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Clinical trial operations take to the field with Web-enabled Clinical Trials Management System from Winchester Business Systems

Companies conducting clinical trials can now work anywhere, anytime using Winchester's CTMS with browser-based Internet portals

WOBURN, MA -- June 19, 2009 -- Winchester Business Systems, Inc., has announced the general availability of Protocol Manager™ Version 8.0. The Winchester Clinical Trials Management System (CTMS) now provides instant access through an Internet Web browser to all authorized users from anywhere at any time. This latest version offers a new Clinical Study Portal designed especially for Clinical Research Associates (CRAs) who monitor clinical trials in the field, in addition to the Investigator Portal that has been available and used at investigative sites for nearly three years.

Though still supported, the “thick client” (full-featured computer connected to a network server) that was needed to run earlier versions of the Winchester CTMS is no longer required. This means that all users who are authenticated by the system, including sponsors, Contract Research Organizations (CROs), Laboratory personnel, Institutional Review Boards (IRBs), Ethics Committees (ECs) and independent contractors, can operate the role-based CTMS from any device capable of accessing the Internet through a browser.

For more than 15 years, Winchester has delivered its CTMS with increasing functionality to streamline the processes involved in clinical trials. Far more efficient than mostly manual, paper-based systems, it replaces cumbersome spreadsheets and local databases with easy to learn and use interfaces into a strictly controlled, highly secure workflow environment that fosters real-time collaboration and enforces regulatory compliance.

The Medicines Company (MDCO) is a pharmaceutical firm headquartered in Parsippany, New Jersey, and one of Winchester's newest customers. MDCO completed its implementation of the Winchester CTMS in 2008, in time for a large clinical trial involving nearly 15,500 patients and 650 investigative sites in 24 countries. According to John Heyburn, director of clinical operations at MDCO, the company has already experienced unquestionable time and productivity improvement over its previous methods.

“With our new system,” said Heyburn, “we’ve reduced investigative site start-up time by 32 percent -- a significant efficiency improvement that means substantial savings in overhead costs and allows sites to begin patient enrollment sooner.” Attesting to its ease of use, Heyburn said that MDCO users typically become productive on the Winchester CTMS after just one, four-hour training session.

The latest improvements are Winchester's answer to a demand for Web-enablement by its installed customer base, some of whom have been using a Winchester CTMS to manage clinical trials since 1993. Recognizing that those who actually conduct clinical trials are best suited to know what they

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want and need, Winchester made it a point to involve its clients directly in the development and testing of the new version. According to Michael Regentz, Managing Director of Winchester, the designs for the Internet portals resulted from extensive study with existing Winchester CTMS users who were presented with specifications and prototypes for their review and feedback.

After experimenting with several development approaches, Winchester CTMS developers decided to retain the IBM® Lotus® Domino® platform they were already using, citing its broad offerings for workflow and application security. "Since it is an all inclusive Internet server platform," Regentz explained, "a system based on IBM Lotus Domino eliminates the need to obtain separate components to serve as database manager, collaboration manager, e-mail router, security system or Web server."

Winchester customers can purchase or upgrade to Protocol Manager Version 8.0 by "Enterprise Adoption" -- a traditional, up-front expenditure licensing model -- or may choose the optional Application Service Provider (ASP) hosting pricing model. The ASP license is based on the IBM model for Software as a Service (SaaS) and allows new customers to pay for the CTMS on a "by-the-trial" basis. Smaller CROs, in particular, can benefit from the flexibility of the ASP license, whereby optional features requested by trial sponsors can be added easily and at little cost, and the overall lower cost of by-the-trial use can be passed painlessly on to the sponsor.

Both the hosted and enterprise license versions have been released with significant improvements in the interfaces to popular Electronic Data Capture (EDC), Clinical Data Management Systems (CDMS), and Interactive Voice Response Systems (IVRS). "The improved interfaces to other eClinical systems virtually eliminate the need for entry of the same data into more than one system," Regentz said. "We believe that these interfaces, combined with anywhere, anytime access from the Internet portals, make the Winchester CTMS an unparalleled real-time window to the conduct and performance of the clinical trial."

About Winchester Business Systems, Inc.

Winchester Business Systems, Inc., is a leading provider of workflow software business solutions to life sciences industry clients who require systems that ensure compliance with FDA Good Practices (GxP) regulations. An IBM Advanced Business Partner, Winchester combines its experience and knowledge of the industry and clinical practices with the application of IBM Lotus and Microsoft® products. Based on an Internet Portal framework, Winchester's software applications streamline processes and extend the information boundaries for all partners involved in managing clinical trials.

Winchester software has helped more than 500 companies successfully conduct clinical trials, track product safety and complaints and manage regulatory documents in support of their product development efforts. For more information, visit the Winchester Web site at <http://www.wbsnet.com>.

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