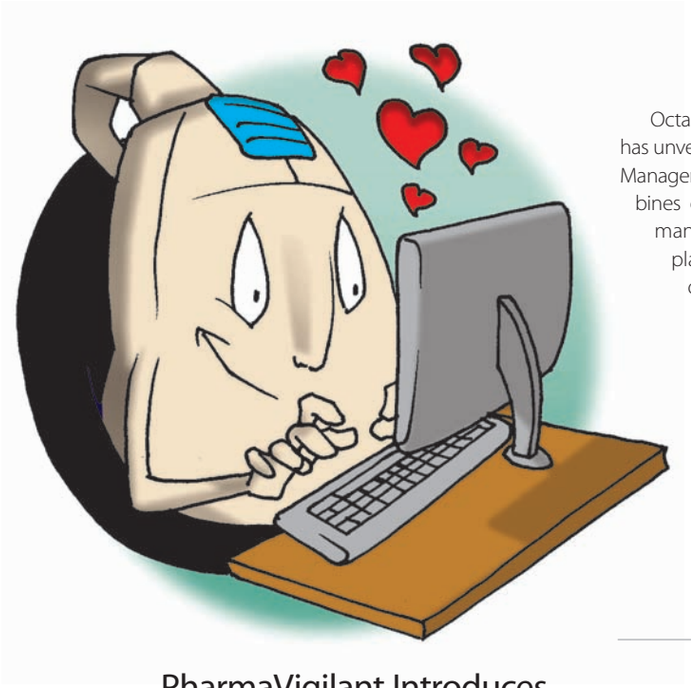

PharmaVigilant Introduces TRIAL MASTER FILE SYSTEM

I-Vault is designed to identify document types at the site and direct them to the proper trial master file folders.

PharmaVigilant's recently launched I-Vault electronic trial master file system provides clinical researchers with a solution that incorporates both electronic data capture (EDC) files and trial master files, which are often recorded on paper.

I-Vault is designed to identify document types at the site and direct them to the proper trial master file folders. This increases the value of on-site monitoring visits, while reducing the time and associated costs. Site documents are available to all users; but subject documents are selected and de-identified before being made available to sponsor users within the system. This creates an electronic fence for subject information that prohibits it from being uploaded to the sponsor. The system has been initially scaled to store up to 1 million documents, enabling companies of all sizes to use the system. I-Vault also incorporates source documents into the system, enabling remote monitoring for the first time within one system.

"Although many companies have mandated EDC for all trials, the other half of the submission, trial master files, is paper-based," says James DeSanti, CEO of PharmaVigilant. "There can't be an end-to-end solution unless both sides of the submission equation are electronic."

In other product news, PharmaVigilant has launched the latest version of its I-Warehouse clinical data storage solution. I-Warehouse 1.5 incorporates import utilities that enable data sets from different formats, including Excel, SAS, and CDISC, to be easily validated and uploaded into the company's data warehouse. It also allows data from multiple sources to be combined and viewed within the same report.

Octagon Research Releases DOCUMENT MANAGEMENT SOLUTION

Octagon Research Solutions Inc. has unveiled ViewPoint for Document Management, a solution that combines existing Octagon document management, authoring templates, and document standards in a preconfigured environment designed to support enterprise authoring processes in the life-sciences industry.

ViewPoint for Document Management incorporates document standards from Octagon's eCTD JumpStart offering and StartingPoint submission authoring templates. By mobilizing these processes through the existing ViewPoint environment and using capabilities such as check-in/check-out and version control, ViewPoint for Document Management offers the structure and standards required to support the entire document life cycle, from authoring through submission.

ViewPoint for Document Management is a perfect fit for small organizations that need authoring capabilities, says Jim Walker, Chairman and CEO of Octagon Research Solutions.

ViewPoint for Document Management can be deployed through ViewPoint's traditional install/implementation model, as well as a new hosted model that eliminates installation, hardware, and validation costs, and provides a connection to Octagon resources.

Partnership Provides Access to INTEGRATED MEDICAL DATA

Wolters Kluwer Health and Isabel Healthcare partner to provide evidence-based medicine access.

Wolters Kluwer Health and Isabel Healthcare have integrated Wolters Kluwer's online clinical decision support tool, Clin-eguide, with the Isabel diagnosis reminder system, offering clients comprehensive access to evidence-based medicine for both diagnosis and treatment.

Clin-eguide provides integrated content from Ovid, Facts & Comparisons, and Lippincott, Williams and Wilkins to enable clinicians to check facts, review evidence, determine treatment, and check drug interactions. Isabel is a validated, Web-based diagnosis decision support and knowledge mobilizing system designed to help reduce and manage diagnosis error at the point of care.

"Improving the consistency and quality of patient care while saving time for busy clinicians and pharmacists is a fundamental benefit of Wolters Kluwer Health's point-of-care products," says Arvind Subramanian, president and CEO of Wolters Kluwer Health Clinical Solutions.

FCG Releases ENTERPRISE CONTENT MANAGEMENT TOOL

First Consulting Group (FCG) has introduced FirstPoint, a cost-effective, Microsoft Office-based enterprise content management (ECM) solution. FCG also offers FirstPoint preconfigured with industry best practices to meet the needs of an entire life-sciences organization, from R&D to marketing and sales.

In addition to managing regulated content, FirstPoint's rules-based workflow engine can facilitate collaborative processes across the many functions often overlooked in ECM deployments, such as legal, finance, and human resources, as well as secure external collaboration.

