Category: Training & Quality Assurance – Completed Project

Standardization and Unification of Deficiency Language in Auditing and Monitoring

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1. Background

Given the ever-expanding diversity and complexity of clinical trials and the regulatory environment, the need for reproducible, consistent, and definitive terminology led the Quality Assurance Unit of Clinical Research Administration at MSK to create a standardized list of detailed descriptions and gradings for observed deficiencies. This list serves as the culmination our efforts to optimize and centralize findings from both internal MSK Auditing and Monitoring Program reviews and external agency inspections.

2. Goals

We streamlined notation and communication of observed deficiencies with the primary intent of improving efficacy in implementation of corrective and preventive actions. By ensuring that our list efficiently encompassed results from all types of reviews, we also hoped to increase the incisiveness of the metrics generated. Additionally, we aimed to emphasize the document as a practical educational resource, a roadmap of the specific elements of review and citation which will evolve simultaneously with changing regulations.

3. Solutions and Methods

We created our list containing 238 unique deficiencies, specified by 57 subcategories and sorted into 10 general categories – *Regulatory Review, Registration, Informed Consent, Eligibility, Evaluation, Treatment/Intervention/Interaction, Toxicity/Adverse Events, Outcome/Response, General Data Quality, and Pharmacy Review.* We efficiently described the spectrum of potential observations from auditing and monitoring processes and, critically, linked each with the applicable institutional, federal, and/or ICH guidelines which underpin each entry. We also worked with our institution's research informatics team to update the selectable deficiencies within our in-house electronic records system from the prior iterations to our new list, as well as modernize our mechanisms for obtaining results reports to simplify the process and allow for alignment of auditing and monitoring results.

4. Outcomes and Future Directions

By utilizing a common language for auditing and monitoring activities, communications between operational and quality assurance teams are enriched; implementation of corrective and preventative actions have been expedited and recommended standard actions created; corresponding policies hyperlinked within the list may be easily referenced to guide re-training and generate targeted educational materials; and metrics from audits and monitoring visits have been harmonized to provide a complete, real-time picture of institutional compliance.

While currently considering this project complete, we naturally anticipate additions over time to account for changing regulations and best practices; these changes will have a ripple effect of required accommodation within future QA projects, such as a planned CAPA response library. Finally, we hope to

maintain communication with institutions who adopt content relevant to their practice, ultimately promoting collaboration and sharing of lessons learned across cancer treatment centers nationally.