



Perspective: IntraLinks SDE — Leading the Way to the Paperless Paper Trail in Drug Safety

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Alan S. Louie, Ph.D.

IN THIS PERSPECTIVE

This IDC Health Insights Perspective highlights a new approach to clinical trial safety document management that should greatly improve the efficiency and effectiveness of communicating drug safety events between key stakeholders. As trials have grown in size and complexity, requirements to share critical drug safety information between sponsors, sites, PIs, and other key parties have also grown, making it increasingly likely that errors will occur, resulting in regulatory noncompliance and its associated penalties. In the same way that EDC and other eClinical solutions have automated and streamlined clinical data and information management, IntraLinks for Safety Document Exchange (SDE) promises to securely automate mandated safety document sharing, eliminate paper and manual processes, and improve overall regulatory compliance and auditability while directly saving significant amounts of both time and money.

Situation Overview

While everyone hopes that drug safety issues never occur during the conduct of a clinical trial, some drug-induced adverse events (AE) and severe adverse events (SAE) are unavoidable. With patient safety as a paramount concern, every drug safety event that occurs during a clinical trial is required to be reported to the trial sponsor within a fixed amount of time and, in the case of SAEs, shared with other trial participants, also within specific timelines. These rules are intended to ensure that drug-specific concerns are identified early and risks to participating patients minimized.

Historically, safety document exchange has been a highly manual, labor-intensive process that included significant copy, fax, and FedEx components. Manual record keeping on all sides tracked sending and receipt of faxes and packages. Lost faxes and packages were commonplace, necessitating wasted efforts to reprepare and resend safety packages. Maintaining full compliance with continually evolving regulatory requirements was an ongoing challenge, and audits often uncovered weaknesses and inconsistencies. As a highly

visible, high-profile regulated process, drug safety document exchange has been well established within organizations for many years. While effectively managed manually when clinical trials were small or largely localized at a few sites within one country, the growth in size and complexity of trials has expanded safety document management needs beyond the capabilities of traditional established project teams.

Industry transformation, triggered by blockbuster patent expirations, has spearheaded cost savings initiatives across the life science value chain. Improving operational efficiency (without sacrificing security) has become a foundational mantra within most, if not all, life science companies, and the clinical development space has not escaped scrutiny. IntraLinks SDE is a viable proven solution for automating and virtualizing safety document management while concurrently improving efficiencies and extracting significant near-term savings. Days saved during the reporting process by using IntraLinks SDE are helping safety teams better manage their increasing workloads as head counts are squeezed and global regulatory burdens grow (e.g., recent 2010 European Pharmacovigilance Legislation that requires nonserious AEs to start being reported individually and within 90 days by European Marketing Authorization Holders).

Safety Document Management and the Cloud

With IntraLinks for Safety Document Exchange fully accessible via a secure Web portal, it becomes possible to deliver the solution either as part of an existing portal implementation or via software as a service (SaaS) independent of sponsor or site location. Most, if not all, life science companies have recognized that IT is not a core competency in their organizations and secure solution delivery by a trusted partner is often the most efficient and effective way to access specific needs looking forward. Private, auditable IT clouds currently provide industry-acceptable repositories for safety documents and supporting processes. In addition, since IntraLinks routinely delivers this service to its customers, it is possible to quickly initiate new efforts and retire capabilities once the trial is complete. While high-quality Internet access is not fully available everywhere in the world today, it is coming soon, and current capabilities are likely to be adequate at most trial sites already.

Custom Workflows Automating Regulatory Compliance

The ability to access prebuilt or create custom automated workflows is an effective way to ensure that regulatory compliance requirements are fully translated into compliant processes and actions if and when a safety event occurs. For example, a drug-associated severe adverse event (e.g., a fatal heart attack impacting a patient in the trial) must be reported to the FDA within 15 calendar days. Trials in multiple countries may also be subject to additional regulatory reporting requirements in other countries whose requirements may be different

from those from the FDA. In either case, automated workflows provide the ability to automate and accelerate the sharing of information between key stakeholders and enable earlier decision making to help minimize patient risk. As a more practical application, custom workflows can automate routine safety document sharing activities, eliminating laborious sponsor efforts while concurrently improving safety document tracking and traceability.

Utilizing IntraLinks SDE can shave days off the reporting process. Gaining an extra day or two by using IntraLinks' electronic distribution methods helps absorb safety teams' increasing workload — whether from an ongoing squeeze on their departmental head count or the increased expected workload as a result of the 2010 European Pharmacovigilance Legislation that requires nonserious AEs to start being reported individually and within 90 days by European Marketing Authorization Holders.

Essential Guidance

The critical need to improve operational efficiency within the life science industry has driven companies to systematically move away from their legacy systems and solutions. This shift has covered all areas across the life science value chain, including the highly regulated clinical development space. At the same time, the size and cost of clinical development efforts are growing as clinical trials have become larger and more global in response to the need to better manage costs, shorten the time needed to conduct trials, and enroll larger numbers of patients in response to increasingly stringent drug safety concerns.

Along with the growth of clinical trials, processes to monitor and manage drug safety have also grown. A significant portion of drug safety management is document sharing. As a historically manual process, safety document processing and management is becoming increasingly unwieldy and prone to errors. The opportunity to automate and streamline this process would seem to be a no-brainer, with the added benefits of rapid start-up, global scalability, proven security, transparent track and trace, and near-term cost savings sealing the deal. IntraLinks for Safety Document Exchange appears ready to fill this need at a time when it is sorely needed.

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- *IDC MarketScope: Worldwide Life Science R&D IT Outsourcing 2011 Vendor Assessment* (IDC Health Insights #HI230026, August 2011)

- *Operationalizing Analytics: SAS Brings the Right Information to the Right Person at the Right Time* (IDC Health Insights #HI227642, March 2011)
- *Perspective: Empowering Transformation in the Life Sciences — Key IT Factors to Consider in the Adoption of New Innovations* (IDC Health Insights #HI226683, January 2011)
- *Best Practices: Key Insights and Drivers Impacting Cloud Solutions Adoption in the Life Sciences* (IDC Health Insights #HI225033, September 2010)
- *Clouds Ahead — A Sign of Positive Change to Come* (IDC Health Insights #HI222288, March 2010)

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