



Intralinks Studyspace™

For Safety Document Distribution

Expedite

- Compliance Reporting

Reduce Risk

- By reducing the amount of time to process safety documents

Decrease

- Overnight shipping costs
- Number of man-hours needed to create safety packages

Improve SUSAR Distribution

Intralinks Studyspace for Safety Document Distribution expedites the document distribution process.

- Enable investigators to securely submit a serious adverse event (SAE) report to a sponsor in real-time, allowing the sponsors to quickly receive the information so they can take immediate action
- Instantaneously disseminate SAEs and suspected unexpected serious adverse reactions (SUSARs) to investigative sites, institutional review boards (IRBs)/ethics committees (ECs), and contract research organizations
- Ensure secure communication
- Provide automatic notification of reports
- Ensure documents are reviewed in a timely fashion in accordance with regulatory guidelines

The Safety Document Distribution Process

Intralinks enables you to establish various automatic distribution rules based on content and handling requirements





Who we work with:

THE TOP 20

pharmaceutical companies

THE TOP 10

biotech companies

THE TOP 5

CROs

17

IRBs

60,000

investigative sites around the globe

OVER 200

biopharmaceutical companies

Benefits

- Reduces average study start-up (SSU) cycle time by 25% - 50%, depending on study size and IRBs (saving 15 days = \$450,000)
- Eliminates the need for overnight mail, reducing costs by \$36,000 per study
- Reduces man hours associated with manual site management processes by 80%
- Saves \$35,000 with every day shaved off of the clinical trial process
- Enables 21 CFR 11 Compliance

With Intralinks Studyspace for Safety Document Distribution, workflows support collaboration by automatically routing SAE reports for internal review. Audit reports are generated that maintain records of report distribution, recipient delivery status, document access, and timing to improve compliance. The solution is fully validated with 21 CFR Part 11 and also has connectors to leading safety systems, which facilitate the seamless routing of SAEs to the sponsor's review team for evaluation.

<http://www.wherepartneringworks.com/>

Intralinks

(NYSE: IL): Intralinks is a leading, global technology provider of inter-enterprise content management and collaboration solutions designed to enable the secure and compliant exchange, management, and control of documents and content between organizations. Thousands of companies and more than two million professionals use Intralinks for everything from ad hoc collaborations to complex, multi-business partnerships in financial services, life sciences, manufacturing, technology, and wide range of other industries worldwide.

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