



Contact information:

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

**PHARMAVIGILANT RELEASES I-BATCH
I-VAULT eTMF's GROUND-BREAKING BATCH UPLOADER**

With One Click, I-Batch Automatically Uploads, Sorts and Places TMF Document Archives into the Correct File

WESTBOROUGH, Mass., December 13, 2012 – PharmaVigilant, an e-clinical provider, is pleased to announce the release of I-Batch, the fastest, most streamlined data loading approach that enables users to import large collections of their unorganized clinical research files into I-Vault 2.7, and have them automatically uploaded into their correct file, every time, without human intervention. I-Batch bypasses the manual filing process to improve accuracy and save Sponsors significant amounts of time, cost and accountability.

Uploading documents into traditional eTMF systems requires the user to organize all of their paper documents, and then manually search through the electronic system to find where the file exists for each document. Secondly, computer time needs to be scheduled in order to upload each document into its correct file, one at a time. While the actual document uploading process may only take around three seconds, it is the navigating and locating aspect that proves to waste the most time. With clinical studies producing a sizeable amount of data, and a trial master file requiring a vast amount of essential and trial-related documents, this manual process is time-consuming for the end-user and comes with a high risk of user-error.

I-Batch takes the manual document sorting and uploading process to the next level - by eliminating it. Now when the user clicks on the "upload" button, the number of files entering the system is transformed from one to infinity. With minimal effort, a user can select the collection of unorganized documents they wish to upload, and I-Batch will automatically insert each file into its correct file in the eTMF system, regardless of file type. In the past, systems have disabled the ability to navigate elsewhere in the system until a document has been successfully uploaded. But with I-Batch, you can select every archive of required documents, and it will create a queue and take care of sequentially processing and uploading each one, avoiding document collision. As a result, the user does not need to be chained to the computer, but instead can go about their daily clinical activities, and automatically receive an email notification upon process completion.

In PharmaVigilant tests, I-Batch was able to upload and correctly sort an entire zip folder of 20 essential trial documents in less than two minutes without human intervention. On top of quickly locating and placing documents into the system, I-Batch has even been configured to automatically version files if an update to a specific document has been made. Furthermore, it has been proven that the number of images being included in eTMF systems has been increasing exponentially over the years, so I-Batch has been configured to even support the upload and dispersion of image files. I-Batch has been proven to work seamlessly in tests ranging from 20mb to 168mb worth of zipped CT, MRI, PET Scans, and other large image file types, streamlining the storage, access and readability of these critical medical images.

“Data needs to be centralized, in order to conduct remote regulatory inspections,” said James DeSanti, president and CEO, PharmaVigilant. “The need for centralized databases on demand will become a requirement, not a vision or a place on a roadmap. I-Batch will be the initial linchpin in moving massive amounts of data into systems, minimizing human intervention, in order to meet this goal.”

About PharmaVigilant:

Based in Westborough, Mass., PharmaVigilant is a SaaS company providing broader technologies to streamline the clinical trial process for biopharmaceutical companies. Its full suite of patient-based technology automates the collection, management and analysis of clinical trial data and most importantly puts that data in the sponsors' hands when and how they want it. Sponsors rely on PharmaVigilant 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.