Category: Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Transforming Risk Management: Technological Evolution of MSK's Clinical Research Quality Assurance Program

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1. Background

In 2017, a newly restructured clinical research quality assurance (CRQA) unit at Memorial Sloan Kettering Cancer Center (MSK) was initiated to substantially improve risk management of the clinical research enterprise. At the time, the unit used systems to collect quality assurance data on clinical research in various formats and platforms that were not originally intended to be interconnected and did not follow symmetrical connection points useful in generating a comprehensive overview of clinical research programs. CRQA's strategy was to restructure and strengthen existing systems, leading to dramatic steps in efficiency and effectiveness while producing an improved employee and customer experience.

2. Goals

CRQA set out to consolidate and improve existing systems to facilitate the extraction of useful data for analyses, while reducing system maintenance. This resulted in restructuring these data collection systems to streamline the collection process and reduce variability while improving report outcomes and accountability. In turn, processes and guidelines required standardization for a comprehensive integration. The overall goal of restructuring was to improve the retrieval and analysis of data to further mitigate institutional risks and identify clinical research process improvement opportunities.

3. Solutions and Methods

Standard guides were developed to identify clinical research-related deficiencies consistently across all CRQA. Protocol information management system (PIMS), MSK's main clinical research and information technology system, was identified as the platform to centralize CRQA data and to enhance from a passive tool to an active tool. Finally, operational dashboards were developed to allow clinical research departments to have real-time and direct access to relevant data, significantly reducing CRQA's time and effort as most queries and requests can be addressed quickly.

4. Outcomes

The original strategy for PIMS was to transition it from a passive tool to an active tool. In an innovative manner, CRQA went one step further and transitioned the system into an *interactive* tool accessible not only to CRQA, but also to clinical research departments. This transformation of PIMS has since shown to increase compliance, communication, transparency, data access, and collaborative relationships between CRQA and clinical research departments. The accessibility of real-time data through the development of dashboards enables CRQA and clinical research departments early identification of deficiencies and trends, while simultaneously identifying potential process improvements. The dashboards have demonstrated to be powerful tools in highlighting gaps, trends, outstanding regulatory tasks, and keeping clinical research departments abreast of these issues.

5. Lessons Learned and Future Directions

Achievement of these successful improvements required a time commitment and collaboration with subject matter experts. Most interim steps for these initiatives needed to be done sequentially to avoid errors and to permit testing. The next goal is to interconnect the data of all CRQA, which consists of four

separate programs, into a comprehensive dashboard that can provide a bird's-eye view of all clinical research activities and can forecast and prevent major deficiencies across MSK's clinical research portfolio. Additionally, we will explore inclusion of automation and advanced analytics into our systems to augment and magnify the impact of process redesign, further enhancing both the effectiveness and efficiency of CRQA's risk management for MSK's clinical research enterprise.