



## Clinical Trial Market Expected to Grow 50% by 2015

What does this mean for the CRO market? Functional service CROs may be better equipped to serve niche and regional markets through strategic alliances and project governance.

This month the Pharma Times Online reported that the clinical trial market was expected to grow 50 percent through 2015. The global revenue for CROs is also projected to climb and surpass 32 billion USD. Two reasons given for growth are emerging markets and late stage development support.

### The Current Situation

The pharma market, as well as the CRO market, are already very consolidated. Sponsors in the industry are already having to decide whether to outsource to global full-service CROs or whether to use functional or regional CROs.

Emerging markets of interest include China, Brazil, India, Russia, Southeast Asia and Central and Eastern Europe. The Office of the Inspector General reported that 50 percent of patients in U.S. clinical trials came from these emerging markets. Therefore, it comes as no surprise that efficient management of global clinical trials is the key to drug development success.

This brief portrait of the clinical trial market has led experts to predict that there will be a need for more strategic partnerships with CROs. Outsourcing strategies will involve searching for a CRO's "niche", or specialized clinical trial service, for the highest quality results. These niche services can be based on therapeutic area or service expertise like biostatistical analysis or ePRO solutions.

### CRO Trends

To compete in the global market, the ultimate goal is profitability. The traditional strategy of "one-stop shopping" for a global full service CRO may be diminishing as Sponsors look to increase speed and efficiency while cutting costs in order to remain competitive. According to Beroe, a procurement intelligence firm, functional and

regional CROs usually have faster turnaround time on a project and provide better local market support than global CROs.

According to InPharma, more global and complex studies will need to outsource to CROs with specialty services. Outsourcing to "strategic" CROs can be advantageous when needing to perform specific clinical trial functions (i.e. ePRO) in certain therapeutic areas. InPharma states, "it is safe to say that the average number of outsourced services in a typical clinical trial is increasing".

**Table 1: Typical reasons Sponsors Outsource [1]**

Reduce and control operating costs	Reduce time to market
Improve / focus on company core business / competency	Access capabilities not otherwise available elsewhere
Service / quality improvement	Free internal resources for other purposes
Organizational strategy	Reduce risk
Competitive advantage	Gain flexibility
Skill enhancement	Industry transformation

Source: PharmaTimes Online

### Strategic Alliances

Forming partnerships based on strategies and specialties is becoming increasingly important. The discussion of strategic alliances is also relevant to the full-service versus strategic CRO debate. A factor in selecting CRO services, especially for global trials, is "localization". Regional CROs, such as those who have global reach and potential but operate primarily in one geographic area, can be beneficial.

As regulatory requirements become more complex and change continuously, a regionally-based CRO may be more competent in (*cont.*) >

understanding these requirements. For example the European Union recently updated legislation and regulatory requirements on pharmacovigilance (see below). A CRO based in Europe with extensive experience with EMA may be best suited to assist foreign companies operating within the EU.

### Project Governance & CROS NT

If Sponsors are going to use multiple CROs for trials, it could require extra time to manage multiple outsourcing providers. Experts in the industry recommend the CROs form relationships with "specialty service" providers like technology companies.

The CROS NT Group is comprised of a functional service CRO and an IT branch, ARITHMOS. CROS NT provides expertise in biometric services like statistical methodology and statistical programming, data management and pharmacovigilance. ARITHMOS works very closely with CROS NT to provide quality technology solutions for clinical trials. ARITHMOS expertise lies in ePRO solutions, data integration and computer system validation.

The business model of the CROS NT Group fits in with the trend of the clinical trial market and CROs. While not a "one-stop shop" for all clinical

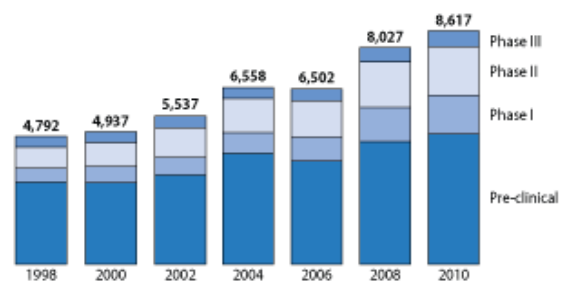
operations, CROS NT provides the quality data analysis and technology solutions. Being European based, the CROS NT Group understands regulatory requirements both on an individual state level and on a regional level (EU, EMA).

### Conclusion

The clinical trial market is expected to grow beyond 2015 and into 2021, according to industry experts. As the pharma industry consolidates and needs to continue to manage global trials effectively, there will be more of a need for strategic CRO outsourcing.

Source: CenterWatch News Online

### Drugs in worldwide clinical development



Source: Pharmaprojects

## EU Pharmacovigilance Legislation Takes Effect



The European Medicines Agency (EMA) has released the new formats for compliance with new European Union legislation on pharmacovigilance. The

legislation was passed in December 2010 to improve patient safety.

There are an estimated 197,000 deaths per year in the EU caused by adverse drug reactions (ADR). The new EU legislation aims to better identify medicines with suspected ADRs to implement the proper safety monitoring activities.

On 1 July, the EMA released a document with the new legal obligations for the pharma sector. The new legislation is in regards to "electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency".

