

# THE EFFECTIVENESS OF AN INNOVATIVE COMPETENCY-BASED EDUCATION AND TRAINING PROGRAM ON AUDIT FINDINGS (2020 VS 2021)



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## Background

Routine education and training of staff to build their clinical research competencies is crucial to address any gaps related to clinical research practices, compliance, and audit readiness. The industry standard of the “one-size-fits-all” Good Clinical Practice (GCP) training may not fully prepare investigators, and other research staff for audits. Clinical Research Services Quality Assurance Unit (CRS-QAU) created an innovative education program consisting of tailored training designed to build greater research competencies. We sought to determine if the innovative education and training program was effective in reducing audit findings within one year.

## Design/Methods

CRS-QAU’s education and training program offered training to all new employees on a quarterly basis in 2020. After the audits in 2020, CRS-QAU’s education and training administrators reviewed the areas of deficiencies in order to provide tailored training to employees. The innovative, competency-based trainings were offered in 2021 to new and existing employees on a monthly basis. We also provided individualized and group training as needed to support continuous learning and improve performance in their specific roles. Findings from audit reports received from the University of Miami’s (UM) internal clinical research auditing body, sponsors, cooperative groups were collected. Audit reports included verification of research compliance, and validation of data submitted by clinical research staff. Audit findings were grouped into eight categories, and differences were analyzed comparing 2020 and 2021 data using the chi square test.

## Audit Finding Results 2020 vs. 2021

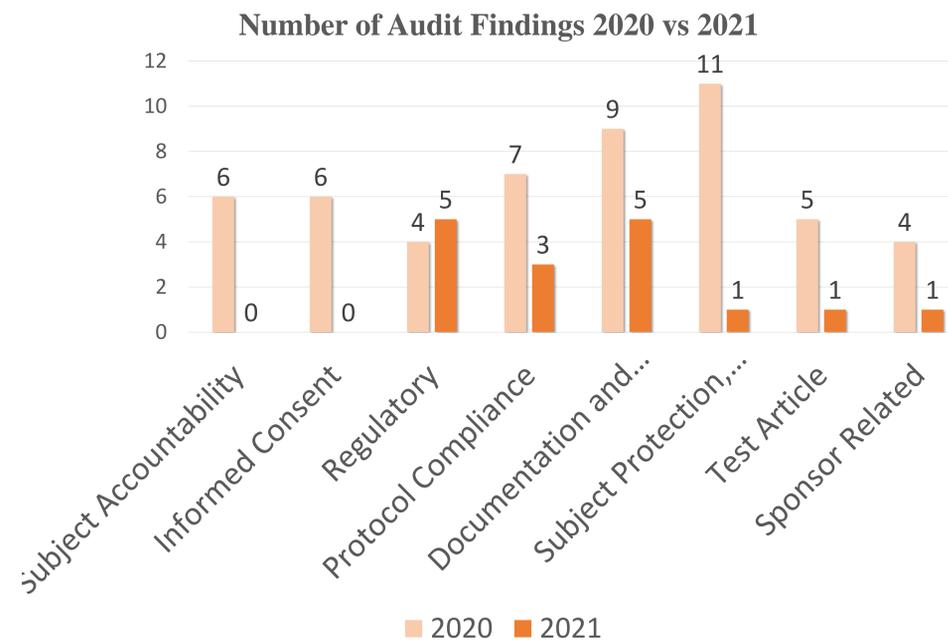


Table 1: Number of Audit Findings 2020 vs. 2021

Category	Number of Findings by Yr.		Percent +/- by Category <sup>a</sup>
	2020	2021	
Subject Accountability	6	0	- 100%
Informed Consent	6	0	- 100%
Regulatory	4	5 <sup>b</sup>	+ 25% <sup>c</sup>
Protocol Compliance	7	3	- 57%
Documentation and Data	9	5	-44%
Subject Protection, Adverse Events	11	1	-91%
Test Article	5	1	-80%
Sponsor Related	4	1	-75%
<b>Total</b>	<b>52</b>	<b>16</b>	<b>-69%***</b> <b>(&lt;0.001)</b>

p-value is in parentheses

\*\*\* p < 0.001

Abbreviation: Yr., Year;

<sup>a</sup> Percent increase/decrease (+/-) in audit findings by category

<sup>b</sup> A cooperative group audit found one item of consent content that impacted several studies

<sup>c</sup> This represents a slight increase in audit findings in the 'Regulatory' category

## Results / Conclusions

Comparing the 2 years, the greatest improvements in compliance occurred in subject accountability, informed consent and subject protection, adverse events reporting (- 91-100%). Substantial improvement occurred in test article, sponsor related, protocol compliance, documentation and data (- 44-80%). The only area of increase was regulatory (+ 25%). Overall, a 69% decrease in the total number of findings was found in 2021 compared to 2020 [ $\chi^2 (7, 13) = 42.57, P < .001$ ]; [ $\chi^2 (7, 18) = 42.57, P = 0.90$ , respectively] (Table 1).

CRS-QAU developed an innovative education and training program for its clinical research teams. Providing ongoing, tailored, competency-based education and training, performed in greater frequency and on an individualized (as needed) basis, is effective for reducing audit findings in key categories and over a short period of time (within 1 year).