



# ABCs of E-Records Management

## Executive Summary

Organizations across all industries face major challenges surrounding how they capture, manage and store electronic records. An electronic record or E-Record is defined as any combination of text, graphics, data, audio, pictorial or other information represented in digital form that is created, modified, managed maintained or transmitted by a computer system or application.

With ever increasing use of information technology, computing systems, the Internet and wireless devices, more and more day-to-day business processes are being automated. More often than not in today’s economy, business transactions are conducted through electronic interfaces and applications. One result of this movement toward electronic transactions and the “paperless workplace” is that a vast number of electronic records are now being generated automatically by software applications and computing systems across the organization. Regulatory bodies around the world are issuing strict mandates governing the way regulated companies manage their E-Records.

The main thrust of virtually all E-Records mandates is that E-Records should be trustworthy and readily accessible yet subject to secure access control with strong audit capabilities. A critical component of E-Records management is the need for a comprehensive audit trail to ensure the trustworthiness and validity of electronic records. This audit trail must be computer generated and capture any changes made to the record as well as who made the change and the time at which the change was made. The audit trail must also ensure that data cannot be overwritten to ensure that the information contained within the E-Record is tamper-proof. Any attempt to edit or overwrite the data must be recorded in the audit trail.

## A Delete Example

| Product ID        | Action   | Qty             |
|-------------------|--|-----------------|
| Viagro            | Make   | 1000            |
| Viagro            | Calibrate Test Eqmt                                | -               |
| Viagro            | Test Initiated                                     | 1000            |
| <del>Viagro</del> | <del>Test Result. Foreign Particulates Found</del> | <del>1000</del> |
| Viagro            | Bottle   | 1000            |
| Viagro            | Ship   | 1000            |

A Delete is performed on the Test Result row. This command can be done by the application software or manually by a person.



| Product ID | Action              | Qty  |
|------------|---------------------|------|
| Viagro     | Make                | 1000 |
| Viagro     | Calibrate Test Eqmt | -    |
| Viagro     | Test Initiated      | 1000 |
| Viagro     | Bottle              | 1000 |
| Viagro     | Ship                | 1000 |

The resultant database now is missing information about the test. Bottles of medicine get shipped with foreign particulates that may be harmful to patients.

**Figure 1:** An example of a delete to a pharmaceutical trial database.

*E-Records mandates require that all changes to electronic records be tracked to ensure no critical data is lost or obscured.*

The audit trail provides a complete record of all human interactions with the data. In the absence of a paper record, the audit trail may provide the only evidence that an electronic record has been modified or deleted.

Beyond the need to comply with regulations, companies are realizing that effective methods for managing E-Records and maintaining audit trails can significantly enhance the operational efficiency of an organization. Effective management of E-Records can also help companies improve customer service and financial accountability while providing a powerful tool to combat fraud or legal challenges.

## E-Records Issues

Most organizations have computing environments comprised on multiple applications, databases and computing environments that may be incompatible. The number of systems that collect electronic records across an enterprise can be staggering. At one site alone, a company inventoried 75 different systems that create electronic data and that would be subject to E-Records mandates. Most legislation governing the management of electronic records applies to all systems including those that were deployed or developed before E-Records mandates went into effect. This means that most companies face the challenge of somehow adding E-Records and audit trail capabilities to existing or legacy applications. The rapid and cost-effective implementation of E-Record audit capabilities requires the support and expertise of software vendors and system integrators. To date, few pure software solutions have emerged that address E-Records management and compliance by capturing and generating audit trails. DataMirror *LiveAudit*<sup>™</sup> is an innovate solution that provides out-of-the-box support for real-time E-Records audit trails without requiring programming or modifications to existing or legacy applications.

Aside from the ability to capture and generate audit trails, companies also face challenges in the transmission and storage of E-Records audit information. The continuous capture of audit trails may require substantial storage space to preserve all the audit data. One relatively small health care company found that in a single year it generated 200,000 data file creation entries in the audit file. Larger companies with more numerous and complex software systems can expect to capture very large volumes of data in the audit file.

These companies will require the ability to effectively manage and flow large volumes of data between primary applications and computing systems that drive the business (and generate the electronic records) and other systems where the audit information can be stored and analysed. There is a clear need to capture, transform and flow electronic records between different systems and physical locations for examination and analysis by internal auditors, compliance officers or legal counsel as well as for review by governing bodies. DataMirror *Transformation Server*<sup>™</sup> provides proven a real-time solution for flowing data across multi-platform environments.

