

Implementation of a Fully Electronic Regulatory Binder for Clinical Trials During COVID Pandemic

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1. Background

At the start of the COVID pandemic, most staff were transitioned to work remotely. To adequately address the challenges, the University of Nebraska Medical Center implemented eReg Lite—an eRegulatory management system designed to help sites quickly pivot to remote workflows—to achieve a fully electronic binder. After February 2021, our organizations transitioned to eReg and continue to show improvements.

2. Goals

Goals achieved through the implementation of eReg Lite included: collecting electronic signatures, standardized tracking of outstanding regulatory requirements, and remote monitoring sessions for sponsors.

3. Solutions and Methods

eReg Lite and eReg help create a standardized electronic regulatory binder using an NIH template. eReg Lite and eReg allow for email notification for principal investigators, clinical staff, and other team members.

4. Outcomes

After implementing eReg lite and eReg, our organization saw an increase in our regulatory coordinators' efficiency. The regulatory coordinators met and exceeded previous metrics despite the COVID pandemic and remote working challenges. The regulatory coordinators improved the tracking of outstanding requirements and received electronic signatures (21 CFR part 11). Using the standard reports in eReg Lite and eReg, the regulatory coordinators could easily view what requirements were still outstanding for clinical staff on an individual and protocol level.

5. Lessons Learned

The COVID-19 pandemic required an innovative solution to continue providing clinical trials. By implementing eReg Lite and eReg, our organization provided continued regulatory compliance efficiently and cost-effectively to the Fred and Pamela Buffett Cancer Center. Our cancer center continued to provide ongoing and new clinical trials to our population regardless of the COVID pandemic and remote working obstacles with eReg Lite and eReg.