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**Subject:** Clinical Studies - Speed of Yellow issue includes Exco's Growth Strategy  
**From:** "PharmaPubs" <info@pharmapubs.com>  
**Date:** Mon, Nov 28, 2011 3:05 pm  
**To:** <bryony@jforpc.com>

## JCS Weekly News

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### HIGHLIGHTED ARTICLE

Diana L. Anderson's  
BRIC and Mortar

Clinical Trial Growth in Latin America, Eastern Europe and Asia

Brazil, Russia, India and China — collectively known as the BRIC — are four countries on similarly accelerated paths of economic development spurring a groundswell of R&D activity. In this report Diana L. Anderson of DAC Patient Recruitment Services gives us a thorough review of the guidelines which govern the recruitment of study volunteers to participate in clinical trials of investigational medical products in these countries.

[More...](#)

## Good Clinical Practice Contacts

- [General Information](#) (Good Clinical Practice Program)
- [Biological Products](#) (Bioresearch Monitoring Branch, CBER)
- [Drug Products](#) (Division of Scientific Investigations, CDER)
- [Medical Devices](#) (Division of Bioresearch Monitoring, CDRH)
- [New Animal Drugs](#) (Premarket Compliance and Administrative Actions Team, CVM)
  - [Enforcement Issues](#) (Office of Enforcement, ORA)

#### Good Clinical Practice Program (GCPP)

##### Members of our staff:

- Joanne Less, Ph.D., Director, Good Clinical Practice Program
  - Bridget Foltz, MS, MT(ASCP), Policy Analyst
  - Sara Goldkind, M.D., M.A., Senior Bioethicist
  - Doreen Kezer, M.S.N., Senior Health Policy Analyst
- David A. Lepay, M.D., Ph.D., Senior Advisor for Clinical Science
  - Marsha Melvin, Policy Analyst
- Kathleen (Swisher) Pfaender, R.N., J.D., Senior Health Policy Analyst
  - Jean Toth-Allen, Ph.D., Biophysicist

##### Contact the Good Clinical Practice Program if you have:

- general questions about FDA good clinical practice regulations and policy
- general questions about the FDA clinical Bioresearch Monitoring Program, and specifically clinical investigator, Institutional Review Board (IRB), sponsor, monitor, and contract research organization programs
  - questions about or suggestions related to [FDA's Information Sheets for IRB's and Clinical Investigators](#)
- questions about reports made pursuant to 21 CFR 56.108(b) and 56.113 involving an FDA-regulated product if you do not know which FDA Center has jurisdiction (e.g., drug, medical device, biological product), including:
  - unanticipated problems involving risks to subjects [21 CFR 56.108(b)(1)]
  - serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations [21 CFR 56.108(b)(2)]
  - suspension or termination of IRB approval of a protocol [21 CFR 56.108(b)(3)]

#### Biological Products

Bioresearch Monitoring Branch  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research (CBER)  
Telephone: 301-827-6221  
Facsimile: 301-827-6748

##### Contact the Bioresearch Monitoring Branch for questions about:

- The legal status of a test article
- Human subject production regulations relating to biologics
  - CBER assigned IRB inspections
  - CBER assigned Clinical Investigator inspections
- Reports made pursuant to 21 CFR 56.108(b) and 56.113 involving a biologic product including:
  - unanticipated problems involving risks to subjects
- serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations
  - suspension or termination of IRB approval of a protocol

#### Drug Products

Division of Scientific Investigations (DSI)  
Office of Compliance  
Center for Drug Evaluation and Research (CDER)  
Telephone: 301-796-3150  
Facsimile: 301-847-8748

Contact DSI: [www.fda.gov/cder/Offices/DSI/index.htm](http://www.fda.gov/cder/Offices/DSI/index.htm)