The E-Records solution that your firm chooses should also include the ability to securely deliver electronic records to examiners via internal networks (intranets or extranets) or the Internet. DataMirror *iDeliver*<sup>™</sup> is an ideal web data delivery solution that enables companies to leverage the Internet and existing systems to transfer electronic records to anyone who needs them – regardless of the different computing platforms, databases or applications deployed. Together, LiveAudit, Transformation server

and iDeliver provide an end-to-end, single-vendor solution for helping companies in all vertical markets manage their electronic records.

### What is LiveAudit™?

LiveAudit extends the capabilities of DataMirror's Transformation Server data integration software to enable firms to capture specified transactions from their software systems for the creation of electronic records. By employing DataMirror's proven real-time capture, transform and flow (CTF) technology, all historical database information is preserved, satisfying requirements for overwrite protection. With LiveAudit, customers have the ability to run reporting tools against the audit file to generate reports required by employees, compliance officers or regulatory bodies. DataMirror iDeliver software empowers companies to securely filter and publish corporate data and E-Records via the Internet so they can easily and seamlessly deliver audit reports to anyone who requires them including compliance officers or legal counsel.

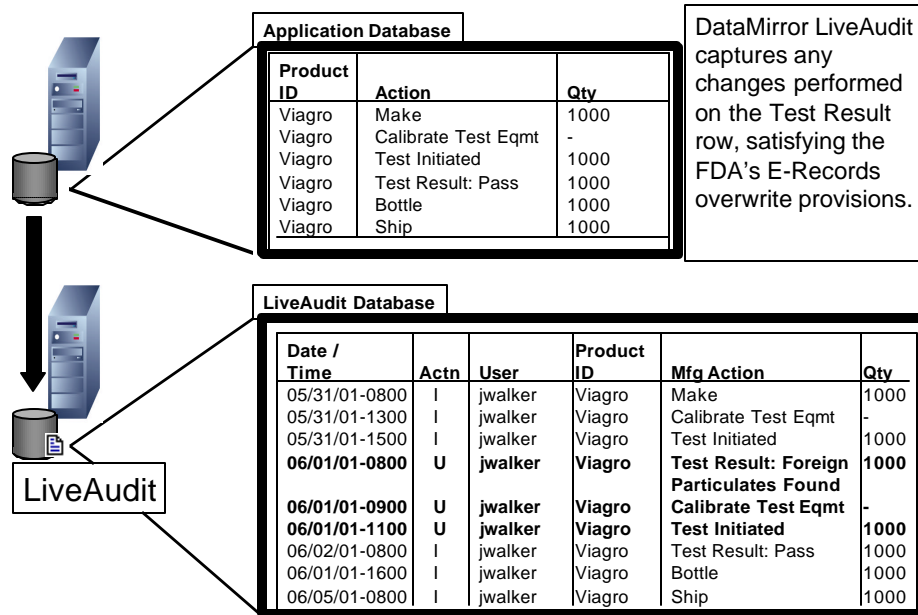
### About Transformation Server

DataMirror Transformation Server transforms the experience of doing business by delivering real-time data flows to the people who need it. Transformation Server technology keeps data flowing from one end of the enterprise to the other and helps people work faster and smarter now. It lets users capture, transform and flow their data in real-time between DB2 UDB, Microsoft SQL Server, Oracle and Sybase across UNIX, Linux, Microsoft Window NT/2000, OS/400 and OS/390. Because Transformation Server is easy to implement and requires no programming changes to applications and databases, customers can realize a rapid return on their software investment. Transformation Server's out-of-the-box support for leading databases make it ideal for a range of applications including EAI, e-Business, business intelligence, customer relationship management and a host of other distributed data applications. DataMirror iDeliver software extends the capabilities of Transformation Server by allowing companies to securely filter and publish corporate data via the Internet.

### Working with LiveAudit

Typically, changes applied to a publication table will be reflected to the corresponding subscription table. An image of the publication table is therefore maintained on the subscription server. However, in some environments, an image of the publication table is not desired. Instead, the subscription table should maintain an audit trail of changes applied to the publication table. In this scenario, the subscription table contains records that represent *delete*, *insert*, *update* and *clear* operations applied to the publication table.

