Paperless goal boosts compliance, efficiency, and saves $160,000 annually

Introduction

Copernicus Group IRB (CGIRB) is an independent institutional review board (IRB), an organization officially designated by the FDA to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, they have the authority to approve, require approval modifications, or disapprove research.

CGIRB assures that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research, both in advance of and during the studies. To accomplish this, CGIRB gathers information from multiple participating research centers such as universities, medical centers, and doctor's offices. They then use a formal group process to review the research protocols and study-related information, as well as investigator qualifications and resources.

Document Management in a Regulated Environment

Running the day-to-day business at an IRB is incredibly paper intensive and requires a great deal of internal and external collaboration and strict controls. In 2006, CGIRB was a leader among independent review boards and was evaluating new ways to leverage technology. A competitive analysis showed that some other IRBs provided web portals so the participating research centers could upload their research-related materials for review. To maintain a leading edge, CGIRB's strategy was to create a full-function portal so their clients could both submit and access the research documentation faster and easier. This portal also enabled CGIRG's staff to process and monitor study materials more efficiently.

At the time, 96 % of documents submitted to CGIRB were received electronically via digital fax, portals and email—and then printed out because CGIRB did not have an FDA 21 CFR Part 11 certified process for electronic document handling.

Incoming documents were printed, copied and couriered to board members for review. If the board needed to access any existing documents, a staff member would have to search through the massive paper archives and courier the printed materials to the board members. After review, the signed outcome letters were copied, shipped back and filed.

CGIRB was generating 22 feet of paper per week that needed to be managed, circulated, filed and ultimately disposed. Because research studies can continue for 10 years or more, the amount of legacy documents that needed to be kept available for review was staggering.

Planning for the Long Term

Existing software solutions that were specifically designed for IRB use were geared to single site organizations, whereas CGIRB manages research studies that involve multiple research centers. These software packages would have required CGIRB to change their processes to match the software using their existing, successful methods. "We want technology to enhance our process – not define it," said **Jennifer Sodrel**, Director, Information Management at CGIRB.

The new system would combine sophisticated document management with a customer portal, and integrate with CGIRB's Protocol tracking system (for non-regulated materials) and with the Sponsor and Clinical Research Organization (CRO) systems in order to make the IRB Submission and Approval process seamless.

Going paperless eliminated 22 feet of paper per week

In the fall of 2006, CGIRB contacted Sitrof Technologies, a long-time Xerox DocuShare partner that specializes in unstructured document management with extensive experience in Part 11 compliance. From their exploratory conversations, CGIRB recognized the value in going beyond a portal solution like their competitors, to a strategy that would take them completely paperless. Sitrof, along with Xerox, had all of the software, professional services and maintenance that CGIRB required.

Building a Solution

Sitrof and Xerox DocuShare collaborated to provide a 21 CFR Part 11-compliant document management system with workflow, version control, and electronic

signatures to handle incoming documents. The solution would help CGIRB improve efficiency, reduce the need for paper and most of all, improve their competitive advantage.

CGIRB understood that the change management aspect of the initiative was the single most important factor in long-term success if the company was to become paper-free. They created an efficient implementation plan using a three-phased approach.

- Phase One: Using DocuShare out of the box.
- Phase Two: Scanning and uploading 5 million legacy pages to an e-file room for viewing purposes only.
- Phase Three: Adding Sitrof's DocuShare Compliance Module to automate the workflow and decision process for electronic records while maintaining Part 11 compliance.

"The collaboration was exceptional," reported Jennifer Sodrel. "We were pushing the limits to customize the system, and Sitrof's ability to make it happen put us out ahead of our competitors."

Phased Approach

Due to the requirements of 21CFR Part 11, CGIRB must validate all regulated systems and processes, so each of these phases included a documentation and validation effort. All changes to existing systems were implemented through a formal Change Control Process and they adhered to all aspects of the Software Development Lifecycle.

The initiative would also necessitate reengineering the company's existing paper processes and workflows—requiring a critically important cultural shift and change management solution for CGIRB employees.

Phase One: DocuShare for non-regulated documents

In mid-2008, Sitrof installed Xerox DocuShare software to manage CGIRB's non-regulated documents, such as vacation requests, business development information, training information, PowerPoint presentations, spread sheets, status reports, RFIs and contracts. The plan was to start with documents that did not require Part 11 compliance, give the staff time to become familiar with DocuShare, work through process changes, customize the software, and get buy-in—before Sitrof installed its Compliance Module a year later.

To improve employee adoption and buy-in, CGIRB created subcommittees, focus groups, team meetings and best-practices teams from lines of business and IT, involving as many staff members as possible. These subgroups examined existing standard operating procedures (SOPs) and processes throughout the transition, bringing people along gradually. This approach proved pivotal to the success of the entire initiative as people brought solutions rather than problems to the table.

Phase Two: Scanning 5 Million pages

To become truly paperless, a major legacy scanning operation was necessary. CGIRB hired a local outsourcing firm, SCDATA, Inc., to work on-site, scanning, indexing and archiving 5 million pages of legacy documents (more than 200,000 pages scanned per month).

Initially, the scanned documents were available through a DocuShare e-file room for "read only" purposes. This allowed users to become familiar with the application and with electronic records. However, because the system was not yet Part 11 compliant for decision-making, the original paper was still routed to board members. Thus, by the end of phase two, users already had nearly a year of hands-on experience with the application.

OCR and Full-Text Search

In addition to making a certified and trustworthy scanned duplicate, Optical Character Recognition (OCR) was applied to each page, converting it to digital text and allowing full text search of all 5 million pages.

