the blood of patients with breast cancer, for example, is potentially a prognostic biomarker, and there is currently research ongoing to find out whether a decrease in CTCs associated with treatment can be used as a predictive biomarker of long-term benefit.

This use of biomarkers as alternatives to clinical endpoints in drug development, alongside an increased understanding of disease and the availability of funds for research into cancer, has meant that oncology has not experienced the downturn in drug development experienced by many other therapeutic areas.

*For more information, visit thomsonreuters.com.*

## MARKET FOR METABOLIC THERAPIES Projected to Reach $48 Billion by 2017

According to Decision Resources' Pharmaview report, Commercial Outlook for Metabolism: 2003-2014, the global metabolism market generated more than $32 billion in sales in 2007, with diabetes therapeutics accounting for almost three-quarters of the total.

With a market share of 19%, Novo Nordisk was the top-ranking company in the metabolism market in 2007, followed by Sanofi-Aventis and Takeda. The report defines the metabolic market as including therapeutics for diabetes and obesity, growth hormones, and agents to treat a variety of niche endocrinology indications.

Over the forecast period to 2017, growth of the overall metabolism market is forecast to increase by a CAGR of 5.7% to $48 billion. Insulins will drive the majority of the sector's growth, increasing in value by more than 70%. Novo Nordisk is expected to remain the leading provider of metabolic therapeutics based on its broad insulin portfolio, while Merck will enter the sector's top five by 2014 as a result of sales of first-to-market DPP-IV inhibitor Januvia.

By contrast, the commercially attractive, yet highly underserved obesity market will remain relatively unfulfilled, despite almost doubling in size. The report projects that the withdrawal of Sanofi-Aventis' Acomplia in Europe and the dearth of agents in late-stage development will leave a significant gap in the obesity market. Poor efficacy and safety profiles of currently approved agents have combined with an unfavorable reimbursement climate to limit sales of obesity agents to date.

"Within the metabolism therapeutic area, the obesity drug market has yet to realize its potential," says Ben Duncan, associate analyst. "The few late-stage candidates in development for obesity all belong to smaller pharmaceutical and biotech companies; therefore, if they can demonstrate improved efficacy over currently available therapies, look for larger pharmaceutical companies to partner with or acquire these organizations."

*For more information, visit decisionresources.com.*

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