Intralinks Studyspace™: Electronic Investigator-Controlled Site File (eISF)

Introduction

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Intralinks Studyspace eISF solution is an intuitive and easy-to-use yet highly secure online document management tool for investigator sites involved in the clinical trial process. eISF adds efficiencies and enhances user experience across the entire content lifecycle. This new offering also dramatically improves regulatory compliance at the investigator site while revolutionizing how sponsors can maintain oversight of participant sites by enabling study monitors and inspectors to securely view documents offsite.

Electronic Trial Master File Systems and eISF

In the last few years, Life Science companies have invested heavily in electronic Trial Master File (eTMF) systems and other workflow and document management tools to improve the collection, filing and submission of all relevant clinical study documentation.

eTMF technology and processes are, however, focused on the trial sponsor, and so are driven by study milestones and submission readiness. These systems cannot be extended to investigator sites files because regulations require that each site involved in a clinical trial must maintain its own independent study binders in order to provide confirmation of the sponsor's conduct, compliance, and the integrity of the trial. The needs of an investigational site are very different; their key requirements include ease-of-use, security, demonstrating control, and supporting multiple studies across different sponsors.

Investigator sites must maintain full control over their investigator site file (ISF).

There is a long-term retention period for the maintenance of these records after the trial is over. Even years after the investigators have retired and the site may no longer even exist, the binders must be kept available for inspection. The sponsor must ensure that agreements are in place without ever having uncontrolled access.

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Replacing Manual Paper-Based Procedures

Over 80% of site-based documentation is still fully paper based, with both cost and risk consequences for the entire clinical trial process. Specific liabilities of paper-based systems include audit and inspection risk, reduced site productivity, manual reconciliation of TMF and site records, and lack of visibility into site performance.

Secure Offsite Access and Management

For large, complex phase III studies, monitoring of study sites is typically the single largest study expense, often accounting for 30% of the entire study budget. The cost of sending one monitor to a site is typically around $5,000 per day, and fully half the duration of those visits is spent reviewing documents. To be efficient, sites cannot stay on paper.

Empowering your Investigators and CRAs

According to a 2013 CenterWatch Global Investigator Site Survey, knowledgeable and professional monitors/CRAs was the top factor impacting preference for working with one sponsor or CRO over another. Good overall protocol design and quality of training and general support round out the top three factors. Today, and in the clinical trials of tomorrow, monitors are the sponsor/CRO ambassadors and their primary role is to assist the site. They clearly need to be focused on site management and providing expert advice on the protocol – not disrupting investigator sites searching for documents.

Intralinks Studyspace eISF grants controlled and secure remote access to site documents by central sponsor monitoring teams and inspectors, so more time during monitor visits can be scheduled for:

- Site relationship building
- Training (e.g., protocol), good clinical practice (GCP), electronic data capture (EDC), and electronic CRF (eCRF) completion guidelines
- Drug accountability

While the following site-based activities can be considered as the responsibility of the central team:

- Source Document Verification
- Investigator file review
- Reviewing informed consent (including the associated video recordings for sites located in India)
- Reviews for adherence to GCP
- Reviews for data consistency
- Review for fraud/misconduct

This can halve monitor time spent at the site, while allowing central and focused teams to conduct thorough and economical reviews of site-based documentation, improving quality and consistency across your sites. Moving these activities to focused teams reduces risk for the sponsor/CRO, especially when the number of onsite visits is reduced through the implementation of Risk-Based Monitoring.

Enabling your CRAs to optimize site visits with high-value activities is critical to obtaining new sites for future studies; moreover, the reduced travel burden, along with the costs and efficiency savings, improves the quality of life for your key staff.

Assisting Small, Poorly Performing and/or Inexperienced Sites

As an industry, we invest heavily in initiating new investigator sites, yet most sponsors quit running clinical trials after one to three studies. Clearly inexperienced, small and/or poorly performing sites would benefit from additional assistance from the sponsor/CRO with study administrative activities – even with financial implications. Investigator-controlled remote access to site documentation could allow sponsors and/or CROs to assist sites in this regard, as long as those teams are kept separate from the traditional sponsor/CRO study team (by establishing a “Great Wall”, for example, barring access to the eTMF system).

Technology and the Clinical Trial

How Can Technology Improve the Clinical Trial Process at our Sites?

The adoption of an effective cloud-based document management system has proven to improve investigator site performance by positively impacting nearly every aspect of the trial, including post study. Most notably, electronic document filing enhances site/sponsor communication and collaboration, facilitates site monitoring, improves site inspection readiness, and contributes to the overall success of the clinical trial.

Key Capabilities Required for any Cloud Collaboration Platform

Requirements for an eISF solution include high site usability to drive adoption, rigorous role-based controls on document access, and comprehensive compliance reporting. The solution should be easy to use – without compromising security or control – and possess mobility capabilities to integrate and manage Bring Your Own Device (BYOD) strategies. The program should rest on a single platform while addressing all collaboration needs and provide centralized, comprehensive reporting and policy management across the entire content lifecycle. Finally, the solution should integrate simply and seamlessly with existing IT solutions.