##### Contact the Division of Scientific Investigations for questions about:

- Human subject protection regulations pertaining to drugs (21 CFR Parts 50, 56, 312, 361)
  - CDER-assigned IRB inspections (e.g., FDA-483's)
- Reports made pursuant to 21 CFR 56.108(b) and 56.113 involving a drug product including:
  - unanticipated problems involving risks to subjects [21 CFR 56.108(b)(1)]
  - serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations [21 CFR 56.108(b)(2)]
  - suspension or termination of IRB approval of a protocol [21 CFR 56.108(b)(3)]
- reporting complaints related to human subject protection/Good Clinical Practice in FDA-regulated drug trials

#### Medical Devices

Division of Bioresearch Monitoring  
Office of Compliance  
Center for Device and Radiological Health (CDRH)  
Phone: 301-796-5490  
Fax: 301-847-8136  
Web site: [www.fda.gov/cdrh/comp/bimo.html](http://www.fda.gov/cdrh/comp/bimo.html)

##### Contact the Division of Bioresearch Monitoring for questions about:

- Human subject protection regulations pertaining to devices [21 CFR Parts 50, 56, and 812]
  - Informed consent, standard operating procedures, records and reports
- Serious or continuing noncompliance by an investigator with FDA regulations or with the IRB's determinations involving a medical device [21 CFR 56.108(b)(2)]
- Reporting complaints related to human subject protection/Good Clinical Practice in FDA-regulated medical device trial

#### New Animal Drugs

Premarket Compliance and Administrative Action Team  
Center for Veterinary Medicine (CVM)  
Phone: 240-276-9200  
Fax: 240-276-9241

##### Contact the Premarket Compliance and Administrative Actions Team for questions about:

- Good Clinical Practice regulations pertaining to new animal drugs for investigational use (21 CFR Part 511)
  - Reporting complaints related to the conduct of studies with new animal drugs for investigational use

#### Enforcement Information

Division of Compliance Policy  
Office of Enforcement  
Office of Regulatory Affairs  
Telephone: 240-632-6800  
Fax: 240-632-6810

##### Contact the Division of Compliance Policy for questions about:

- questions about the overall FDA Bioresearch Monitoring Program, and specifically the Good Laboratory Practice (GLP, nonclinical laboratories) Program
- general Bioresearch Monitoring program enforcement issue

## Woodley Equipment Announces Launch of New USA Office

Woodley Equipment Company Inc, specialists in the international rental of medical and laboratory equipment have announced that they are extending their presence and opening a new office in the USA.

The new office is located in Hopkinton, a town best known as the starting point of the Boston marathon.

Hopkinton is situated just 26 miles outside of Boston, the largest city in Massachusetts and a city well known for its economic and cultural impact on New England. The position of the new site will be perfect in helping to meet the significant increase in demand from both North and South America.

The Hopkinton office boasts three large individual offices with a central office area, warehouse facilities and a loading area. It aims to expand Woodley Equipment's ability to offer dedicated training facilities and support to its fast growing base of customers from North and South America.

The office will facilitate operations and dramatically increase global reach. Shipping costs will also be reduced, and customers will have the option and the convenience of next day delivery. Customer service is always top of the agenda for Woodley Equipment, and the expansion will mean extended office hours so clients can be served even more efficiently.

Woodley Equipment have been providing equipment solutions for over twenty-two years, with the company's head office located in Bolton in the U.K. Their existing client base consists of some of the largest Pharmaceutical and Biotech companies, as well as the majority of the top twenty global clinical research organisations and central laboratories. With the new capabilities of the office, Woodley Equipment can focus on building their excellent reputation and increasing their current client base overseas.

Woodley Equipment Company Inc will be celebrating the launch at the Clinical Business Expo and Outsourcing in Clinical Trials this month in Boston. As gold sponsors of both the events there are lots of exciting give-aways, prizes and also a drinks reception. To arrange to meet with a representative of Woodley Equipment please contact us at [sales@woodleyequipment.com](mailto:sales@woodleyequipment.com) or 08456 777 001 (UK)/ 1-800-471-9200 (US) We can organise a review of your current procedures, and suggest the most effective solutions through our personalised service.