According to Jeff Klein, VP of global solution sales and product development for FCG's life-sciences practice, the benefits offered by FirstPoint across the enterprise and its associated network of partners include:

- Microsoft Office-based user experience for ease of use, greater collaborative participation, and increased productivity.
- A system compliant with FDA 21 CFR Part 11, including audit trail and electronic signatures.
- Established industry best-practice content type and taxonomy model, and automated, rules-driven life-cycle and document processing.
- Easily configurable workflows for document collaboration and content organization and assembly for regulatory processes.
- Federated metadata-driven approach to harmonize content management usage across multiple repositories.

The market is demanding a way to simplify content management especially in terms of usability, platform consolidation, and collaboration, says Jeff Klein, VP of Global Solution Sales and Product Development for FCG's Life-Sciences Practice.

Tata Consultancy Launches **PHARMACOVIGILANCE SOLUTION**

Safety in a Capsule combines TCS's knowledge process outsourcing (KPO) services with the Siebel Contact Center Integration Pack for Oracle's Adverse Event Reporting System.

Safety in a Capsule, the latest drug-safety and pharmacovigilance solution from Tata Consultancy Services (TCS), incorporates software from Oracle and technology from DrugLogic to better enable pharmaceutical manufacturers to identify and monitor adverse drug events and ensure compliance with increasingly stringent regulatory requirements.

Safety in a Capsule combines TCS's knowledge process outsourcing (KPO) services with the Siebel Contact Center Integration Pack for Oracle's Adverse Event Reporting System, as well as DrugLogic's Qscan, a workflow-based analytical tool for identifying, analyzing, and resolving drug-safety risks. The integrated solution streamlines and monitors safety and surveillance processes followed by pharmaceutical and biotechnology companies during a drug's life cycle to minimize risks and costs. It also leverages safety analytics for early insight into a drug's safety profile and rapidly analyzes patterns in adverse events that could indicate emerging drug-safety risks both pre- and postmarket.

"The solution will help improve drug safety, minimize risks, and reduce costs while adhering to good pharmacovigilance practices," says J. Rajagopal, executive VP and global head, consulting, for TCS's life-sciences and medical-device practice.

E-UPGRADES AND ENHANCEMENTS

- Pharmaceutical and medical professionals can now use their BlackBerry smartphones to access the **Epocrates Rx drug and formulary reference guide** produced by **Epocrates**, San Mateo, Calif. This version of Epocrates' software gives pharmaceutical representatives, physicians, and other healthcare professionals remote access to drug information and real-time clinical updates through their BlackBerry devices.

  For more information, visit epocrates.com.
- **Invivodata Inc.**, Pittsburgh, has introduced a new version of its electronic patient-reported outcomes (ePRO) management system. The **EPX ePRO Management System, Version 5.0**, enables sponsors, monitors, and site personnel to more effectively manage ePRO activities related to their clinical studies. The Web-based system allows the uploading of ePRO data collected from the company's DiaryPRO and SitePRO solutions, giving users real-time access to PRO data collected throughout the clinical-trials process. Through this new version, trial sponsors and monitors can capture more accurate and reliable data and gain quick insights into trial progress, allowing them to easily determine whether patients are complying with trial protocols.

  For more information, visit invivodata.com.
- **Phase Forward Inc.**, Waltham, Mass., has introduced a new version of its Web submission data manager product. The **WebSDM 2.6** software reads data from Phase Forward's InForm integrated trial management electronic data capture (EDC) product, allowing data managers to better understand the overall data quality of records under review and detect anomalies and trends to support safety analysis. Other capabilities include validation for use on 64-bit platforms and Oracle's Database 10g, and Web Services API to enable automated data loading and improved integration with external data repositories such as Janus.

  For more information, visit phaseforward.com.
- **Trialstat Corp.**, Ottawa, has added new features to its **ClinicalAnalytics 4.0** on-demand electronic data capture (EDC) platform that further enhance performance, reporting capabilities, and ease of use. The system now offers contract research organizations and biopharmaceutical companies sophisticated graphics-based reporting tools, automated post data entry validation, and optimized study management functionality through its secure browser interface. By combining enterprise sophistication with drag-and-drop simplicity, customers can accelerate the deployment, management, and analysis of their clinical research data.

  For more information, visit trialstat.com.

Follow up

DRUGLOGIC INC., Reston, Va., develops analytical tools for managing risks related to drug-safety issues. For more information, visit druglogic.com.

FIRST CONSULTING GROUP INC., Long Beach, Calif., provides outsourcing, consulting, and systems integration for healthcare, pharmaceutical, and other life-sciences organizations throughout North America, Europe, and Asia. For more information, visit fcg.com.

ISABEL HEALTHCARE INC., Reston, Va., offers a Web-based, diagnosis decision support system. For more information, visit isabelhealthcare.com.

OCTAGON RESEARCH SOLUTIONS INC., Wayne, Pa., offers a suite of regulatory, clinical, process, and IT solutions to the life-sciences industry for the electronic transformation of clinical R&D. For more information, visit octagonresearch.com.

ORACLE CORP., Redwood Shores, Calif., is an enterprise software company that manages, shares, and protects information. For more information, visit oracle.com.

PHARMAVIGILANT, Westborough, Mass., offers solutions to address the complexities of global clinical research. For more information, visit pharmavigilant.com.

TATA CONSULTING SERVICES, Mumbai, India, provides pharmaceutical companies with IT and outsourcing services and business solutions that include clinical data management, statistical analysis, scientific communication, and drug safety and pharmacovigilance. For more information, visit tcs.com.

WOLTERS KLUWER HEALTH, Conshohocken, Pa., a division of Wolters Kluwer, provides information for professionals and students in medicine, nursing, allied health, pharmacy, and the pharmaceutical industry. For more information, visit wkhealth.com.