LiveAudit maintains an audit trail of publication table changes by using the assigned subscription table to keep track of all *delete*, *insert*, *update* and *clear* operations applied to the publication table. LiveAudit is primarily intended for working environments that must satisfy internal or external auditing requirements. LiveAudit gives companies the ability to maintain an audit trail of all table changes to source or publication databases.



**Figure 2:** DataMirror LiveAudit captures and preserves all types of data collected by software systems. For health care related companies, LiveAudit ensures compliance with FDA mandates governing the management of E-Records (21-CFR Part 11).

Under a subscription, auditing can be enabled or disabled individually for each publication and subscription table assignment. This means that it is possible to maintain a replicated image of one publication table while maintaining an audit trail for another publication table. For each publication table that is being audited, you can individually select the standard database operations (delete, insert, update and clear) that will be audited in the assigned subscription table.

In order to associate the standard database operations of *delete*, *insert*, *update* and *clear* applied to the publication table with the corresponding audit record in the subscription table, you can map the &ENTTYP journal control field to a column added to the subscription table. This journal control field conveys a two-character journal code that represents the type of database operation applied to the publication table that led to the audit record being appended to the subscription table.

LiveAudit offers the same support for user exits that is provided for standard database operations. As a result, you can call user-written functions before and/or after an audit record has been appended to the subscription table. When auditing publication table changes, records are always inserted into the subscription table. However, it is important to note that user-written functions associated with record inserts are not always called. The user-written programs that are invoked are those associated with the type of operation applied to the publication table (delete, insert, update or clear).

## Key LiveAudit Features:

- Capture and maintain real-time audit trails
- Log database transactional information in real-time
- Updates and deletes recorded as separate database entries, preserving all historical information
- Built in selection, filtering, transformation and user / timestamp column additions
- Out-of-the-box, non-intrusive integration with existing systems and databases
- Web-enabled, Java-based GUI with drag-and-drop functionality
- Secure, on demand delivery of audit trails over the Internet or corporate networks via iDeliver
- No programming required

## Sample LiveAudit Business Applications

### e-Business

The Internet and other electronic telecommunications networks are increasingly becoming a center for commercial transactions including business-to-consumer (B2C) and business-to-business (B2B) transactions. Many of these transactions take place entirely over the network with no physical goods changing hands. Contracts, software, news articles, technical designs, music, video-recordings, subpoenas, land deeds, stocks, airline ticket confirmations and currency can be transferred across a telecommunications network without a single piece of paper ever changing hands. Such transactions require two critical features that are often in conflict: auditability and privacy.

Audit trails can be used to record customer activity in e-Business environments and enhance customer service. The customer's initial contact is recorded in an audit trail as well as each subsequent action such as payment and delivery of the product or service. The customer's audit trail is then used to respond properly to any inquiries or complaints. A company might also use an audit trail to provide a basis for account reconciliation or to provide a record of sales in case of a tax audit.

LiveAudit provides the necessary real-time audit trails for e-Business activities. As e-Business transactions occur, information is updated and deleted on a database level. Whenever a transaction item is updated or deleted, the information is typically overwritten to save storage space on the server. If an overwrite occurs, all known history of the transaction is lost. LiveAudit solves this problem by creating and maintaining the required history of transactional events in a secure audit journal with overwrite protection. LiveAudit capabilities help companies to respond effectively to customer questions or complaints by providing a record of any and all transactions that have occurred between the company and the customer.

## Corporate Security

Audit trails may be used to investigate crimes that occur on the Internet. Investigators can expose a hacker's country of origin and identity, for example, by following the trail the hacker left in cyberspace. Often hackers unknowingly provide audit trails through their Internet service providers' activity logs or through chat room logs. A corporate employee might have access to a section of a network in a corporation such as billing but be unauthorized to access all other sections. If that employee attempts to access an unauthorized section by typing in passwords, this improper activity may be recorded in the audit trail. LiveAudit provides historical audit trails which can be used to improve the security of a corporate system. An organization's databases can contain sensitive and confidential information which must be tracked and maintained to ensure its security. LiveAudit solves this problem by monitoring all updates and deletes made at the database level and then creating a journal of this information which can then be easily retrieved and reviewed by internal auditors, security staff or police investigators.

