Contact information:
Meghan Morrissey
PharmaVigilant
(508) 475-4222
mmorrissey@pharmavigilant.com

PHARMAVIGILANT SETS NEW TECHNOLOGY BAR FOR INDUSTRY WITH INTRODUCTION OF NEW I-VAULT eTMF SOLUTION

I-Vault eTMF, Version 2.6 Speeds Access to Clinical Data with New User Interface, Enhanced Alerts and Notification System, Optical Character Recognition, Barcode Recognition Technology, Digital Signatures, New Reporting Engine.

Westborough, MA. October 1, 2011 – PharmaVigilant, a clinical trial technology provider, today introduced the latest version of its leading electronic Trial Master File system, I-Vault 2.6. The new enhancements addresses sponsors needs in customized workflow, bulk imports and improved reporting.

I-Vault 2.6 now offers barcode recognition technology that will read barcode(s) from scanned files. By adding barcodes to our system generated Source Worksheets for example, users have the ability to do bulk or batch scans into I-Vault, which reads the file's barcode and determines where the document should be placed within the system. This feature enhances our remote Source Document Verification service, streamlining the scanning process so documents are available in their correct placeholders sooner for EDC comparison.

With new OCR capability, I-Vault can now capture the contents of a scanned document and store it within the system. This allows users to convert their paper documents into searchable PDFs for text search purposes. This functionality also enables you to quickly locate content within the system based on a keyword search.

The enhancement to system notifications creates a more user based system with alerts and views of data catered to the authenticated user. When a notification is now created, it can be specified whether it should be sent to the user responsible for reviewing the document via email. This in turn eases the ability to monitor the TMF content across the life of the study.

I-Vault 2.6 also configures document dependencies to streamline the workflow. The Sponsor can now set the system to require a certain document or folder upon the upload or modified status of another document. Additionally, it can be specified whether certain document types require translations.

The digital signature feature of the system has been updated to allow I-Vault users to reach wholly

electronic workflows through the authorization stage: Signatures are now embedded into the PDF so that information will never become disconnected from the document itself. This ensures that end users can easily verify and retain proof of identity and document integrity without costly, complicated, or proprietary software. The ability to add multiple signatures to a document is also supported.

“Since its inception, I-Vault eTMF was designed to collect, manage, and organize all documents relating to a sponsors clinical trial or program,” said James DeSanti, Founder and Chief Executive Officer, PharmaVigilant. “By raising the technology bar on I-Vault’s existing powerful document management capabilities to include OCR and barcode reading functionality, coupled with dynamic alert and notification features to streamline workflow, and improved digital signature capabilities, PharmaVigilant continues to provide the technology and services necessary for sponsors to transition their trial master files from paper based platforms to submission ready electronic platforms.“

About PharmaVigilant:

Based in Westborough, Mass., PharmaVigilant is an eClinical company providing fully integrated solutions for clinical development. Our suite of site/sponsor centric software and services automates the collection, management and analysis of clinical trial data and most importantly provides data transparency on demand, with total sponsor control. Sponsors rely on us to ease the regulatory and FDA submission and approval process and ultimately go-to market more quickly with top quality drugs. For more information, visit www.pharmavigilant.com.