



## Pharma's Emerging Markets: Key Strategies for the BRICM

The pharma market landscape is changing, and the emerging markets are the industry's hope for growth. In the next decade, this BRICM market could grow to over \$3 billion.



BRIC is a common acronym for emerging global markets - Brazil, Russia, India and China. Add Mexico into the mix and BRICM is pharma's largest engine of market growth.

According to *eyeforpharma's* industry 2011-2012 industry report, while developed markets are expected to have single-digit growth, the BRICM countries are forecasting 50 percent average growth in the next five years.

### Common Challenges

Entering new markets is always a challenge, especially "underdeveloped" markets. A primary challenge is understanding local culture and customs. Another common difficulty is understanding regulatory requirements. A strategic solution would be to acquire local presence expertise through partnerships. To understand a brief market overview and the competitive landscape of the BRICM countries, let us look at each country profile.



### Brazil

Brazil has the largest pharma market in Latin America. There have been several major pharma companies expanding here including GlaxoSmithKline, Novartis and Amgen. In 2009, Brazil spent 10,8 percent of GDP on pharmaceuticals, however intellectual property protection has long been a problem for multinational investors. In the last few years, Brazil's population has grown including a growth in the middle class with demand for pharmaceutical drugs. This and Brazil's commitment to reforming IP laws is attracting big, multinational pharma companies.



### Russia

The Eastern European market, in particularly Russia, has been an engine of growth in pharma - especially in the neighboring European

Union. The Russian pharmaceutical market generated \$1 billion in 2009 with a growth rate of 14,5 percent. Market opportunities include Russians' preference for "foreign" drugs. Barriers to entry are regulatory procedures, which are lengthy and unclear, as well as local language.



### India

India is a potential pharmaceutical gold mine. According to a 2009 report, India's pharma market is valued at \$8 billion and is growing at an average rate of 7,2 percent a year. However, Indian companies have approximately 70 percent domestic market share. Multinationals are now attracted to the country's market potential with a "high quality for low price" strategy, which will require an increase in CRO outsourcing. In 2005, India passed the Product Patent Act to protect IP.



### China

Even if China is lagging behind India in the global share of the pharma market, China is expected to surpass India in the next couple of years due to stronger patent laws, medical insurance for its population (which is 20 percent of the world population), and an increase in drug research sponsorship with Shanghai becoming an important pharma hub. Prescription drug sales are expected to increase by \$40 billion by 2013.



### Mexico

So, why is Mexico now a part of BRIC? The government is looking to expand healthcare coverage, increasing the demand for prescription drugs, especially generics. The market has had an average growth rate of 8,3 percent with \$14.3 billion in sales in 2010. In terms of regulatory requirements, Mexico continues to align itself with U.S. standards. A significant advantage in the Mexican market is access to the Internet. More pharma companies are able to use the Web to communicate and advertise with patients and pharmaceutical drug users.

## CROS NT Enhances Partnership with Proinnovera GmbH

The two CROs will collaborate on operational and business development activities starting with the **BIOEurope Partnering Meeting** in Düsseldorf, Germany.

CROS NT has recently adopted a business development strategy of forming partnerships. For the CROS NT Group, partnerships can be beneficial in three ways:

- To cover strategic geographic markets with a local presence
- To expand service coverage
- To increase professionalism

 CROS NT has been searching for partnerships that would enhance its functional and analytical service offerings by joining forces with a clinical operations CRO. For this reason, CROS NT has formed a strategic partnership with **Proinnovera GmbH**, a full service CRO based in Germany with therapeutic expertise in dermatology. Since CROS DE, the wholly-owned subsidiary of CROS NT, was established last year in Augsburg, Germany, this partnership was an opportunity to expand market opportunities in German-speaking regions. Proinnovera was also a partner of the German CRO, Estimate, before it became CROS DE. The partnership with Proinnovera is two-fold. CROS NT also decided to collaborate with the

German CRO regarding business development and marketing activities.

The first joint marketing effort for CROS NT and Proinnovera will be the **BIO Europe 2011** Conference in Düsseldorf, Germany 31 October - 2 November. BIO Europe is a biotechnology partnering conference which allows delegates to pre-schedule one-on-one meetings with potential clients and partners. CROS NT CEO, **Paolo Morelli**, will attend along with Proinnovera's Managing Director, **Burkhard Breuer** and Project Manager, **Veronika Kunert**. As partners, CROS NT and Proinnovera can add full clinical services along with functional biometrics in data management and statistics.

For more information on Proinnovera GmbH, visit the website at [www.proinnovera-cro.de/](http://www.proinnovera-cro.de/)

CROS NT and Proinnovera are now scheduling meetings for BIO Europe 2011. If you are attending the conference and would like to meet with a partner representative, please contact Mary Wieder at [mary.wieder@crocnt.com](mailto:mary.wieder@crocnt.com).

## EMA and FDA Continue to Collaborate; Run Pilot Program

There is some good news for those pharma companies and CROs working internationally. The European Medicines Agency, the official regulatory body of the European Union, and the Food and Drug Administration, regulatory body for the United States, are continuing to collaborate in terms of Good Clinical Practice (GCP) standards.

The two regulatory bodies have begun a pilot programme to "increase information-sharing and collaboration on inspections related to clinical trials".

The EMA and FDA have also run a joint pilot programme with the Australian Therapeutic Goods Administration for active pharmaceutical ingredients. This pilot programme found that the three regions had 97 sites in common.

