

### For Immediate Release

# Life Sciences Companies Speed Time to Market with New Cloud-based Electronic Trial Master File (eTMF) Solution

**PLEASANTON, CA** — **October 18, 2012** — Veeva Systems announces today that Vault eTMF, the first electronic trial master file (eTMF) solution developed from the ground up as a multitenant cloud-based service, is now generally available. With full support for the DIA TMF Reference Model, Vault eTMF gives sponsors, sites and CROs around the globe real-time and secure access to clinical documentation at every point in a trial's set-up, execution and archival. Vault eTMF is built on the Vault Platform, the most modern, scalable and secure cloud-based platform available for regulated content management. Vault eTMF enables life sciences companies of all sizes to streamline trial document collection, management and analysis, speeding time to market while improving compliance and submission quality.

According to a new study by Cutting Edge Information, each day a clinical trial extends over schedule, drug developers lose as much as \$600,000 in foregone sales for small/niche products or as much as \$8 million for blockbuster drugs. With the growing competitive pressure to simultaneously go global with a new drug, the greater number of outsourced partners and increasing complexity of today's advanced-disease-state drug trials, life sciences companies are struggling to efficiently conduct clinical trials. And in the area of trial master files, there has been little technological advancement for many years, leaving significant room for improvement.

"Life sciences companies have been making tremendous strides in the smart adoption of new technologies across their clinical trials," said Glen de Vries, co-founder and president of Medidata Solutions Worldwide, a leading global provider of cloud-based clinical development solutions. "However, sponsors' needs to more easily manage and access trial documents have been underserved by cloud-based solution providers — until now. We think that Veeva's innovative technology provides the much needed streamlined document support throughout the study lifecycle."

Peter Gassner, co-founder and CEO at Veeva Systems, added, "The clinical trial process is collaborative. It involves sponsors, sites, CROs and global regulatory authorities. There is a clear need for a cloud-based solution to facilitate this collaboration in a predictable, compliant and efficient way. With our cloud-based Vault eTMF application, we intend to set the new standard for sharing trial documents across the global life sciences industry."

In addition to the advantages of being built on a multitenant cloud-based platform with usability that rivals leading consumer websites such as Amazon and LinkedIn, Vault eTMF offers deep functionality to address the specific business requirements of clinical teams, including:

- **Study & Site Start-Up** the use of essential document templates, the ability to quickly provision accounts for external users in seconds, and robust real-time status reporting helps to streamline processes that are laborious and painful today.
- **DIA TMF Reference Model Support** fully supports the documents, properties, relationships and hierarchies of the TMF reference model for both core and recommended documents, speeding implementations and making it easy for users and administrators to better manage their clinical trial documents.
- Binder Organization enables easy organization of documents into simple lists or complex hierarchical structures. Binders can be predefined according to the DIA TMF Reference Model or configured on the fly by end users.



- Submission-Ready Rendering automatically creates submission-ready documents and captures the
  relevant content details for submissions processing, eliminating the need for inefficient document
  post processing.
- Auditor Review Support quickly provides read-only access to an auditor with permissions down to the document level. Also, the intuitive system navigation decreases auditor downtime.
- **Document QC Workflow** review document content and metadata simultaneously via an efficient quality control (QC) workflow with QC-specific status reporting.
- Application Integration leverages the open, published Vault API so customers can easily integrate
  programmatically with eClinical systems like CTMS, EDC, site portals, submission publication tools,
  scanning solutions and other complementary systems.

## **Advantages of Vault Enterprise Content Management Solution**

Vault eTMF is part of Vault Enterprise, the only complete suite of business process-specific, life sciences content management applications in the cloud. Spanning every major part of a life sciences company – from R&D to clinical trials to manufacturing, medical communications and marketing – Vault Enterprise gives pharmaceutical, biotechnology and medical products companies the ability to deploy a single technology solution globally. All Vault Enterprise applications are built on the cloud-based Vault Platform, which provides support for regulatory requirements such as 21 CFR Part 11, point-and-click reporting and system administration, consumer-style search tools, an open web services API and a modern multitenant architecture for seamless version upgrades and superior reliability.

## **About Veeva Systems**

Veeva Systems is the leader in cloud-based business solutions for the global life sciences industry. Committed to innovation, product excellence and customer success, Veeva has over 150 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Founded in 2007, Veeva is a privately held company headquartered in the San Francisco Bay Area, with offices in Philadelphia, Barcelona, Budapest, Paris, Beijing, Shanghai and Tokyo. For more information, visit <a href="https://www.veevasystems.com">www.veevasystems.com</a>.

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