

THE IMPACT OF HAVING A ‘QUALITY’ QUALITY ASSURANCE SYSTEM ON AUDIT FINDINGS FROM 2020-2022



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Background

Clinical research monitoring and auditing are an important element of any clinical research quality assurance program. They are conducted to determine adherence with federal regulations, and to focus on preventing questionable practices. The main goal of quality assurance (QA) is to prevent problems. This requires the selection of competent and responsible investigators who can recruit and train proficient staff on the importance of ethical reporting. However, in clinical research there may be deviations. Therefore, a sound QA system should detect issues through routine monitoring and auditing that recognizes both random and systemic errors. When problems are detected, it is necessary to act quickly and effectively to correct and prevent them via education and training.

Goals

Clinical Research Services Quality Assurance Unit (CRS-QAU) partnered with the institutional monitoring and auditing departments to provide ongoing monthly education and training for staff focusing on how to prevent, identify/detect, and ethically report any issues. Individualized and group training was provided as needed to support continuous learning and audit-readiness. Findings from audit reports received from the University of Miami’s (UM) internal clinical research auditing body, sponsors, and cooperative groups were collected. CRS-QAU sought to determine if the quality assurance system in place was effective in reducing audit findings from 2020-2022. Audit findings were grouped into eight categories, and differences were analyzed comparing 2020 to 2021, and 2021 to 2022 data using the chi square test.

Solutions and Methods

There were 8 areas that we investigated: subject accountability, informed consent, test article, sponsor-related, protocol compliance, regulatory, documentation and data, subject protection and adverse events. The greatest improvements in compliance occurred in test article and sponsor-related (-60 - to -75%) from 2020-2021. The only areas of increase from 2020 -2021 were protocol compliance (+30%), regulatory (+83%), documentation and data (+ 70%), and subject protection, adverse events (+22%). Substantial improvement occurred in several categories (-9 to -64%) from 2021-2022; test article remained stable year over year from (-60%). A 10% increase in the total number of findings was found in 2021 compared to 2020 [$\chi^2 (7) = 31.65, P <.001$]; and there was no increase nor decrease in the total number of findings in 2022 compared to 2021, [$\chi^2 (7) = 36.03, P <.001$].

Outcomes

Audit findings increased from 2020 to 2021 due to various factors such as reduced training, transitioning from onsite to remote monitoring and auditing processes, and staff turnover due to the coronavirus pandemic. However, when remote monitoring and auditing processes stabilized, and training increased to support the rate of new hires, we found that providing competency-based clinical research education and training, performed in greater frequency, and on an individualized or group basis (as needed), was effective in reducing audit findings in key categories, and kept them stable over a short period of time.

Results

Table 1: Number of Audit Findings 2020 vs. 2021 vs. 2022

Category	Number of Findings by Yr.			Percent Increase / Decrease by Category ^a	
	2020	2021	2022	2020 vs 2021	2021 vs 2022
Subject Accountability	6	4	2	-33%	-50%
Informed Consent	8	5	11	-38%	+54%
Regulatory	6	11	4	+83%	-64%
Protocol Compliance	10	13	14	+30%	+8%
Documentation and Data	10	17	17	+70%	-
Subject Protection, Adverse Events	9	11	10	+22%	-9%
Test Article	5	2	2	-60%	-
Sponsor Related	4	1	4	-75%	+75%
	58	64	64	+10%***	-

p-value is in parentheses
***p < 0.001
Abbreviation: Yr., Year.
^a Percent increase/decrease (+/-) in audit findings by category

Lessons Learned and Future Directions

The focus of quality assurance and auditing should be on prevention, not on the data being error free because some errors may remain undetected despite QA, and auditing. The aim of QA is to prevent, identify, train, and report problems in a prompt, and effective manner to avoid audit findings that could result in fines and/or sanctions.