# Standardization and Unification of Deficiency Language in Auditing and Monitoring

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## 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

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

## Deficiency Language Standardization

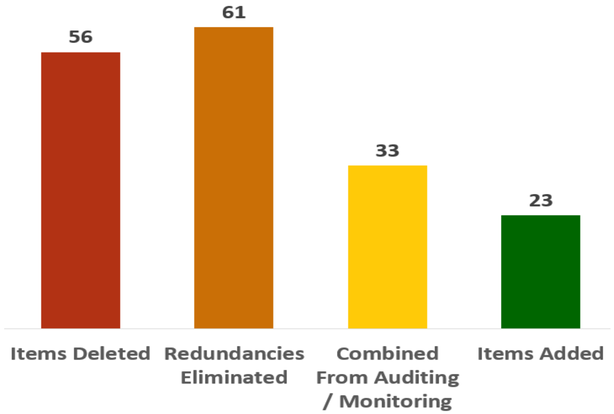
The current finalized list contains 242 unique deficiencies, each linked with the applicable institutional, federal, or ICH guideline(s); these are specified by 57 subcategories and sorted into 10 general categories:

- ▶ Regulatory Review
- ▶ Eligibility
- ▶ Evaluation
- ▶ Toxicity / Adverse Events
- ▶ General Data Quality
- ▶ Informed Consent
- ▶ Registration
- ▶ Treatment / Intervention
- ▶ Outcome / Response
- ▶ Pharmacy Review

| Category | Sub-Category | Deficiency | Rating | Associated Policy and/or SOP(s) | SOP Effective Date(s) |
|---|---|---|---|---|---|
| Eligibility | Eligibility | Enrolled participant does not meet eligibility criteria | Major | | |
| Registration | Registration | Failure to register participant | Major | SOP# CR-401 | 9/8/2017 |
| Registration | Registration | Participant not registered before intervention/interaction | Major | SOP# CR-401 | 9/8/2017 |
| Evaluation | Baseline | Specimen samples collected protocol-defined timeframe | Major | SOP# CR-901 | 11/22/2017 |
| Evaluation | During Study | Questionnaire/survey not completed | Major | SOP# CR402 | 1/3/2017 |
| General Data Quality | General Data Quality | Missing or delinquent data | Major | SOP# CR-413 | 8/3/2018 |
| Informed Consent | Informed Consent Document | Consent form does not contain all required signatures and/or initials | Major | SOP# IC-701 | 23-Jun-16 |
| Informed Consent | Informed Consent Process | Non-English speaking participant: interpreter not used | Major | SOP# IC-704 | 10-May-18 |
| Outcome / Response | Outcome / Response | Research document not certified | Lesser | SOP# CR-414 | 2-May-18 |
| Outcome / Response | Outcome / Response | Tumor measurements/evaluation of status or disease not performed, not reported, or not documented per protocol | Major | SOP# CR-423 | 5/14/2018 |
| Regulatory Review | Delegation of Authority Log | Individual missing from, assigned incorrect responsibility, and/or did not sign Delegation of Authority log | Major | SOP# CR-416 | 1/3/2017 |
| Regulatory Review | Delegation of Authority Log | Missing Delegation of Authority log | Major | SOP# CR-416 | 1/3/2017 |
| Regulatory Review | Delegation of Authority Log | Original Delegation of Authority log missing from paper binder | Lesser | | |
| Toxicity / Adverse Events | Toxicity / Adverse Events | Failure to report a Serious Adverse Event/AE of Special Interest | Major | SOP# RR-408 | 4/25/2018 |
| Toxicity / Adverse Events | Toxicity / Adverse Events | Late reporting of a Serious Adverse Event/AE of Special Interest | Major | SOP# RR-408 | 4/25/2018 |
| Treatment / Intervention / Interaction | Protocol Therapy Diary | Required research document(s) not certified | Lesser | SOP# CR-414 | 2-May-18 |
| Pharmacy Review | Adequate Security | Study-supplied agent is stored in an unsecured area | Major | IP QA SOP# 0401 | Pending |
| Pharmacy Review | Return of Study Agent | Unused/un-dispensed NCI-supplied study agents not returned, transferred or locally destroyed within 90 days when participants are in follow up and no NCI-supplied study agent is being administered | Major | IP QA SOP# 0401 | Pending |
| Pharmacy Review | Study Agent Storage | Temperature monitoring documentation is not completely or correctly maintained | Major | IP QA SOP# 0401 | Pending |

## Review and Simplification of Language

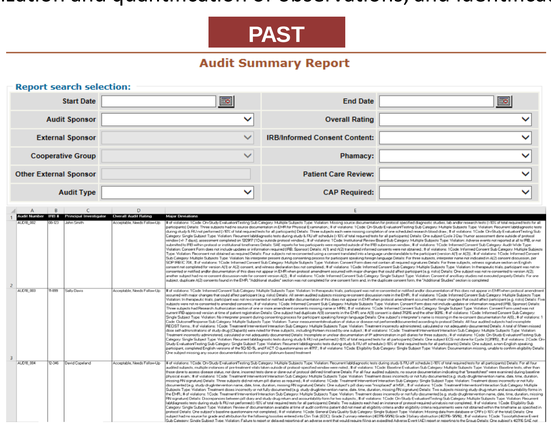
Deficiencies/findings were collected from institutional and external (FDA, NCI, EMA, Sponsors, etc.) reports. The list created was reviewed and simplified **to ensure consistency, accuracy, and uniformity without redundancy.**



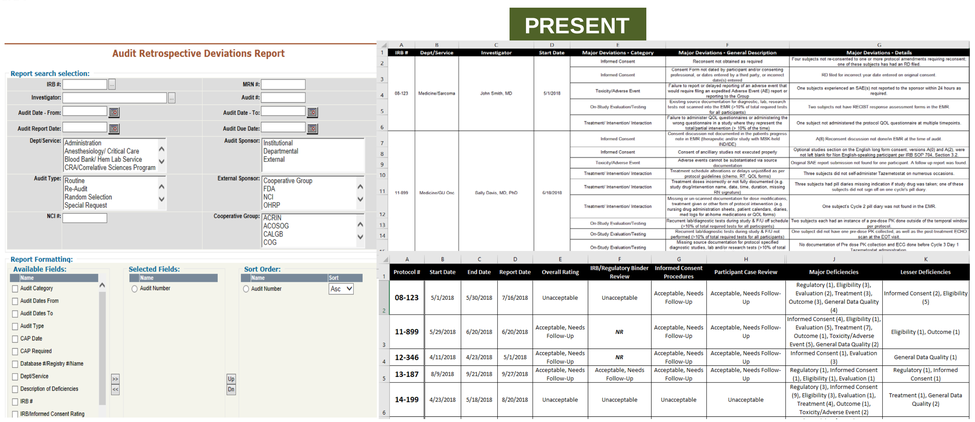

## Reporting Optimization

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.

**PAST**




**PRESENT**




## Outcome and Future Directions

By using a common language for auditing and monitoring activities, communications between operational and quality assurance teams are enriched; implementation of CAPAs have been expedited and recommended standard actions created; corresponding policies may be easily referenced to guide re-training and generate targeted educational materials; and metrics have been harmonized to provide a complete, real-time picture of institutional compliance. Over time, we anticipate additions to account for changing regulations and best practices; these changes will affect future projects such as a planned CAPA response library.

## Acknowledgments

We thank all the staff from the CRQA Auditing and Monitoring teams for their thoughtful contributions, with special thanks to Dawn Caron and Michael Ayerov of the CRIT team for their significant efforts.