

# 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

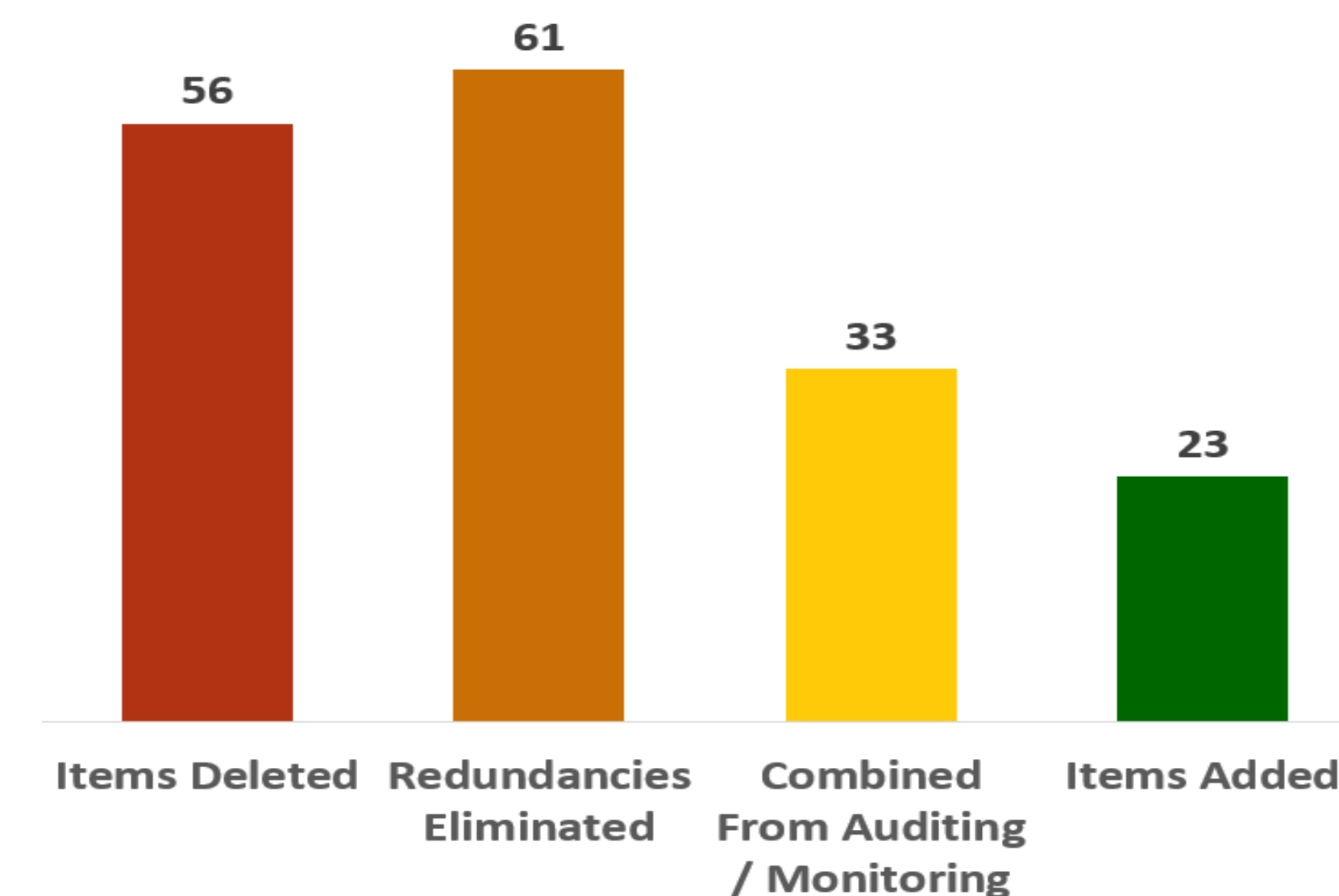
The current finalized list contains 242 unique deficiencies, each linked with the applicable institutional, federal, or ICH guideline(s); these are specified by 57 subcategories and sorted into 10 general categories:

- ▶ 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**

**Audit Summary Report**

Report search selection:

Start Date: [ ] End Date: [ ] Overall Rating: [ ]

Audit Sponsor: [ ] IRB/Informed Consent: [ ]

External Sponsor: [ ] Patient Care Review: [ ]

Cooperative Group: [ ] CAP Required: [ ]

Other External Sponsor: [ ] CAP Requested: [ ]

Audit Type: [ ] CAP Requested: [ ]

Report Formatting:

Available Fields: [ ] Selected Fields: [ ] Sort Order: [ ]

Table columns: A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z

**PRESENT**

**Audit Retrospective Deviations Report**

Report search selection:

IRB #: [ ] MN #: [ ]

Investigator: [ ] Audit #: [ ]

Audit Date - From: [ ] Audit Date - To: [ ]

Audit Report Date: [ ] Audit Due Date: [ ]

Dept/Service: [ ] Audit Sponsor: [ ]

Audit Type: [ ] External Sponsor: [ ]

Report Formatting:

Available Fields: [ ] Selected Fields: [ ] Sort Order: [ ]

Protocol #	Start Date	End Date	Report Date	Overall Rating	IRB/Regulatory Binder Review	Informed Consent	Participant Case Review	Major Deviations	Lesser Deviations
08-123	5/1/2018	5/30/2018	7/16/2018	Unacceptable	Unacceptable	Acceptable, Needs Follow-Up	Acceptable, Needs Follow-Up	Regulatory (1), Eligibility (1), Evaluation (2), Treatment (3), Outcome (3), General Data Quality (4)	Informed Consent (2), Eligibility (5)
11-899	5/29/2018	6/20/2018	6/20/2018	Acceptable, Needs Follow-Up	NR	Acceptable, Needs Follow-Up	Acceptable, Needs Follow-Up	Informed Consent (4), Eligibility (1), Evaluation (5), Treatment (7), Outcome (1), Toxicity/Adverse Event (2), General Data Quality (2)	Eligibility (1), Outcome (1)
12-346	4/11/2018	4/23/2018	5/1/2018	Acceptable, Needs Follow-Up	NR	Acceptable, Needs Follow-Up	Acceptable, Needs Follow-Up	Informed Consent (1), Evaluation (3)	General Data Quality (1)
13-187	8/9/2018	9/21/2018	9/27/2018	Acceptable, Needs Follow-Up	Acceptable, Needs Follow-Up	Acceptable, Needs Follow-Up	Acceptable, Needs Follow-Up	Regulatory (1), Informed Consent (1), Eligibility (1), Evaluation (1)	Regulatory (1), Informed Consent (1)
14-199	4/23/2018	5/18/2018	8/20/2018	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Regulatory (1), Eligibility (1), Treatment (1), Outcome (1), Toxicity/Adverse Event (2)	Treatment (1), General Data Quality (2)

## 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

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