

REFRAMING CLINICAL RESEARCH DEVIATION REPORTING: FROM COMPLIANCE BURDEN TO CONTINUOUS IMPROVEMENT

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Background

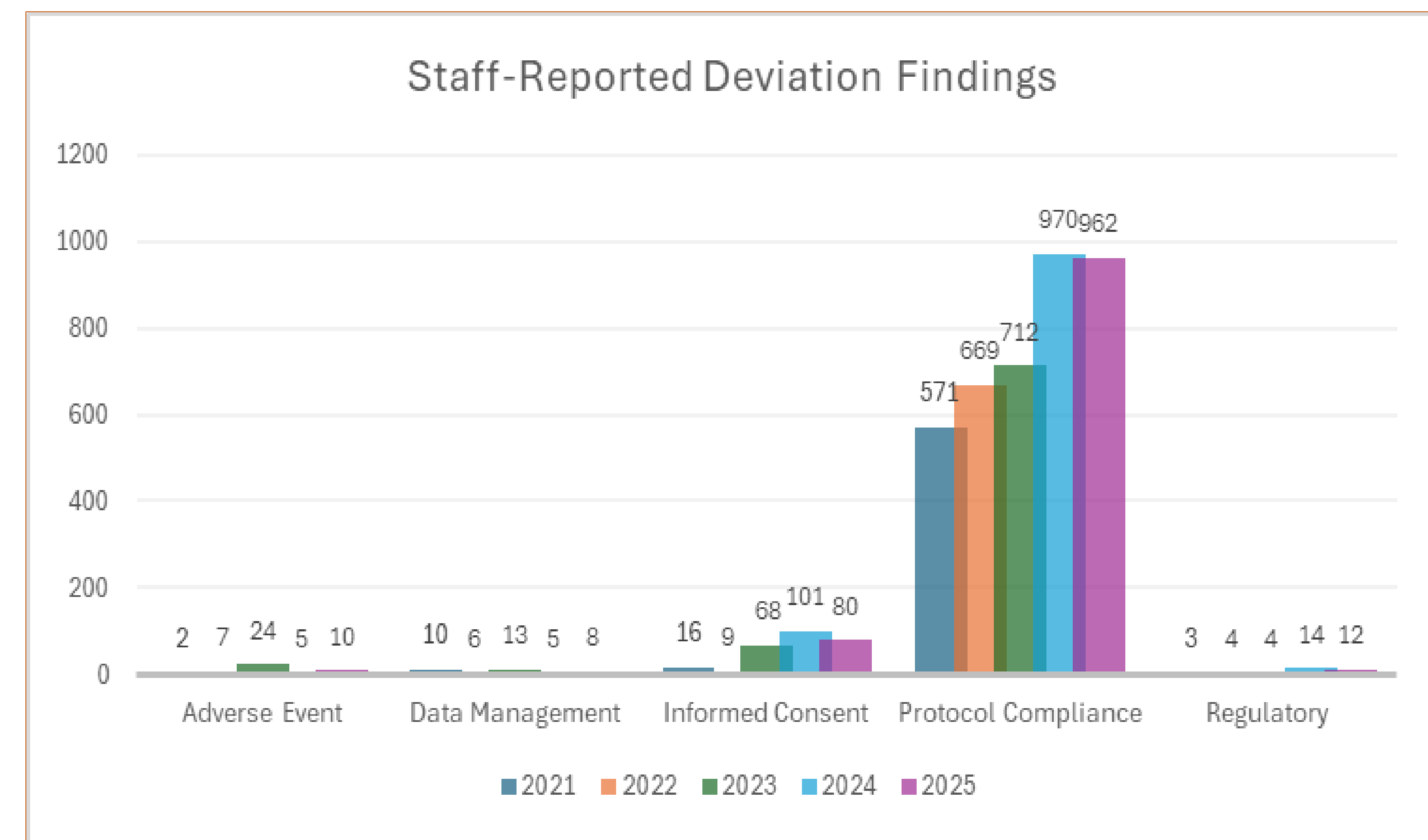
Clinical research operates within a highly regulated environment where adherence to protocols helps to ensure participant safety and data integrity. Deviations occur when there are alterations from the methods, procedures, or timelines detailed in the approved clinical trial’s study protocol. This could impact patient safety, data integrity, or the trial’s validity. In other words, at times deviations are inevitable, especially in complex studies. Historically and traditionally, deviations have been viewed as failures, creating a ‘punishing’ or ‘shameful’ atmosphere that discourages transparent reporting. Deviation reporting in clinical research is often misunderstood as a negative reflection of staff performance or organizational quality. This perception can lead to missed opportunities for improvement, and increased risk of repeated errors. This mindset undermines quality management efforts and limits an organization’s ability to identify systemic issues.

Goals

The SCCC-CRS Education and Training team sought to determine if training hours predicted a reduction in deviation findings, and whether there were significant correlations between training and person hours, and staff reported deviations between 2021-2025.

Solutions and Methods

Staff-reported deviation data were collected from 2021 – 2025. The data included verification of research compliance, and validation of data submitted by clinical research staff. The total number of training and person hours were correlated with the total number of staff reported deviations. Simple linear regression tested whether total training hours predicted a reduction in the total number of deviations reported by clinical research staff over time.



Total Number of Staff Reported Deviation Findings	
2021	602
2022	695
2023	821
2024	1095
2025	1072
Year over Year Comparison	Percent Change
2021 – 2022	15%
2022 – 2023	18%
2023 – 2024	33%
2024 – 2025	-2%

Outcomes

Comparing the data over five years, staff reported deviations increased by 15% from 2021 to 2022, 18% from 2022 to 2023, 33% from 2023 to 2024, but decreased by 2% from 2024 to 2025. A Pearson product-moment correlation coefficient was computed to assess the strength and direction of the linear relationship between the total number of training and person hours, along with the total number of staff reported deviations. Total number of training hours ($r = .95, p < .05$), and person hours ($r = .91, p < .05$), were significantly correlated with staff reported deviations indicating that staff’s comfortability reporting deviations improved over time. Simple linear regression analysis was used to test if the total number of training hours significantly predicted a decrease in the total number of deviations reported over time. A significant regression was found ($F(1,3) = 11.98, p = .04$). The R^2 was .80, indicating that the total number of training hours explained approximately 80% of the variance in deviations reported. For each one-point increase in the total number of training hours, reported deviations decreased by .19.

Lessons Learned and Future Directions

CRS-QMU 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, was effective in encouraging staff to practice transparent reporting, and provided the education and training team with actionable insights which may have influenced the reduction in deviation occurrences in 2025. Deviation reporting should be perceived as a cornerstone of quality improvement rather than a punitive task. By fostering a culture of empowerment and using deviation data as a strategic tool for education, training, and process optimization, organizations can transform challenges into opportunities for growth. It is important and necessary to use a quality management focus to reframe clinical research deviation reporting as a tool for continuous improvement.