



Averion Select's Winchester's Protocol Manager, paraFILE, and adWATCH Systems to Manage Clinical Trials



Overview:

- ❑ **IBM Business Partner:**
Winchester Business Systems, Inc.
- ❑ **Customer:**
Averion Inc., a provider of clinical trials support for biotech, pharmaceutical and medical device companies in the design.
- ❑ **Product:**
Winchester's Clinical Trials Management System (CTMS) Protocol Manager™, Document Management System paraFILE, and Adverse Event Reporting System adWATCH.

Business Challenge

To improve Averion's team communication, better integrate operations and manage client's trial data more efficiently.

Solution:

Cambridge, Massachusetts, May 17, 2004— Winchester Business Systems (WBS), an IBM Premier Partner specializing in clinical systems for pharmaceuticals, announced today that Averion Inc. (Averion) has selected Winchester's software to meet the diverse and critical needs of its pharmaceutical, biotechnology, and medical device clients.

Averion, a leading Contract Research Organization with more than 20 years of experience managing clinical trials, will use Protocol Manager, Winchester's clinical trials management system, paraFILE document management system, and adWATCH adverse event reporting system to increase the efficiency of its project management services. These technologies make critical data about protocols, patients, enrollment, investigators, treatment results and trial progress available to all members of the project team inclusive of project managers, monitors, data managers, operations, and finance.

"Protocol Manager and adWATCH will allow us to improve team communications, integrate our operations and manage trial data more efficiently for our clients." said Bonnie Neuhardt, Averion's Chief Information Officer. "This investment reinforces Averion's commitment to providing our clients with decision making and oversight tools for hastening product development times".

We are committed to our clients and employees to offer the latest technology innovations to improve the product development process for our

clients.” commented, Dr. Philip Lavin, Averion President and CEO.

Protocol Manager and adWatch are proprietary software systems developed and supported by Winchester. Protocol Manager increases the efficiency of communications between parties involved in clinical trials by allowing access to global clinical trial data electronically. Protocol Manager eliminates the need to transcribe, mail and fax traditional paper forms about regulatory documents, budgets, and schedules about investigators patients, clinical-trial staff, and all related components of a clinical trial.

adWatch insures patient safety by automatically collecting adverse events from patient data in Protocol Manager and alerting professional monitors when adverse events occur. adWatch then populates the MedWatch forms with the information required by government regulatory agencies and electronically transmits the forms to the FDA.

paraFILE is an electronic document management system that can be tailored to fit the enterprise and each department’s different requirements. paraFILE helps users capture, author, edit, distribute, retrieve, and manage electronic documents globally -- documents from

any computer source or application.

“We are pleased to be a part of the product development process,” said Michael Regentz, Winchester’s Managing Director. “Winchester has the business knowledge and is committed to insure success of this effort to streamline clinical trials management.”

About Averion:

Founded in 1983, Services include Program Planning, Study Design, Clinical Monitoring, Medical Monitoring, Data Management, Database Development, Biometrics, Medical Writing, Data Monitoring Committees, Compliance and Validation, and FDA Representation. Averion’s service uniqueness is based on the integrity of the processes supporting them and the personal commitment of the individuals on staff. Averion’s corporate headquarters are located in Framingham, Massachusetts. Along with its alliance partners, Averion supports clinical trials throughout North America and Europe. Visit Averion’s web site at www.averioninc.com.

About Winchester Business Systems

Founded in 1989, Winchester Business Systems, Inc. is a leader in

providing software business solutions to the pharmaceutical, biopharmaceutical, and medical device industries. As a Premier Business Partner for IBM, Winchester combines its knowledge of the industry, clinical practices with the application of IBM’s collaborative technology to these areas. Winchester clients include pharmaceutical and biotechnology companies as well as other CROs like Averion. You can visit Winchester Business Systems’ website at www.wbsnet.com for more details.

winchester business systems



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This case study illustrates how one customer uses Winchester products and services. Many factors have contributed to the results and benefits described. Winchester does not guarantee comparable results. All information contained herein was provided by MDS Pharma Services or Winchester.