### Office location and contact details:

Suite 104

65 South Street

Hopkinton

MA01748

USA

T: 1-800-471-9200 / 1-508-625-1692

F: 1-508-625-1721

## EXCO INTOUCH SECURES GROWTH INVESTMENT FROM SEP

Mobile patient communication leader to use funds to accelerate growth strategy

LONDON, UK - 29 September, 2011 - Leading growth equity and venture capital group Scottish Equity Partners (SEP) has led an initial £3m pound investment in Exco InTouch, the leading provider of mobile patient communication and management solutions for the pharmaceutical and healthcare sector.

SEP has taken a minority stake in the company which will use the funds to accelerate its expansion, enabling it to take advantage of significant growth opportunities in the clinical technology sector, particularly in the emerging mobile patient communication market.

Exco InTouch, whose clients include nine of the world's top 10 pharmaceutical businesses, has developed an innovative suite of patient-focused services which are delivered using a combination of cell-phone and internet technology. Used in clinical trials, the company's services benefit both patients and pharmaceutical clients: supporting patient recruitment and retention; aiding compliance; and facilitating the electronic capture of patient reported outcomes data (ePRO) during clinical trials and in Late Phase observational studies.

The company's services have already successfully supported more than 600,000 patients participating in clinical trials in more than 70 countries, including working with Pfizer on the industry's first ever mobile-enabled clinical trial. Benefits include significantly improved patient communication and compliance as well as ease of integration with users' proprietary systems.

Demand for its services is growing exponentially as pharmaceutical companies are increasingly adopting smart technology to optimise clinical trial execution. Exco InTouch is also targeting opportunities in the broader healthcare market as its mobile platform can also be used to manage patient education, medication compliance and measure effectiveness.

The business, which is already generating profits and employs some 40 staff, has its headquarters in the UK and bases in the United States and recently opened a second UK office in Nottingham to accommodate up to 30 more staff. Its strategy is focused on a patient-centred solution, a stance supported by regulatory authorities.

Exco InTouch, which was founded in 2004 by Chief Executive Tim Davis and Chief Technology Officer Mike Hansen, benefits from a highly experienced senior management team. The company is headed by Executive Chairman Neil Rotherham, co-founder of ClinPhone, another clinical technology business which he steered from start up to a successful IPO on the London Stock Exchange, before it was acquired by Parexel, one of the world's top contract research organisations.

SEP will support the company through its next growth phase, enabling it to invest further in people, technology and infrastructure and to further enhance its revolutionary mobile technology platform. Jan Rutherford, a Partner at SEP, joins Exco InTouch as a non-executive director. She brings on board a wealth of experience in providing strategic support to high growth companies in the healthcare sector as well as previous experience in working for Novartis and Quintiles.

Jan Rutherford said: "We have great confidence in the Exco InTouch management team who have an outstanding track record in the clinical technology sector. We see significant growth opportunities for what is truly game-changing technology. They are conducting pioneering work with world leaders in drug development which is helping to make healthcare more efficient, effective, accessible and patient-centric."

Dr. Neil Rotherham, Executive Chairman at Exco InTouch, adds, "We were attracted to SEP's extensive industry experience and heavy investment in the market sector we work in. SEP will be able to complement and challenge us, as well as helping our continuing growth. This financial year has proved highly successful for us, with particular growth in our ePRO, and patient engagement services that are used for patient retention, recruitment and compliance in clinical trials and other healthcare settings."

### Media Contacts

For Exco InTouch: Fiona Robinson, The Scott Partnership, 1 Whiteside, Station Road, Holmes Chapel, Cheshire CW4 8AA Tel: +44 1477 539539 Fax: +44 1477 539540 e-mail: [exco@scottpr.com](mailto:exco@scottpr.com)

For SEP: Valerie Darroch, Corporate Affairs Email: [valerie.darroch@sep.co.uk](mailto:valerie.darroch@sep.co.uk) Tel: + 44 7970 737708

### About Exco InTouch

Exco InTouch is the leading provider of interactive patient communication and engagement solutions using internet and cell phone technology. Using a combination of software and services, the company provides a variety of innovative ePRO, recruitment, retention and compliance services that are used by BioPharma sponsors, CROs and patient recruitment agencies.