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eISF Use Cases

There are three primary use cases associated with the eISF solution: providing an online repository for filing site-based trial documentation, facilitating secure remote monitoring, and maintaining the trial archive.

Online Filing of Investigator Site Files

The repository for site documentation pertaining to a clinical trial is required to be independently maintained by the site and kept separate from the study sponsor – the pharmaceutical company and/or CRO.

Document access management under manual recordkeeping systems severely decreases site productivity. Electronic documentation management increases site efficiencies through remote and rapid document retrieval and review, with managed permissions.

Remote Monitoring

Traditionally, numerous audit findings at sites require excess site visits by sponsor staff to review paper documentation. Monitors typically visit sites every four weeks. These site visits can be very disruptive to the actual research process, and monitors' time is costly.

The eISF provides remote monitoring of the site's documentation. Remote monitoring reduces trial site disruption by precluding many monitor site visits and associated costs.

Inspection-Ready Archive

The eISF solution provides long-term online archiving of site documentation while maintaining independence and ensuring availability for inspection.

Retention of the documents within the TMF (including the investigator site file) and the medical records of trial subjects is a legal requirement. The sponsor and the chief investigator must ensure that the documents contained, or which have been contained, in the TMF as well as the medical files of trial subjects are retained for at least five years after the conclusion of the trial.

Trials where data are used to support a marketing authorization have further requirements. Here, the documentation should be retained for at least 15 years after completion or discontinuation of the trial, or for at least two years after the granting of the last marketing authorization in the EC (when there are no pending or contemplated marketing applications in the EC), or for at least two years after formal discontinuation of clinical development of the investigational product. Additionally, the sponsor or other owner of the data must retain all other documentation pertaining to the trial as long as the product is authorized. This documentation must include the trial protocol, any standard operating procedures used for conducting the trial, all written opinions on the protocol and procedures, the investigator's brochure, case report forms on each trial subject, final report and audit certificate(s), if available, and staff training records. Further, the final report must be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorized.

Records relating to the full traceability of the IMP for Advanced Therapies have longer retention periods. These are 30 years after the expiry date of the product or longer if required by the clinical trial authorization. This will include the relevant documentation contained in the sponsor and investigator files as well as the trial subjects' medical records.

Intralinks Studyspace eISF Summary

Intralinks Studyspace: Electronic Investigator-Controlled Site File (eISF)

The eISF solution is built upon the Intralinks Studyspace platform. This externalized document management system has a 16-year track record of success in the Life Sciences industry.

Over 200 Life Sciences companies and 60,000+ investigator site users have trusted Intralinks® with their most confidential content.

Document Access and Organization

Intralinks' eISF system provides very simple storage and retrieval methods for documents at the investigator site. Users can access the eISF with an intuitive interface, anywhere, anytime.

Control of Content

Permission management and reporting are made easy with Intralinks' eISF. Fine-grained folder organization and document-level permissioning ensure security. Document protection is controlled by an auto-embedded Digital Rights Management (DRM) feature which allows "Unsharing" and watermarks documents to prevent screenshot copying and printing. Protected documents also cannot be altered.

Inspection Readiness

The document organization provided by Intralinks' eISF helps sponsors and investigator sites prepare for reviews by the inspectors. Users can gain pre-onsite inspection intelligence, utilize summary and completeness reports, and directly access previous versions of all documents.

Granting Remote Access to Investigator-Controlled Documentation

Sponsors define the structure and definition of the site binders. Study- or sponsor-level templates may be used. The investigator site saves documents directly to the Intralinks Studyspace folder in the cloud.

The system then performs a number of automated tasks on these documents. Each file is encrypted with its own unique key, before Digital Rights Management technology is embedded for protected content in order to retain and demonstrate control of the document through the sharing process. Access controls based on user groups and roles are then applied and email notifications with direct links to the content and/or folder are distributed. All activities are recorded in the audit trails, including any failures of the alerting procedure, such as an 'Out-of-Office' response.

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Remote Monitoring

Ease of folder and file permissioning, with on-demand access reporting, makes it simple to manage access for CRAs and other remote users.

Users can choose to access permissioned content via a web-browser with multi-lingual support, apps for accessing from Android and iOS smartphones and tablets, or with our secure desktop-integrated tools that provide a similar browsing experience to that associated with consumer-centric “sync’n’share” tools like Dropbox®, Google Drive™, and Microsoft® OneDrive™ (formally SkyDrive) – but with the control, security and trust associated with Intralinks.

In Summary

Intralinks eISF securely stores all documents for each site across studies and sponsors, while ensuring the Investigator always maintains control over their study binders and their contents, even when sharing sensitive content. Review tasks can be performed remotely with complete confidence while reducing the time spent visiting the site. Investigators benefit from reducing their reliance on paper and eISFs can be placed in long-term storage, remaining easily available if required by an inspector even decades after the completion of the trial.

Over 2,100 active clinical studies are running on Intralinks Studyspace and 99% of the Fortune 1000 companies trust Intralinks to secure their most commercially sensitive content in the cloud.

For eight years running we’ve been voted #1 by Gartner in the “Enterprise Collaboration and Social Software Suites” – and Intralinks Studyspace eISF enables you to offer this platform to your Investigator sites.