Category: Regulatory – Completed Project

Digitalizing and Automating Clinical Research Protocol Regulatory Binders for Greater Efficiencies

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1. Background

Management of onsite clinical research (CR) protocol regulatory binders and external stakeholder review is resource intense and inefficient. We describe the best practices in place at Memorial Sloan Kettering (MSK) since 2015 for electronic regulatory binder digitalization and subsequent 2019 automation of five key regulatory document types.

2. Goals

Our primary objective was to show the efficiency gains for automating five electronic regulatory (eReg) time and effort (TE) intense document types versus traditional paper-based manual methods

3. Solutions and Methods

Staff TE was assessed before and after automation. Two questionnaires were used to assess satisfaction with virtual eReg system performance for active external monitors, and with MSK research regulatory associates (RRA) who have responsibility for maintaining these digital files.

4. Outcomes

Annual RRA TE saved with automation was 609 hours per year (20 percent average decrease), and a reduction of manual processing across these five document types by 70 percent (mean 70 percent, standard deviation 39.7 percent, range 5-100 percent). Seventy percent of monitor survey respondents were satisfied with virtual access to the eReg binder application overall, with only 14 percent not satisfied, and 16 percent being neutral. RRA survey respondents noted their overall satisfaction with automation (84 percent) and would recommend that other sites set up their eReg binder in the same way (93 percent). Most users (77 percent) noted automation improved their ability to perform higher level regulatory tasks.

5. Lessons Learned and Future Directions

eReg automation allows for the more efficient use of RRA staff and monitor TE. Automation of regulatory binder paper-based processes saved staff significant TE that can be reallocated for higher level regulatory tasks.