Category: Training and Quality Assurance – Work In Progress

Improving Clinical Research Quality and Efficiency Through the Implementation of a Risk-Based Audit Approach

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1. Background

In 2017, the Clinical Research Administration (CRA) was formed at Memorial Sloan Kettering Cancer Center (MSK). A primary goal was to increase the quality and efficiency of clinical research conducted at MSK.

2. Goals

As part of the CRA initiative, the Clinical Research Quality Assurance (CRQA) Unit, under the Clinical Research Compliance division of CRA, was charged with increasing the number of yearly clinical trial audits to provide a more comprehensive understanding of the issues encountered during study conduct so, in turn, they could be adequately and successfully addressed.

3. Solutions and Methods

A risk-based audit approach was adopted, which identifies and targets critical findings within clinical trials conducted at MSK. Similar to the approach utilized by regulatory agencies (e.g., FDA), CRQA audit staff conduct efficient, high-quality audits of assigned clinical trials within ~5 business days. To accomplish this, 4-6 research participants are randomly selected, using selection process and tools. Additionally, the clinical trial is analyzed to identify critical time and data points (e.g., informed consent documentation and procedures, eligibility, baseline/screening assessments, adverse events/serious adverse events). A risk-based audit approach is also utilized to target critical regulatory documents for review during the audit.

4. Outcomes

In 2016, prior to the risk-based audit approach implementation, only 22 audits were conducted on MSK clinical trials. Contrastingly, in 2019, following the implementation of the risk-based audit approach, 98 audits were conducted, which is a 345.5% increase. The impact of this approach has allowed an increase in the number of clinical departments and services, conducting clinical trials, to be audited, exposing issues experienced across the MSK Clinical Research portfolio and, in turn, for those issues to be analyzed and addressed. Additionally, this has led to an increase in collaboration across CRA to effectively improve: (1) processes and workflows related to regulatory and participant management, (2) audit databases and clinical systems, (3) education on targeted/common issues and improve knowledge and implementation of root cause analysis, and (4) external audits and inspection results.

5. Lessons Learned

Ultimately, through the implementation of the risk-based audit approach, CRA has been able to target issues that significantly impact clinical research at MSK. As a result, initiatives have been implemented

or are in the process of being developed to successfully address these issues with the overall goal of increasing the quality and efficiency of clinical research conducted at MSK.