

Memorial Sloan Kettering Cancer Center

Standardization and Unification of Deficiency Language in Auditing and Monitoring

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Memorial Sloan Kettering Cancer Center



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

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.

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

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.

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	Deficiency	Rating	Associated Policy and/or SOP(s)	SOP Effective Date(s)
	Enrolled participant does not meet eligibility criteria	Major		
	Failure to register participant	Major	SOP# CR-401	9/8/2017
	Participant not registered before intervention/interaction	Major	SOP# CR-401	9/8/2017
	Specimen samples collected protocol-defined timeframe	Major	SOP# CR-901	11/22/2017
	Questionnaire/survey not completed	Major	SOP# CR402	1/3/2017
у	Missing or delinquent data	Major	SOP# CR-413	8/3/2018
nent	Consent form does not contain all required signatures and/or initials	Major	SOP# IC-701	23-Jun-16
ess	Non-English speaking participant: interpreter not used	Major	SOP#1C-704	10-May-18
2	Research document not certified	Lesser	SOP# CR-414	2-May-18
2	Tumor measurements/evaluation of status or disease not performed, not reported, or not documented per protocol	Major	SOP# CR-423	5/14/2018
Log	Individual missing from, assigned incorrect responsibility, and/or did not sign Delegation of Authority log	Major	SOP# CR-416	1/3/2017
Log	Missing Delegation of Authority log	Major	SOP# CR-416	1/3/2017
Log	Original Delegation of Authority log missing from paper binder	Lesser		
nts	Failure to report a Serious Adverse Event/AE of Special Interest	Major	SOP# RR-408	4/25/2018
nts	Late reporting of a Serious Adverse Event/AE of Special Interest	Major	SOP# RR-408	4/25/2018
ry	Required research document(s) not certified	Lesser	SOP# CR-414	2-May-18
	Study-supplied agent is stored in an unsecured area	Major	IP QA SOP# 0401	Pending
t	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
	Temperature monitoring documentation is not completely or correctly maintained	Major	IP QA SOP# 0401	Pending



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.

