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

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1. Background

As clinical research costs soar both sponsors and clinical sites are looking to find ways to reduce costs, decrease efforts, and improve compliance. One way to do this is to move to an electronic regulatory binder and electronic regulatory signature process. Industry sponsors have already begun moving to an electronic system but clinical research sites are still lagging behind. This could be due to the daunting task of implementing the system and ensuring 21 CFR Part 11 compliance. It could also be due to the differences in clinical sites, how many different types of electronic regulatory/eSignature systems are currently on the market, and not knowing what system would work best for the individual site.

2. Goals

The goals are to provide the background behind 21 CFR Part 11, costs associated with eRegulatory systems, the benefits and challenges of implementing an eRegulatory system, and lessons learned from a site that has implemented an eReg/eSignature system.

3. Solutions and Methods

Challenges for implementing an eRegulatory/eSignature system include the multiple vendors for an eRegulatory/eSignature system, the costs of a system, the vagueness of 21 CFR Part 11 and the associated guidelines, obtaining buy-in from each of the research team members, not having a implementation already established, and assuring that the system is 21 CFR Part 11 Compliant.

Benefits include improving the workplace environment for team members, decreasing costs to the clinical site, improving compliance, increasing efficiency, increasing productivity, increase availability of the regulatory documents, and improve security of the regulatory documents.

4. Outcomes and Future Directions

As a site that wanted to implement an eRegulatory and eSignature system we initially completed a pilot process for eSignatures to determine the benefit this would have on our site. We chose this pilot because it was our greatest need so that we could increase compliance, increase efficiency and productivity, and decrease duplicative efforts due to lost documents. We chose to utilize the eSignature system for documents that are not predicate documents and were low risk level documents. Once determining which documents we would utilize the eSignature system for we completed training and validation of the system and implemented the new eSignature system. After completion of the pilot program it was determined that this system improved compliance and improved the work environment of the Regulatory Team as well as decreased costs for the Research Department and decided to move to an entire eRegulatory/eSignature system.

We chose a system that would integrate with our protocol management system because the users were already familiar with the system and because the data input of the protocol management system could feed directly to the eReg system which would further decrease duplicative efforts. Although the system was costly we felt the reduction in cost from decreasing duplicative efforts, filing efforts, and learning the system balanced the cost out. Additionally the system was intuitive and could be built for our individual site needs. After choosing we validated and implemented the system and learned a great deal along the way.