The EMA has stated that the reason for collaboration is the "foundation for a more efficient use of limited resources, improved inspectional coverage and better understanding agency's inspection

procedures". This being said, during the GCP pilot programme, the EMA and FDA shared over 250 documents in relation to 54 different medicines and arranged 13 clinical trial inspections.

As a CRO based in Italy, and most operations done in Europe, the CROS NT Group could certainly benefit from a joint collaboration from the EMA and FDA as it aims to form more partnerships in the U.S.

This year, the CROS NT Group has formed the Statistical Scientific Board, which is a think tank for statistical methodology comprised of prominent statisticians with expertise in regulatory bodies. The Board consists of members from Italy, Germany, the UK and the U.S., all with experience in either EMA, FDA or both.



# Events

## SPANISH ePHARMA DAY 2011

### CROS NT Group to Sponsor and Present at Spanish ePharma Day

The CROS NT Group is proud to sponsor the first inaugural Spanish ePharma Day to be held 27 October in Barcelona, Spain. The theme is "Optimizing Value and Quality in Clinical Data with Standards and Data Integration" and is intended to engage the Spanish and Portuguese pharma, CRO and biotech market.

The event will be conducted in both Spanish and English. Executive Director of Global Operations for i3, Fernando Martinez, will deliver the opening remarks. Presenting from CROS NT will be **Valentina Cavestro**, Senior Data Manager, who will present on "Integration of different study devices in Oracle RDC" as a case study report.

ARITHMOS, the IT entity of CROS NT, will also Sponsor the event. A presentation will be given on ARITHMOS' new software packet, Project Portfolio Management System, which is a set of modules designed to control and analyze projects and business resources - from Business Development to Project Management to Finance and Administration.

Registration for Spanish ePharma Day is still open. The early bird rate applies until 30 September. Please visit the website for more information and to register for the event:

[http://www.epharmaday.org/ePharmaDay2011/index\\_spa\\_2011.html](http://www.epharmaday.org/ePharmaDay2011/index_spa_2011.html)

### CROS NT to Exhibit and Present at PhUSE



PhUSE - Pharmaceutical Users Software Exchange - is hosting its annual conference October 9-12th in Brighton, UK. As always, CROS NT will be present, sending five representatives from its statistics team. Presenting will be last year's winner for Best Presentation in Pharmacokinetics, **Stefano Vezzoli**. Also presenting will be CEO, **Paolo Morelli** on "How To Develop Top Level

SAS Programmers". CROS NT will be exhibiting at **Booth #22**. Also in attendance will be CROS NT SAS Programmers, Matteo Ferrari and Marco Bertasini as well as Head of Statistical Programming, Valeria Visonà.

We invite you to visit our booth to learn more about our statistical expertise in clinical trials.

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## CROS DE Included in German Biotech Report

CROS DE, the wholly-owned German subsidiary of CROS NT, has been included in the "Cluster Biotechnology Bavaria" survey and report released in August. The survey consisted of small and medium-sized Contract Research Organisations (CRO), pharma and biotech companies which have an office located in the Bavaria region of Germany.

Since 2009, there are 13 newly established entities in the Munich area. In total, there are approximately 129 small to medium-sized biotech companies in Bavaria which includes 61 CROs. CROS DE is one of the newly established CROs in the region, having opened its Augsburg office in 2010.

CROS DE GmbH is included in the company profile section of the report alongside pharma and biotech powerhouses like Amgen, Astellas and Pfizer. The German CRO subsidiary offers data management and statistical services as well as experience and expertise in Oncology, Dermatology and Respiratory therapeutic areas. CROS NT's Vice President, **Frank Freischläger** and Chief Operating Officer, **Thomas Zwingers** are based in Germany.



For a link to the report, read the CROS NT [press release](#) available on the website.

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## Diabetes is the Fastest Growing Market in Pharma

Diabetes is the fastest growing therapeutic area in the pharmaceutical industry. According to PharmaTimes online, 285 million people around the world (or 6,4 percent of the population) is living with diabetes. This figure could grow to 438 million (or 7,8 percent of the population in the next decade.

Over the next decade, the industry expects to see a shift in the age group most effected by diabetes - from ages 49-59 to 60-79. There is also an increase in the number of patients with Type II diabetes. This means there will be a need for new drug treatments.

The main drug treatments in circulation are insulin or oral anti-diabetes treatments. Some well-known treatments within the European Union are Eli Lilly/Amylin's Byetta and Novo Nordisk's Victoza.

With the rapid growth of this market, experts expect the costs of preventing and treating the disease to rise to \$490 billion by 2030.

CROS NT and its IT entity, ARITHMOS, have already been confronted with the possibility of running diabetes trials, in particular with Electronic Data Capture. As cell phones are becoming a standard for conducting "eClinical" trials, CROS NT has been exploring the capabilities of smartphones and diabetes trials. Working with a mobile technology expert in Milan, **TechMobile**, CROS NT and ARITHMOS have the capability to collect and analyze data using a Blackberry connected to a Dominomobile Meter which is Glucometer.



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### About the CROS NT Newsletter

The CROS NT newsletter is published bi-monthly alternatively with the ARITHMOS newsletter. The goal of the newsletter is to share relevant news and events from the biopharmaceutical sector and showcase work CROS NT has been doing in industry. Content is produced in-house by CROS NT staff. You can find all of our newsletters archived on our website at <http://www.cros.it/newsletters>.

### About the CROS NT Group

CROS NT is a global analytical service CRO with expertise in biostatistics and data management, completing over 800 projects. The IT subsidiary, ARITHMOS, provides IT solutions like ePRO and data integration to increase trial success rates. Project governance between data analysis and technology is a niche for superior clinical trial results.