Established in November 2004, Exco InTouch is a profitable and steadily expanding organisation whose services are proven with over 600,000 subjects across 67 countries. The company has a significant track record within the industry and is currently working with 9 of the top 10 pharmaceutical companies; it also has preferred provider agreements in place with a number of global CROs and recruitment agencies.

The company employs around 40 people with two UK bases and two in the United States and plans to expand its workforce further. Its operations staff are highly experienced with expertise in mobile telecommunications, providing a flexible and highly customer focused service.

Its solutions are delivered in the local language and the company is compliant with Safe Harbour, HIPAA, FDA 21 CFR 11 and global data protection and privacy legislation.

For more info on Exco InTouch visit <http://www.excointouch.com>

### About Scottish Equity Partners

Scottish Equity Partners (SEP) is a leading independent, owner-managed venture capital and growth equity firm with a 20 year track record of successful investing. Operating from offices in Glasgow and London, it invests in innovative, high growth potential companies in the IT, healthcare and energy sectors. With significant funds available and an integrated investment team, SEP has the resource and experience to add value from investment through to exit and has been selected as the partner of choice by many of the UK's leading technology companies. For more information see [www.sep.co.uk](http://www.sep.co.uk)

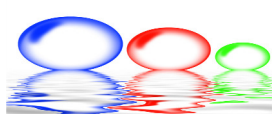
Recent portfolio exits include the sale of web traffic management company Zeus Technology to Riverbed Technology Inc (NASDAQ: RVBD) for a total price of up to \$140m, and the sale of multimedia home networking company Gige Networks to Broadcom Corp (NASDAQ: BRCM). SEP also exited from cancer therapy company BioVex which was acquired by Amgen Inc. (NASDAQ: AMGN, SEHK: 4332) in a deal worth \$1bn which earned SEP the Venture Deal of the Year award in the Unquote British Private Equity Awards 2011.

SEP's current portfolio comprises award-winning high growth companies including several in the healthcare sector: Cmed ([www.cmedgroup.com](http://www.cmedgroup.com)) which combines full clinical research services with advanced clinical data capture and management technology; and healthcare informatics company Aridhia ([www.aridhia.com](http://www.aridhia.com)). It also includes Media Ingenuity ([www.mediaingenuity.com](http://www.mediaingenuity.com)) a specialist in online marketing services and technology for the financial services sector; managed IT services provider Control Circle ([www.controlcircle.com](http://www.controlcircle.com)); flight search engine Skyscanner ([www.skyscanner.net](http://www.skyscanner.net)); wireless communications leaders picoChip ([www.picochip.com](http://www.picochip.com)) and ipaccess ([www.ipaccess.com](http://www.ipaccess.com)); energy-related technology specialist ARKeX ([www.arkex.com](http://www.arkex.com)); semiconductor company Elonics ([www.elonics.com](http://www.elonics.com)); oil technology business Deep Casing Tools ([www.deepcasingtools.com](http://www.deepcasingtools.com)); and IT analytics company Sumerian ([www.sumerian.com](http://www.sumerian.com)).

For more info visit <http://www.sep.co.uk>

-Ends-

## Guidance for Industry-Acceptance of Foreign Clinical Studies



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## Proposed Regulations and Draft Guidances

*Draft regulations and guidances are documents that have been proposed, but FDA has not made a decision as to whether the proposal will be adopted in whole, in part, or not at all. Each FDA draft document lists how to submit comments to the agency concerning the draft.*

*The entries below are listed in reverse chronological order by publication date.*

6/1/2011: [Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions, Draft Guidance for Industry and FDA Staff](#)

This draft guidance document is intended to clarify the types of in vitro diagnostic (IVD) products that are properly labeled "for research use only" ("RUO") or "for investigational use only" ("IUO"), and provide the responses of the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to some frequently asked questions about how such products should and should not be marketed. This document is intended for manufacturers and distributors of RUO and IUO IVD products and any other entities who label IVD products.