Marketing authorisation holders have until 2 July

2012 to electronically submit information on medicinal products registered in the EU. According to InPharma, companies can develop their own electronic means to submit data via the EMA's EudraVigilance Gateway or use the EMA's own data entry and submission tools.

The EU says the new legislation will ensure patient safety by setting out clear tasks for all those involved in the EU pharmacovigilance system including Member States, marketing authorisation holders and the EMA. The legislation will also involve stakeholders through direct patient reporting of suspected adverse drug reactions.

### Free Webcast on Oracle Argus Safety



On Thursday, 15 September, Oracle will be hosting a [free webcast](#) on Oracle Argus Safety, an application for drug safety and risk management providing pharmacovigilance solutions from clinical development to post-marketing surveillance.

# Events



## CROS NT Group Wraps up DIA Chicago Event



CROS NT was pleased to again participate in the DIA Annual Meeting. This year's show in Chicago presented CROS NT with the opportunity to showcase itself as a functional service provider to the American market. The IT branch of CROS NT Group, **ARITHMOS**, exhibited for the first time at the DIA Annual Meeting, sharing exhibition space with CROS NT. The decision to exhibit together was based on the idea to highlight CROS NT Group's niche offering to the clinical trial market: project governance between data analysis and technological solutions.

This year, CROS NT distributed white, leather-bound USB keys to show participants. While we indeed wanted to provide show-goers with a nice "gadget", the USB keys contain important marketing material concerning CROS NT Group services, news and events. CROS NT also gave away an iPad 2 as part of a lottery, however the prize was more than just a marketing tool. ARITHMOS has been working on a project to incorporate Electronic Data Capture with the iPad which is revolutionizing clinical trials.


Overall, the CROS NT Group was pleased with the quality of exhibitors and is looking forward to next year in Philadelphia.

To see photos, visit our Facebook page: <http://www.facebook.com/crosntgroup>.

## Where can you find us next...

After the DIA Annual Meeting, the CROS NT Group is taking a brief event "hiatus". July and August are off months in the event circuit as CROS NT and ARITHMOS gear up for the busy fall season.

September. At the end of September, **Paolo Morelli** will attend the *European Respiratory Society (ERS)* Annual Meeting in Amsterdam.

 In October, the CROS NT Group is busy exhibiting and presenting at events on both sides of the Atlantic. CROS NT will exhibit at the 5th Annual Clinical Forum in Basel, Switzerland and present and exhibit at PHUSE in Brighton, UK.

The next event we will attend is the *Society for Clinical Data Management (SCDM)* conference in Baltimore, Maryland, USA. Marketing Officer, **Mary Wieder** will attend on Monday, 12

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## CROS NT Joins Ipsen's Preferred Providers List

In February of this year, CROS NT hosted **Ipsen**, a global biotechnology company, at its Verona office to bid to be a preferred provider. Under the leadership of Business Development Manager, **Gudrun Skiba**, Ipsen selected CROS NT last month to be a Preferred Provider for NIS studies. Being a Preferred Provider means that CROS NT

is recommended to Ipsen affiliates based on local need and prices and services. In June, Ipsen released a [press release](#) to announce its new business strategy which includes an investment in growth and broadening partnerships.



## Valeria Visonà Joins BIAS Steering Committee

**Valeria Visonà**, Head of Statistical Programming for CROS NT, was elected to the BIAS Steering Committee during its annual congress in Turin, Italy.

Valeria joins fellow colleagues, **Lisa Comarella**, Head of Statistical Methodology, and **Paolo Morelli**, CEO and Statistician, on the BIAS Steering Committee.



BIAS, Biometrici Dell'Industria Associati (Biometrician Industry Associates), is a prestigious Italian organization comprised of statisticians and data managers. The committee works with pharmaceutical companies and Contract Research Organizations as well as with universities and scientific companies. BIAS is made up of professionals in the industry who take a problem-solving approach to risks and changes affecting the profession of statistics and data managers.

BIAS, Biometrici Dell'Industria

"For me it is an opportunity to expand the views and knowledge of the world of clinical trials by having the chance to meet with others in the industry (other CROs, pharmaceutical companies, hospitals, etc) and to suggest to the committee themes and topics of study which we could also maybe use internally at CROS", says Valeria.

Valeria has been a Senior Statistician at CROS NT since 2009 and is now the Head of Statistical Programming. She has been a member of BIAS since 2008.

## CROS NT Published Authors

CROS NT has been working to put its expertise and knowledge on display. In the spring edition of IPI (International Pharmaceutical Industry) magazine, Chief Operating Officer, **Thomas Zwingers** published an article on adaptive trials in Oncology, "[Adaptive Designs: A Method for the Future of Cancer Research](#)". Thomas focused on the significance of making changes to a study in process based on new information especially in the area of oncology which has special features different from other therapeutic areas. Oncology is one therapeutic area of expertise and experience for the CROS NT Group.



Adaptive trials is a topic that CROS NT has been studying and following for awhile. Head of Statistical Methodology, **Lisa Comarella**, and her team of **Stefano Vezzoli** and **Luca Girardello**, first wrote an article on the importance of considering adaptive trial design. On 28 June, their article was published on the eyeforpharma website, "[Pharma Forecasting: the use of Adaptive Designs in Clinical Research](#)".

In the future, CROS NT will look for more opportunities to showcase its work. Keep checking the "Scientific Documentation" and "News" sections of our website for more publications.

### 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>.

