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AACI Commentary

Less Paper, Better Trials

Recommendations for Implementing an Electronic Regulatory Document Management System

By the AACI Regulatory File Management Working Group

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Commentary Overview

- AACI's Regulatory File Management Working Group's recommendations for implementing an eRegulatory system are organized around three broad categories: planning, training, and expansion.
- While the upfront costs of eRegulatory implementation are high, there can be a good return on investment if it is used widely across a cancer center.
- Shifting to paperless regulatory document management requires setting implementation goals, determining the scope of the project, and obtaining buy-in from necessary stakeholders.
- Success in eRegulatory implementation can be measured by savings in both time and costs of physical storage space.
- In tandem with training, developing a communication plan will help to introduce the new eRegulatory product to staff.

To help create a common nomenclature for cancer clinical trial regulatory file systems, AACI established a Regulatory File Management Working Group in October 2018, comprised of AACI leadership, members from AACI cancer centers, and other relevant stakeholders.

After polling cancer centers about the types of regulatory file management systems in use, the working group found that many centers were in the process of either choosing an electronic regulatory (eRegulatory) system vendor package or developing their own cloud-based system. The survey's findings created an opportunity to share lessons learned by centers that had adopted eRegulatory binders.

In formulating the following recommendations for implementing an eRegulatory system, the working group landed on a set of guidelines structured around three broad categories: planning, training, and expansion.

Planning for an eRegulatory System

While the upfront costs to implement an eRegulatory system are high, there can be a good return on the investment if it is used widely across a cancer center. At the outset, a clinical trials team shifting to paperless regulatory document management should set implementation goals, determine the scope of the project, and obtain buy-in from necessary stakeholders.

Identifying human resources needs is vital, and establishing one or two full time equivalent positions, such as a project manager, is critical to an eRegulatory program's success.

Drilling down, this first phase of implementation requires identifying which trials to enter into the electronic system and answering questions like, "Will an electronic system be used prospectively?" (only on future trials that open after a set date) and "Will there be a concerted effort to convert current documents over to the electronic system?"

Similarly, a determination must be made about which data reports will be required from the electronic system. A number of considerations will be involved in this step, including the types of documents that will be uploaded and accessed, the time it will take to obtain e-signatures, the number of users accessing the system, and the number of administrative tasks required.

A clinical trials office might also want to build service fees into sponsor budgets for study start-up, or perhaps a conversion fee for documents, to underwrite remote monitoring.

Other preliminaries to a successful eRegulatory implementation would include creating business rules for a site map, setting up a binder, adopting a consistent file and folder naming system, and setting a goal for regulatory system user access (for example, after 6 months of use, 80 percent of staff should be using the electronic system).

Key measures of success that can be tracked before and after implementation also fall into broad categories of time saved—in entering data, obtaining signatures, and activating trials—and money saved on supplies and storage space.

Many constituencies might be affected by a move to eRegulatory documents: the university or health system, for example, along with cancer center leadership, end users, clinical trial colleagues, Data Safety Monitoring Committee (DSMC), and sponsors. Typically, the cancer center's regulatory department uses the regulatory document system most often and clinical trial coordinators are the second largest group using the system.

A big project like this requires being aware of, and activating, all available physical institutional resources, like cloud storage and computer labs and systems available at affiliate and network sites, as well as personnel such as information technology (IT) support and a project manager to oversee implementation, training, and auditing.

It's also good to know your limits. What are the "must-haves" of the project, and what can you do without? For instance, is integration with other systems a "must"? (Some clinical trial sites chose not to integrate into an institutional review board system.) Consider too the "look" of the product — flexibility, customization, and in-house versus off-the-shelf solutions.

Training and Expansion

Creating a training plan goes hand in hand with deciding what eRegulatory system to use and how to implement it. Determining the number of departments and users in the system is a good first step. Next, consider customized trainings for different role groups like principal investigators, and select a type of training model — examples include train the trainer, large and small group training, one-on-one training, and training with a vendor.

Training can be enhanced or extended by incentivizing departments to upload documentation or surveying users on their ability to use the system with targeted questions. In some cases, site monitors are trained by the corresponding research coordinator, while training at network sites can be done via webinar and directly with principal investigators, as necessary.

In tandem with training, developing a communication plan will help to introduce the new eRegulatory product to staff, set an implementation timeline, and describe what to expect and changes to workload. Online or supplemental tools such as guidelines, handouts, and a website can also be offered.

Trial sites should also consider what resources are needed for ongoing system maintenance. For example, if a vendor announces that a new version or upgrade is released, a trial site staff member will need to review the changes, determine the impact on staff, communicate the impact to end users and possibly update workflows.

Finally, once an electronic regulatory system is in place, further optimization will help to ensure its continued viability. After the system is implemented, determine how ongoing compliance to established business rules will be achieved, and retrain as needed. Where applicable, expanding its use to affiliate and network sites is a natural step up in realizing greater value from the new system.

For Further Reading

The 2019 AACI Clinical Research Innovation annual meeting featured two **abstracts** on eRegulatory binders:

GOING LIVE With an eRegulatory System: Lessons Learned in Managing the Change Process During an eRegulatory Rollout at a Comprehensive Cancer Center

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Overcoming the Burden of Paper Regulatory Binders Through eReg and eSignature Implementation

A. Green, M. Brown, K. Linsenmeyer, J. Gonzalez
The Ohio State University Comprehensive Cancer Center, James Cancer Hospital & Solove Research Institute

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