**Comments are due by August 30, 2011**

5/24/2011: [Financial Disclosure by Clinical Investigators, Guidance for Clinical Investigators, Industry, and FDA Staff \(PDF - 151KB\)](#)

This guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators, 21 CFR part 54. This document is a revision of the Guidance for Industry: Financial Disclosure by Clinical Investigators dated March 20, 2001. The revised guidance addresses issues raised by the Office of the Inspector General (OIG), Department of Health and Human Services, in its report, OEI-05-07-00730, The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information as well as questions FDA has received from industry and the public.

**Comments are due by July 25, 2011**

04/13/2011: [Proposed Rule - Disqualification of a Clinical Investigator](#)

The proposed rule will amend the regulations to expand the scope of clinical investigator disqualification. Under this proposal, when the Commissioner of Food and Drugs determines that an investigator is ineligible to receive certain test articles (drugs, devices, or new animal drugs), the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

**Comments are due July 12, 2011**



RGCC Ltd is activated in the field of molecular oncology and during the last period is focused in cancer stem cell's (CSCs) research. CSCs which exhibit properties of self-renewal and pluripotency may be the cause of recurrent disease. In RGCC's facilities some of the protocols that have been set up and are performed, are: a) isolation and cultivation of CSCs through sphere-formation assays by using an appropriate growth medium which contains growth factors and ingredients essential for CSC's growth, expansion and proliferation, b) characterization of CSCs by gene expression analysis assays [reverse transcription (RT) and Real - time PCR analysis] identifying several molecular markers such as nanog, oct3/4, sox2, nestin and cd34 genes which define CSCs phenotype. The second panel of CSCs characterization includes protein analysis assays by using flow cytometry. Finally, cell banking protocols are performed in order to create a master bank of several types of CSCs for further analysis.

Having a highly equipped laboratory and trained personnel, RGCC Ltd through all those innovative assays, can provide extensive and precise research analysis services concerning CSCs in every pharmaceutical industry and organization.

### Recent Relevant Publication

#### **Correlation between Cancer Stem Cells and Circulating Tumor Cells and Their Value**

Maria Toloudi, Panagiotis Apostolou, Marina Chatziioannou, Ioannis Papisotiriou

Research Genetic Cancer Center (R.G.C.C. Ltd.), Filotas, Greece

Case Rep Oncol 2011;4:44-54 (DOI: 10.1159/000324403)

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Our processes:

- \*allow systematic questioning that is directly relevant to the indication, protocol and site and promotes thorough evaluation of the protocol and workload involved
- \*ask the right question of the right person at the right time, and always involve the investigator
- \*allow rapid updating of information as a trial moves from design phase to start-up

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Contact Tonya Butterworth at [feasibility@centralglobal.com](mailto:feasibility@centralglobal.com) to see if we can help with your next clinical trial.

### **Labtech International comes of age**

Established 18 years ago to meet a need by customers to source high technology instrumentation backed up with a high level of support, Labtech International Limited has grown from strength to strength in a very competitive market to become a leading life science distributor.

Recognising that a personal approach to solving analytical problems backed up with excellent technical support is a sound basis on which to grow a business, Labtech International has matured to become a foremost supplier of leading edge life science instrumentation. It is this focussed approach by a dedicated team of highly qualified specialists that has attracted major manufacturers such as NanoDrop (Thermo Electron Corporation), Tecan and Illumina to select Labtech as the sole distributors of some of their products in the UK. Brian Page, MD, says that "Labtech must be doing something right if increasing numbers of premium manufacturers appoint Labtech to sell and support their products and to give us sole responsibility for product support demonstrates significant confidence in our capabilities".

Tecan announced their endorsement of Labtech International's distribution in January by stating that "Labtech's 18 years of experience in selling, supporting and servicing microplate equipment will ensure that customers continue to receive the same quality products and technical support that they have come to rely on".