This strategic innovation added minimal incremental cost while significantly increasing long-term value, usability and ROI. Adding OCR and full text search was very forward thinking at the time and resulted in streamlining the clinical research process. Each document was also compressed to within 5 % of its original size. The OCR and compression process continues today for all newly entered hardcopy and electronic documents.

Phase Three: 21 CFR Part 11 Compliance and Case Management

Adding Sitrof's DocuShare Compliance Module provided a robust document management collaboration tool supporting CGIRB's mission-critical functions. Features of this module include electronic signature capabilities and the "Change Status" function. Much of what a review board does can be thought of as case management and each "case" goes through a series of status changes throughout its lifecycle.

Results: green, efficient, cost-effective, compliant and competitive.

CGIRB was able to transform itself from a paper-reliant company with millions of pages of legacy documentation into a completely digital, paperless organization in less than two years. Going paperless has enabled CGIRB to improve efficiencies internally, and enabled the review board to perform more thorough rapid review by providing secure access to all electronic documentation and data for current, pending and past studies.

As a result, the company dramatically reduced expenses and created a truly "green" work environment by nearly eliminating paper, printing, storage, shipping and other document handling costs.

Time Savings

Access to study documents also underwent significant change. Because these are dynamic documents that are never fully retired, they can be in use for more than ten years.

Due to scanning and performing OCR, all the 1.5 million documents (totaling more than 5 million pages) in the legacy repository can now be searched via DocuShare, enabling staff and board members to quickly find the right passage in protocols and investigative brochures that may be 200 pages or more. In addition to time savings, the risk of missing something is virtually eliminated.

Enthusiastic, More Productive Users

This three-phase implementation approach, coupled with employee-led review and oversight committees, fostered a positive, productive atmosphere for long-term change management. There is complete buy-in from the knowledge workers (Project Managers, IRB Administrators, QA and IRB Board Members) who today are more effective and efficient than ever. The review process has been streamlined through innovative use and integration of numerous digital technologies including scanning software, CGIRB legacy systems, DocuShare CPX and Sitrof's DocuShare Compliance Module and custom software.

The resulting across-the-board efficiency has allowed CGIRB to increase business without increasing staff. Clerical staff (whose primary role was to file paper) can now expand their skill set into other areas, improving the company's ability to maintain staff and reduce turnover. In short, CGIRB is now able to do more with less.

Getting Drugs to Market Faster

Finally, CGIRB gained competitive advantages and improved its service to pharmaceutical clients by becoming more efficient in its review and approval process—thus enabling clients to get drugs into the market faster.

In the past, working with documents meant printing and copying packets to be couriered to board members for review. Signed outcome letters would then be copied, shipped back and filed. Today, board members simply apply their e-signature and send documents electronically to the pharmaceutical client, or provide them through CGIRB's electronic portal. Now the entire collaboration, signature and document lifecycle is handled in a fraction of the time. The board performs more efficient reviews, thanks to immediate, secure access to documentation for current, pending and past studies.

Now, with updated SOPs and the technology in place to exchange electronic documents, paper is conserved, shipping costs are reduced and approval documents are accessed instantly—dramatically improving CGIRB's ability to achieve more efficient and speedy clinical trials for their clients.

Reduced Storage – Reduced Risk – Full Compliance

Converting all paper documents to digital dramatically sped up retrieval of these valuable documents and nearly eliminated storage costs. CGIRB no longer risks losing paper documents, and a single document can easily and securely be shared among numerous board members simultaneously. All decisions and collaboration are now based on certified, validated, paperless records. Mission critical "case" documents no longer have to be printed to maintain compliance.

Competitive Advantages

Having a fully validated and certified paperless review process gives CGIRB a tremendous competitive boost. As one of the top five IRBs in the United States that is over ten years old, CGIRB had a huge undertaking with its full conversion to paperless, and its competitors have not been able to follow suit. New competitors may move in a paperless direction somewhat easily, as they do not have the wealth of legacy documentation to convert, but these upstarts do not come to market with the level of expertise of the more established CGIRB.

Benefits

- Accelerated the Clinical Research startup and maintenance cycle by improving study and site approval turnaround times, thus increasing the speed in which a drug can make it to market.
- Enabled more efficient and precise Board Reviews and allowed unprecedented access to all legacy and new documentation during reviews via electronic searches and data access.
- Increased IRB visibility and further enhanced the protection of human research subjects by increasing efficiency and bringing more focus to IRB tasks rather than admin functions.
- Increased site monitoring capabilities by allowing remote access to all study and site documents and submissions.
- Integrated with Sponsor and CRO systems in order to make the IRB Submission and Approval process seamless.
- Reduced paper, printing, shipping and document handling costs.

Solution at a Glance

- Xerox DocuShare enterprise content management
- Sitrof's DocuShare Compliance Module
- Optical Character Recognition (OCR)
- Integration with CGIRB's Protocol tracking system (for non-regulated materials)
- Integration with CGIRB's Sponsor and Clinical Research Organization (CRO) systems
- 24x7 Customer Support

The DocuShare implementation created a paperless environment that generated Significant Savings and ROI

Over the life of the paperless initiative, CGIRB expects to save more than $2 million.

- Annual savings in office supplies and shipping approx $102,000

- Preparation time for audits decreased 98 %

- Saved $58,000 by eliminating the need to manually file paper documents

- Gained critical compliance with CFR11 and eliminated print costs previously required for compliance

- Customers save time and money: Submissions via a portal reduced submission time from 1.5 hours to a few minutes. Shipping costs for paper approval documents are eliminated.

For more information, call 1.800.735.7749 or visit docushare.com

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