## Intellectual Property Protection

Consider an inventor racing to patent a marvelous new invention or a biotechnology firm seeking to patent a new designer gene. In recent years, we've seen numerous legal challenges regarding patent infringement and intellectual property rights. Audit trails can help investigators determine without a doubt that the invention's documentation was complete by the stated date, protecting the inventor or scientist's rights. LiveAudit can provide an audit trail including dates, times, users and other information which would be crucial to any investigation regarding intellectual property. Whenever an *add*, *delete* or *insert* is made on the database level all events are recorded as they occur in real-time. This information is secure and could be used in a legal setting to determine patent and intellectual property rights.

## Financial Services

To help combat the rise in Internet fraud, financial services companies including banks and brokerage houses doing business on-line could soon be required to keep detailed and costly records of all on-line transactions and make them available to the police investigators. The Organisation for Economic Cooperation and Development (OECD) has already tabled proposals to this effect which may soon be adopted. Financial services companies with an on-line presence would be required to maintain reliable subscriber registers and log files and would have to hand these records to the police on demand. The Council of Europe also recently backed a call from the EU and law enforcement agencies to retain and archive electronic records of phone calls, e-mails, faxes and Internet traffic.

LiveAudit works on the database level to ensure that all activity is tracked and recorded in a chronological event log. Under normal operating circumstances, information that is recorded in a database will overwrite itself when updated or deleted. LiveAudit has the capability to create a complete and accurate historical record which captures all the essential information required by investigators while ensuring that key information cannot be overwritten or lost. LiveAudit provides a basis for confirming that receipts from all sales have been deposited into your accounts and ensures accountability for all corrections and adjustments. The historical record of sales, receipts and delivery of products or services captured by LiveAudit can also be used for business reporting, planning and forecasting and to support budget preparations.

## Compliance with FDA E-Records Regulation 21 CFR Part 11

Pharmaceutical, health care, food services and medical equipment companies are now required by the Food and Drug Administration (FDA) to create audit trails of their electronic records to make these

records readily available for FDA review. It is expected that regulatory authorities worldwide will soon follow suit and require companies to track audit information and comply with E-Records mandates. IT departments are struggling to find a cost-effective solution that will work seamlessly with their existing systems. The compliance standards outlined by the FDA in 21 CFR Part 11 mandate that solutions must have the following:

- Operator-independent, computer-generated, user and date/time stamped audit trails of operator entries and actions that create, modify or delete electronic records
- Any changes made to E-Records shall not obscure or overwrite previously recorded information
- E-Records must be made readily available for FDA review and copying
- Established requirements to ensure that electronic records and electronic signatures are trustworthy, reliable and generally equivalent substitutes for paper records and traditional handwritten signatures.

LiveAudit for DataMirror Transformation, combined with iDeliver software for web data delivery, enables FDA-regulated companies to create real-time audit trails that preserve all historical information and publish them securely over the Internet or corporate intranets for internal reporting or examination by compliance officers and legal Counsel. LiveAudit provides an out-of-the-box solution that meets the FDA E-Records requirements. LiveAudit provides health care organizations with the ability to capture audit trail information generated by software applications without requiring programming modifications to these applications.

## Conclusion

The business advantages of electronic records over traditional hard copy documents are significant. They include compact and highly efficient storage, the ability to analyse and process the data, and to provide backups or duplicate copies of the data for increased availability and resiliency against data loss or corruption. New legislation governing E-Records management may be viewed more as an opportunity than a burden. An effective organization-wide E-Records solution like DataMirror LiveAudit allows companies to achieve new operation efficiencies, enhance service levels and more effectively manage their most valuable asset—their enterprise data.

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## About DataMirror Corporation

DataMirror (Nasdaq: DMCX; TSE: DMC) delivers solutions that let customers integrate their data across their enterprises. DataMirror's comprehensive family of products unlocks *The experience of now™* by providing advanced real-time capture, transform and flow (CTF) technology that gives customers the instant access, integration and availability they demand today across all computers in their business.

Over 1,500 companies use DataMirror to integrate their data. Real-time data drives all business. DataMirror is headquartered in Toronto, Canada, and has offices worldwide. DataMirror has been ranked in the Deloitte and Touche Fast 500 as one of the fastest growing technology companies in North America.



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