When considering new technology or applications, scientists like to discuss the issues they face with competent

specialists who will identify the most appropriate solution to their particular problem. Many suppliers of instrumentation are limited in this respect and fail to provide the customer with sufficient facts on which to make an informed decision. Support is also an important consideration and again this is an area where Labtech excels and continues to develop.

The Cancer Research Centre in Liverpool is a good example of where this approach has been appreciated.

"Where one can spend a lot of time sourcing scientific equipment for the laboratory by perusing trade journals there is no substitute for an equivalent reliable UK based agent capable of providing a reliable service. Over the past couple of years Labtech International have provided us with a very efficient sales service, cost effective deals helpful advice including post sales, in short a service second to none which we have been very satisfied with".

The Labtech International approach of offering technical excellence in products and services that address both the needs of the end user and the demands of the life science market means that Labtech will continue to be the preferred option for manufacturers and scientists for years to come.

#### About Labtech International Limited

Based in Ringmer, Sussex, Labtech International Limited is a foremost distributor of life science instrumentation in the United Kingdom and France. Representing many major manufacturers on an exclusive basis Labtech International Limited provide exceptional technical, applications and service support together with personal service that ensures a high level of customer satisfaction. Committed to continuous development of products and services, Labtech International Limited endeavours to provide significant added value for its customers at all levels.

## JCS WATCH

... in the July issue of JCS...

#### The Collaborative Opportunities for Research Excellence (CORE) Programme Supports Nanotechnology Studies

In February 2010 the National Science and Technology Council's Subcommittee on Nanoscale Science, Engineering, and Technology released a supplement to the President's 2011 Budget entitled **The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry**. This publication describes research and development programmes planned for 2011 by those US government agencies that are participants in the National Nanotechnology Initiative (NNI) and notes the establishment of the Collaborative Opportunities for Research Excellence (CORE) programme. By: Walter Chalkley, of Thomson Reuters [...More](#)

#### Cardiovascular Safety Watch Column

A potential cardiovascular safety biomarker that is currently receiving a lot of attention is blood pressure. More specifically, the biomarker of interest is drug-induced changes in blood pressure (increases or decreases) for non-cardiovascular drugs. While antihypertensive drugs, for example, are designed to have an effect on blood pressure (lowering it), non-cardiovascular drugs are not expected to change blood pressure in either direction, and any such change would be considered an off-target effect. By: J. Rick Turner of Quintiles [...More](#)

#### Current Status of International Multicentre Clinical Trials in China

In recent years, an increasing number of multinational companies have established their late stage clinical trial centres in China. On September 6th 2009 the State Food and Drug Administration (SFDA), P.R. China, first released its Annual Report on Drug Registration Approval, showing a progressive increase in synchronous research participation of new global drug development, as well as a steady rise in applications for clinical trials in international multicentres. By: May Lan of The Scott Partnership [...More](#)

#### FDA's New Risk Evaluation and Mitigation Strategy for Opioids -- CNS Watch

According to a recent report by the Substance Abuse and Mental Health Services Administration, prescription drug abuse continues to be a grave problem. The US Food and Drug Administration (FDA) had also recognised a substantial increase in the number of postmarketing reports of abuse, misuse, addiction and overdose resulting in fatalities associated with extended-release and/or long-acting opioid drugs. By Henry Riordan of -- Worldwide Clinical Trials [...More](#)

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## Company Watch

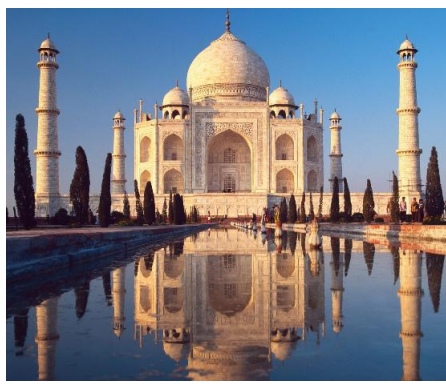
**Synexus**, the world's largest multi-national company dedicated to the recruitment and running of clinical trials is **expanding its operations in Gdynia, Poland** when it moves to new premises later this year. It has also recently increased the capacity of its original centre in Wroclaw by several hundred square metres.

