Standardization and Unification of Deficiency Language in Auditing and Monitoring
Karima Yataghene, MD and Michael McGinn, BS
Memorial Sloan Kettering Cancer Center

**BACKGROUND**
Given the ever-expanding 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 gathers and summarizes observations from both internal MSK Auditing and Monitoring Program reviews and external agency inspections.

**PROJECT GOALS**
- Unify notation and simplify communication of observations across continuum of review
- Improve quality of CAPAs and efficacy of implementation
- Provide roadmap-style tool for operations teams to perform gap analysis
- Harmonize QA metrics and increase flexibility for data requests
- Emphasize as a practical educational resource evolving simultaneously with changing regulations

**DEFICIENCY LANGUAGE STANDARDIZATION**
The current finalized list contains 242 unique deficiencies, each linked with the applicable institutional, federal, or ICH guideline(s); these are specified by 57 subcategories and sorted into 10 general categories:
- Regulatory Review
- Eligibility
- Evaluation
- Toxicity / Adverse Events
- General Data Quality
- Pharmacy Review
- Informed Consent
- Registration
- Treatment / Intervention
- Outcome / Response

**REVIEW AND SIMPLIFICATION OF LANGUAGE**
Deficiencies/findings were collected from institutional and external (FDA, NCI, EMA, Sponsors, etc.) reports. The list created was reviewed and simplified to ensure consistency, accuracy, and uniformity without redundancy.

**OUTCOME AND FUTURE DIRECTIONS**
Results from auditing and monitoring activities are systematically entered into MSK Protocol Information Management System (PIMS) managed by MSK’s Clinical Research Informatics Technology (CRIT) Unit. CR QA and CRIT worked in collaboration to increase the scope and refine the structure of electronic reports. Users are now able to generate reports selecting desired column data, as well as separate deficiencies in individual records for ease in filtering the report and generating counts. Coordination of auditing and monitoring reports allows for visualization and quantification of observations, and identification of trends.

**REPORTING OPTIMIZATION**
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