Category: Regulatory – Completed Project

Fast Financials: An Automated Approach to Financial Disclosures

A. Foster, J. Buthorn, A.M. Gonzalez-Dadiz, K. Yataghene

Memorial Sloan Kettering Cancer Center

1. Background

A financial disclosure form (FDF) is an essential document used to determine if an investigator on a clinical trial (protocol) has financial disclosures that may represent a conflict of interest. This form is collected prior to study initiation, throughout the study as required, and at study completion to ensure any potential bias is appropriately mitigated. As of 2015, all FDFs at Memorial Sloan Kettering Cancer Center (MSK) are stored electronically within the Protocol Information Management System (PIMS) which is an in-house developed application that supports protocol submission and management including regulatory binder storage. Historically, FDFs were obtained using templates provided by the trial sponsor. This required the study team to pre-fill the applicable form with study identifiers and distribute to all investigators for wet-ink or electronic completion and signature. Once signed, all forms were to be collected and uploaded to the regulatory binder. This manual process was redundant, inefficient, labor-intensive, and time consuming.

2. Goals

Our goal with this PIMS enhancement is to decrease time of completion, streamline reconciliation efforts, and maximize regulatory compliance. Collected metrics will compare how long FDF completion took before and after this enhancement. Future metrics will aim to quantify overall compliance benefit.

3. Solutions and Methods

Effective August 24, 2020, PIMS was enhanced so that FDFs can be completed, e-signed, and automatically filed in the electronic regulatory binder for each clinical trial. To support this automated capture, a standardized electronic template was developed for use across all industry-sponsored trials. This form is automatically filled with select fields from PIMS (protocol title, principal investigator, MSK IRB number, and sponsor protocol number). With a few clicks, the study team can distribute this form to all applicable study investigators by adding to their PIMS UserWork (task list) and notifying them by email. Once completed, the FDF is automatically filed in the appropriate folder within the regulatory binder. This decreases potential room for error while ensuring timely completion and reduced administrative efforts. Additionally, the PIMS system is 21 CFR Part 11 compliant as required by the FDA.

4. Outcomes

Using the new automated workflow, the time needed to reconcile one FDF was decreased 90 percent (from 20 minutes to two minutes), contributing to a savings of $10.26 per FDF. In 2019, 12,694 FDFs were completed using the historical process, not accounting for ad hoc requests. Had the new workflow been utilized, the study teams would have saved $130,240.40, not accounting for additional investigator efforts. We are still collecting metrics to demonstrate an increased regulatory compliance with this new workflow.

5. Lessons Learned

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Sponsor engagement has been challenging; however, most have been agreeable to the use of our new form with a handful requiring minor modifications. Future expansion would include usage of this platform for non-industry trials. Additionally, this automated platform will support the development of dashboards to support ongoing enhanced regulatory oversight.