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Subject: Clinical Studies -The Death of CNS Drug Development: Overstatement or Omen?

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HIGHLIGHTED ARTICLES IN CURRENT ISSUE

Drug-Drug Interactions Studies

A Regulatory and Study Design Perspective

The Death of CNS Drug Development

Overstatement or Omen?

Leveraging Ethnobridging

To Accelerate Global Drug Development

The Adoption of a Centralized Method

for Significantly Improved Data Quality

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 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.

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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JCS Watch pages in the current issue include:

Companion Diagnostics

In today's world the usage of companion diagnostics is becoming more common, as they allow for an increase personalisation of treatments by identifying the patients who are most likely to respond, or who are at lower or higher risk of a particular adverse event. By: Alejandra Muntañola, Project Manager at Thomson Reuters

Cardiovascular Safety Watch Column

Off-target drug-induced blood pressure change, as a cardiovascular safety biomarker for non-cardiovascular drugs, is a topic discussed in this issue's Cardiovascular Safety Watch page. This topic has been discussed at several scientific meetings during 2011, and most recently at the annual meeting of the Cardiac Safety Research Consortium. A summary of the recent discussion is presented by Rick Turner of Quintiles.

The Death of CNS Drug Development: Overstatement or Omen?

The past year has been notable for several large pharmaceutical companies fundamentally abandoning or severely restricting their neuropsychiatric drug development efforts, citing costly and long drug development periods with disproportionately lower chances of successful central nervous system (CNS) drug applications. Henry Riordan and Neal Cutler of Worldwide Clinical Trials look into CNS drug development.

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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.

Other topics covered in JCS include:

Regulatory

Drug-Drug Interactions Studies: A Regulatory and Study Design Perspective

Two drugs can interact with each other pharmacokinetically and/or pharmacodynamically. Pharmacodynamic (PD) interactions lead to a change in drug response without any alterations in plasma concentrations. In this article, Dr Mario Tanguay and Jean-Francois Gagné of PharmaNet/i3 focus on issues such as regulatory framework and strategy, study design considerations, sample size and statistical considerations, and when to conduct DDI studies during drug development.

The Impending Sunshine Act: A Review for Clinical Trial Sponsors

Jessica Dolfi and Sondra Pepe of Medidata provide an enlightening review of the Sunshine Provision of the Patient Protection and Affordable Care Act (PPACA), which is one of the most highly anticipated changes in the clinical trial environment in recent years, requiring drug and device manufacturers to disclose all payments to physicians. The article points out that while some pharmaceutical, biotechnology and medical device companies are spending tremendous resources to comply with this legislation, many are unaware of the scope and detail of the impending legislation.

Market Reports

Clinical Trials Market in Ukraine (Part 2)

The history of clinical trials in Ukraine officially dates back to 1996, when the first regulatory permission to carry out multicentre international clinical trials was granted. This indepth article by Mariya Dimova, Oleksii Gaydamak, Maxim Belotserkovsky and Tomasz Anyszek follows on from Part 1 (JCS September issue), and focuses on the important topics of who is already active in Ukraine, and evaluation of the potential of the Ukrainian clinical trials market - mutual benefits.

The Impact of Regional Healthcare Variation on Globalised Clinical Research -- Globalisation of Clinical Research: Benefits and Risks

Petr Denisov, Paola Antonini and Michael Murphy, of Worldwide Clinical Trials, conclude that while the inclusion of emerging countries in global clinical research offers significant advantages, the case study they present appears to confirm how each trial must be considered in all particular features before endorsing the involvement of emerging regions and countries. This includes the trial's targeted disease and its standard treatment, accessible patient population, and technology requirement for a proper execution. The case study looks at the feasibility of a cardiovascular trial in the Russian Federation.

Central and Eastern Europe: The Most Consistent Emerging Region for Clinical Development

Shaylyn Pike of Cutting Edge looks into opportunities in Central and Eastern Europe. For many companies looking to expand their marketing operations into emerging markets, the first step is often clinical development. Running a clinical trial in an emerging market allows a company to begin networking with regulatory officials and key opinion leaders. It also introduces the company to the cultural differences associated with these new markets without the must-sell-now pressure that jumping right into marketing would generate.

Leveraging Ethnobridging to Accelerate Global Drug Development

Stanford Jhee of PAREXEL International explores the intense financial and competitive pressures on the biopharmaceutical industry, which make global drug development more important than ever. The imperative to quickly introduce products into as many countries as possible has increased dramatically in recent years as biopharmaceutical companies endeavour to maximise the commercial success of new therapies. In this demanding environment, Asian markets such as Japan, China and South Korea offer particularly attractive growth opportunities.

Resource for Multisite Studies and Emerging Markets --Poland

Following European Union accession on 1 May 2004, Poland has implemented EU directives 2001/20 and 2005/28 and established a friendly environment for clinical trials. Tomasz Kowalczyk of Premier Research provides us a focus on Poland, and explores issues such as healthcare system characteristics, regulatory background, regulatory submissions, facts and

myths about Poland, patient population, costs, quality, and IMP/laboratory logistic procedures.

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New Insight into the Impact and Treatment of Migraine

Dr James Sawyer, CEO, Prism Ideas, explores the recent developments in migraine. Migraine is one of the most commonly reported medical conditions in the world, and is associated with substantial personal and socio-economic impacts. The World Health Organization has ranked migraine as the 19th leading cause of disability worldwide, accounting for 1.4 per cent of all years of healthy life lost to disability.

Why ABPM Should Be Mandatory in All Trials of Blood Pressure-Lowering Drugs

Traditionally, blood pressure (BP) has been assessed with the auscultatory technique introduced into clinical medicine at the end of the 19th century. Despite being inaccurate and misleading, this technique has survived largely unchanged for over 100 years. This article is by Eoin O'Brien, Professor of Molecular Pharmacology at the Conway Institute of Biomolecular and Biomedical Research, University College Dublin, and covers issues such as advantages of ABPM, detection of white coat responders, absence of placebo response, reduction in patient numbers, and technological development of ABPM.

IT & Logistics

Preserving Sample Integrity in Clinical Trials via use of Insulated Shippers

~JCS Speaks with ICON Central Laboratories~

In this article, Andrew Roche and Caroline Brooks of ICON Plc detail the results of the most recent innovation at ICON Laboratories focused on continual enhancement of data quality. The innovation comprises an insulated ambient sample shipper which has been carefully selected to prolong maintenance of room-temperature conditions within the shipper and thus decrease the exposure of the contents of the shipper to the extreme seasonal conditions typically experienced in certain parts of the world.

The Adoption of a Centralised Method for Significantly Improved Data Quality and Substantial Time and Cost Savings

Amey Furlong of ERT states that, increasingly, the issue of cardiac safety is becoming a major concern for clinical trials sponsors. Cardiac safety is one of the most prominent causes of late phase delays, labelling changes, and product recalls of drugs entering the market. Problems such as these can lead to a variety of negative repercussions for a company, such as severe cost implications, loss of trust from consumers, and demise of company reputation as a result of product recalls. These factors can significantly impact a company's revenue in the long run. The article concludes that the introduction of the centralised model has provided the industry with significant improvements to the traditional decentralised paper-based ECG methodologies.

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CENTRICAL

Global Clinical Trial Feasibility

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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