

In Conjunction with IBM Life Sciences Winchester Presents the 15th Annual Executive Workshop



Streamline Clinical Trials Using a CTMS



Winchester Business Systems continues its nationwide seminar series on the benefits of electronic clinical trial management at the IBM Innovation Center in Waltham, MA on Wednesday, May 13, 2009. Discussed at the seminar will be areas of potential savings through a centralized, shared approach to trial management. This complimentary, full-day event, is invaluable to any life science professional involved with trial management.

Conference Chairman: Michael O. Regentz, CSI, Managing Director of Winchester Business Systems, Inc. Elite Faculty Includes: Rodney Sassaman, Technical Consultant, IBM Innovation center Scott A. Wallace, Sales Executive, IBM Healthcare and Life Sciences Michael O. Regentz, CSI, Managing Director, Winchester Business Systems Robert S. Saldana, PharmD, MSc, Principal Consultant of Stage One Biotech Tomasz H. Zastawny PhD, DSc, MSc, Managing Director, ECRC

Learn how a centralized, collaborative system can increase accuracy, reduce time and improve the overall clinical development process. In this seminar, you'll get the latest perspectives on the following topics:

- How to effectively manage and retain good investigators by providing easy-to-use tools to manage trials and by accurate and timely payment.
- How to realize "Early Warning" signals of potential bottlenecks and barriers to trial progress.
- Creating an integrated and collaborative work environment for clinical trial management designed to help streamline and automate the operations of clinical trials and enable better and faster reporting.
- A review of changes to SOPs that can improve clinical operations when moving to an electronic environment.
- Areas of potential savings available through a centralized, collaborative approach to trial management.

SESSION OUTLINE

8:00 Registration

8:30 Introduction to the Innovation Center and IBM Life Sciences

Using IBM's worldwide innovation centers help business partners and customers grow your business locally and globally:

- Training and one-to-one technical assistance to build and test your solutions
- Linkage to IBM's sales support for sales opportunity assistance
- Collaboration opportunities with IBM, other Business Partners, IT professionals and academia

Rodney Sassaman

8:40 Exciting Technology Happenings for Life Sciences Companies

IBM's Life Sciences spans the world with technology solutions toward a "Smarter Planet." No longer is it just good enough to throw computers at a problem. Thoughtful and successful companies are applying the latest in "smart technologies" to solve information system problems.

Scott Wallace

9:00 Introduction & Seminar Agenda – the Scope of CTMSes in 2009

Overview, Industry Background & Call to Action, and Seminar learning objectives

Michael Regentz

9:30 The "Main Drivers of Efficiency" have a dramatic effect on quality.

Keys to clinical development success, Main drivers of efficiency in clinical development, and Key outcome markers of quality

Dr. Robert Saldana

10:45 Clinical development data systems – The Business Case

The "business case" illustrates not only how to accomplish your data systems goals, it can reap significant rewards in efficiency, improvements in quality, and pay for themselves in short order.

Dr. Robert Saldana

12:00 Lunch

12:30 Clinical development data systems – Challenges to implementation

> Over the last decade there has been increasing interest in using information technologies as basic management tools across all areas of pharmaceutical product development. How clinical research management processes are designed and planed have a dramatic impact on how the trial is run from start to finish, and ultimately: (i) how much the entire process cost and (ii) how long it took to collect all data and analyze it. A well-planed clinical study based on proper technology can enhance design efficiency and some components reuse -- improve workflow and effectively apply standards all through organization. Advance planning, utilization of latest technologies available on today's market let you chose how to run clinical studies and manage your clinical research department effectivly.

Dr. Tomasz Zastany

1:30 Successful implementation of new clinical development system – a case study

For nearly 20 years, Winchester's customers have been deploying systems to help manage clinical trials. This presentation will provide a compendiums of the best practices and clues to the successful deployment of a CTMS.

Michael Regentz

2:00 Winchester CTMS demonstration – case study approach

The Internet provides a vast array of options for deployment of a CTMS. A demonstration is the best way to "see for yourself" how one works.

Michael Regentz

2:30

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Lessons Learned and "Where do I go from here?"

Moderator:	Michael Regentz
Panelists:	Rodney Sassaman Scott Wallace Robert Saldana Tomasz Zastawny

IBM Life Science Workshop Series - Streamline Clinical Trials using a CTMS - May 13, 2009 -Waltham, MA

Venue:

IBM Innovation Center 404 Wyman Avenue Waltham, MA 02454

From the North: Take Route 128 South to exit 28, Trapelo Road. Turn left at the end of the ramp onto Trapelo Road. Cross over Route128. At the first set of lights, turn right onto Smith Street (Smith Street becomes Wyman Street). Travel approximately one quarter mile to the IBM North Entrance, 404 Wyman Street. Proceed into the garage.

From the South: Take Route 128 North to exit 27B, Winter/Wyman Street. Stay right at the exit ramp. Turn left at the lights onto Wyman Street. Travel 0.6 miles to the IBM North Entrance, 404 Wyman Street. Proceed into the garage.

Registration Card:

Yes, Please Register me for the *complimentary* Winchester and IBM Life Sciences' Annual Seminar on How to <u>Streamline Clinical Trials using a CTMS</u>

Name:	Position:		
Email Address:	Phone Number:	Fax Number:	
Company Name:			
Address:			
City:	State:	Zipcode:	