The new dedicated research centre in Gdynia will have the capacity for four full-time investigators, with an increase from one hundred to three hundred square metres of space and will include a wide range of diagnostic instruments to cover Synexus' expanding therapy area coverage.

Dr Radoslaw Janiak, Synexus Country Manager for Poland says he is delighted with Synexus' progress in Poland: "Being part of Synexus' worldwide operations means that **we are increasingly involved in large global clinical trials**, we are able to recruit the right numbers of patients within the right time frame and that's exactly what sponsors are looking for. We are seeing considerable interest from a number of leading pharmas and CROs who are keen on the developments we have underway to increase our capacity here. In addition, the conference we organised in December has helped to raise awareness of the importance of clinical trials in Poland and has caught the attention of a number of senior medical professionals keen to develop their role and that of their organisation, in the vital area of clinical research and the importance of the sector to improving healthcare in Poland."

Synexus has been operating in Poland since 2006 from its site in Wroclaw and expanded its operations there in August 2009 when it acquired three new dedicated research centres in Warsaw, Gdynia and Katowice, following its takeover of CLCC.

Chief Executive Michael Fort believes that there is substantial scope to develop his company's business in Poland: "We are continuing to see increased levels of interest for clinical trials throughout the CEE, not least in Poland where our sites are very well located and staffed by highly qualified and experienced professionals. The pharma companies and CROs we are talking to continue to express their enthusiasm for increased capacity across the CEE and we are keen to help meet their demands." Source: Synexus.



#### Think Medicine -- Think India

India is undisputedly an acknowledged leader in the global pharmaceutical industry, measured by any yardstick, whether number of facilities filing DMFs, facilities inspected by the USFDA, number of patent challenges, or volume of APIs & formulations exported, etc. In spite of considerable achievements, several untapped business segments and markets exist, and the room to enhance the country's pharmaceutical exports is vast.

Sophisticated chemistry capabilities, lateral thinking abilities in developing non-infringing processes, disciplined approach to adherence to stringent guidelines, dedication to manufacturing excellence, etc., notes T.S. Jaishakar of Quest Lifesciences, makes

India a favourite destination to source or outsource various

components of the value chain.[more](#)

## Regulatory

Airborne Particle Monitoring: Impact of ISO 21501-4 Calibration

Dependable, consistent and repeatable results in monitoring airborne particles in cleanrooms and clean zones depends both on the sampling technique of the analyst and on the performance of the particle counting instrument. The control of the sampling technique often is the subject of a unique SOP (standard operating procedure) while the performance of the instrument is typically reviewed and verified through an annual or semi-annual calibration process. The calibration process itself has been subject to a greater degree of variability in actual or practice throughout the lengthy life of the instrument than would be desired, due to different calibration techniques magnified by infrequent maintenance and calibration. Joe Gecsey of Met One (Hach) explains how this variability can be minimised by the implementation of the ISO 21501-4 calibration standard.

## Market Review

#### A Snapshot of the Clinical Trial Experience in South Africa

South Africa is a multi-cultural society that celebrates diversity in its population of an estimated 49.99 million. The South African population consists of four ethnic groups, with approximately 79.4 % African, 9.2% Caucasian, 8.8% Mixed Ancestry and 2.6% Indian and Asian. Socio-economic inequalities between populations and disparate access to healthcare have led to a spectrum of disease seen in South Africa's citizens today. **Dr. Stefan Astrom, CEO of Astrom Research International, Dr Nirvana S. Pillay, of Xcell Bioconsulting and Bastian Koster of Von Seidels Intellectual Property Attorneys** take a look at how the diversity of patients in South Africa offers a host of clinical conditions ideal for inter-ethnic comparisons and genetic studies. [more](#)

