Ensuring Institutional Compliance with ClinicalTrials.gov Registration and Reporting Requirements
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Overview: Food and Drug Administration Amendments Act (FDAAA) 2007 enacted legislation to ensure that applicable clinical trials be registered and results reported on a publicly available database – ClinicalTrials.gov, for the purpose of formalizing human subjects research and results tracking in the United States. More recently, the Center for Medicare and Medicaid Services (CMS) rules require submission of an National Clinical Trial (NCT) number with all research-related billable services. Compliance with the regulations and rules varies widely by and within institutions where research is conducted. Ultimately, sponsors of applicable clinical trials will be held accountable for compliance, and enforcement of the regulations is anticipated. This report describes for other organizations the process we have undergone to ensure institutional compliance with FDAAA 2007 regulations pertaining to registration and reporting of applicable clinical trials, as well as with the new CMS rule related to billing for services conducted in a qualifying clinical trial.

Methods: We conducted a comprehensive institutional audit for compliance with FDAAA 2007 requirements, as well as the International Committee of Medical Journal Editors (ICMJE) expectations, regarding registration, updating, and results reporting on ClinicalTrials.gov. Most applicable clinical trials conducted at our site are sponsored by industry or cooperative groups, and ClinicalTrials.gov registration, updating, and results reporting is the responsibility of the sponsor. However, an average of 25 studies approved each year are investigator-initiated and are deemed “applicable” by either the FDAAA regulations or the ICMJE standards. Our baseline audit looked at 50 active clinical trials approved since FDAAA was enacted and that were investigator-initiated (for which the ClinicalTrials.gov requirements are the investigator’s responsibility). These are the trials for which the institution, as the employer of the investigator-sponsor, may be at risk for noncompliance. The general findings of the baseline audit indicated we were in full compliance with registering 54% of our investigator-initiated applicable trials on ClinicalTrials.gov. For studies requiring registration under FDAAA, 82% were registered. For studies requiring registration under ICMJE standards, only 32% were registered. FDAAA also requires updates and results reporting in ClinicalTrials.gov. However, 22% of studies registered in compliance with FDAAA did not have any updates posted, though they should have posted updates based on current study status. We found that there was a lack of education, infrastructure and monitoring in place to ensure institutional compliance. We also lacked a system for capturing the NCT number required to meet the new CMS rule. To address these issues, we implemented a number of programmatic changes, which will be outlined in the poster presentation.