

Electronic Regulatory Binders – A Homegrown System

M. Kovak, D. Wade, B. Scanlon, B. Lehman, J. Holley, P. Newman, L. Hutchins, A. Annis

UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Record storage for our office had become a challenge. We were out of space and out of money. All of our regulatory records were maintained on paper for close to 300 studies. Paper binders were taking up physical space and printing and binding materials were costly.

2. Goals

The electronic system is a shared folder on the University's Network Server that is accessible only to those in the Cancer Clinical Trials and Regulatory Affairs Office (CCTRA). This project needed to address these goals:

Goal 1: Establishing a consistent method of storing regulatory binders electronically.

Goal 2: Establishing an official process for monitoring access.

3. Solutions and Methods

An organizational system for the electronic binders was created by the CCTRA regulatory team. This organizational system included the following:

- Creating trial folders with consistent naming conventions
- Creating an SOP for monitors

Once these items were created, setting up prospective trials that hadn't started yet were implemented into this structure at the time of study start up. Space was a clear concern for us. We decided we needed a stopping point for all ongoing clinical trials. This allowed us to have a uniform mechanism for accessing regulatory binders. We chose an implementation date and then took the following steps:

- Placing a note to file for every trial that had a paper binder
- Training all regulatory team members on the new format
- Reviewing the new system at a staff meeting for all staff
- Creating an SOP for external monitors.

During the initial transition, monitors struggled with the new concept but adapted with time. We are now completely electronic except for the few items that are stored with original signatures.

4. Outcomes

We went from a file room with several hundred binders of regulatory documents to using manila folders to hold all wet signature documents must still be kept on paper at this time. The regulatory team can

Category: Regulatory – Completed Project

keep these files in one locked drawer at their desk. Although the project had an initial increase on staff workload during the transition, staff are now fully engaged. Many of the records they receive are already in an electronic format and can be saved rather than printing and filing. Costs are significantly lower for supplies and the electronic storage costs have been minimal.

5. Lessons Learned

It was not a quick process for transitioning all paper documents to the electronic format; the process took several months for the full regulatory team to complete (5 FTEs). Since then, we have participated in several demonstrations for companies who supply electronic regulatory binders. We have found that these systems are costly and not as easy to manage as our homegrown system. We feel that we saved significantly with our homegrown process.