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## Therapeutic

### Paediatric Pharmaceutical Medicine -- Paediatric Clinical Research and Considerations for Clinical Trials

Children and adolescents suffer from many diseases for which safe and effective pharmacotherapy has been developed for adult patients. However, children may have a disease process that is similar to or vastly different from their adult counterparts. While it has been understood from an intellectual perspective that clinical trial information is critical for this population, two factors have led to a lag between utilisation of pharmaceutical agents, and knowledge of their action and dosing in children: growth and development issues, and ethical concerns. It is also recognised that this patient population is vulnerable and thus demanding of a cautious approach when they participate in clinical trials. **Cynthia Jackson & Rick Turner, of Quintiles**, evaluate processes to embrace this distinction, while developing protocols, protecting safety, and gathering useful data have been the challenges of paediatric pharmaceutical development. [more](#)

## Logistics

### ABPM in Clinical Trials -- 3D Perspectives

Despite Ambulatory Blood Pressure Monitoring (ABPM) being used for the management of hypertension in specialist centres for over twenty years, and increasingly by GPs, its use in clinical trials remains surprisingly rare. Conventional blood pressures measured over a clinical trial could be considered a 2D perspective on any BP changes, as this only provides a snapshot of a patient's blood pressure at one point in time. Neil Atkins of Dabl Ltd explains the benefits of ABPM, which provides full 24-hour profiles at each visit, adding a new dimension to the data and the possibilities for analysis. [more](#)

## Russia & Eastern Europe

### Clinical Trials in Russia.

This is a brief extract of the report compiled by Synergy Research Group, a Russia based CRO, discussing the steps taken by Russian Authorities for the formation of a civilized market of clinical trials in Russia and improvement of the research attractiveness of Russia for foreign sponsors. By **Anna Ravdel of Synergy Research Group**. [more](#)

### Optimising Time and Money in Clinical Trials -- Russian, Ukrainian and Eastern European Perspective

Russia, Ukraine and Eastern Europe represent productive geographies with fast-enrolling clinical trials. These trials, with the patients and pivotal data coming from Russia, Ukraine and Eastern Europe, enable biopharmaceutical companies to bring their products to market in a cost-effective way while optimising time and money during the pharmaceutical product development process. In this article **David Passov of ClinStar** analyses three very important points: What results are biopharmaceutical companies achieving by conducting trials in these geographies? Are they saving valuable time and therefore, money? Are regulatory approvals being obtained using data from trials conducted in Russia, Ukraine and other parts of Eastern Europe? [more](#)

### Comprehensive Feasibility Assessments in Eastern Europe -- Luxury or Necessity?

The necessity of conducting Comprehensive Feasibility Assessments in Eastern Europe is a vital issue. Conducting trials in emerging markets such as Eastern Europe offers the appealing prospect of substantive gains. However, to tap into these rewards requires a detailed understanding of a number of key issues. **Dr. Guy Patrick of Central Global Limited** reviews the processes involved. [more](#)

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### The Costs Involved in Conducting Clinical Trials

**Malgorzata Szerszeniewska, the MD and CEO of EastHORN Clinical Services** explores the high level of variation in the cost of conducting clinical trials. Clinical trials are always expensive and complex undertakings. The economics of drug development demand a highly developed discipline in clinical project management, particularly so when trials are conducted outside of the traditional and relatively similar regions of North America and Western Europe. The attraction of conducting trials in Central and Eastern Europe, Latin America and Asia is that these countries can offer access to large numbers of patients at significantly lower cost without sacrificing quality and regulatory acceptability. [more](#)

## BOOK REVIEW

### Clinical Trials Audit Preparation A Guide for Good Clinical Practice (GCP) Inspections

**Andrew E Mulberg, Steven A Silber, and John N van den Anker**

The relevance and importance of the regulatory environment for new drug development cannot be over-emphasised. Regulatory affairs professionals at biopharmaceutical companies keep in constant dialogue with regulatory agencies throughout development, and their input to study teams and executive management is critical throughout the process. Regulatory agencies conduct various audits during the development and manufacture of biopharmaceutical drugs. One of these is the good clinical practice audit. This book provides an excellent introduction to this topic, and a roadmap for successfully navigating such audits.... [more](#)



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