Category: Quality Assurance – Completed Project

Reframing Clinical Research Deviation Reporting: From Compliance Burden to Continuous Improvement

E. Dawkins, N. Surana, J. Brown

Sylvester Comprehensive Cancer Center, University of Miami

1. 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.

2. Goals

The Sylvester Comprehensive Cancer Center (SCCC)-CRS education and training team sought to determine if training hours increased clinical research staff's comfortability to report deviation findings, and whether there were significant correlations between total number of training hours, person hours, and staff reported deviations between 2021-2025.

3. 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.

4. Outcomes

Comparing the data over five years, staff reported deviations increased by 15 percent from 2021 to 2022, 18 percent from 2022 to 2023, 33 percent from 2023 to 2024, but decreased by two percent 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 percent of the variance in deviations reported. For each one-point increase in the total number of training hours, staff-reported deviations decreased by .19.

5. 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. This requires a systems-based, proactive, and data-driven approach that views deviations as valuable insights and leverages them into process inefficiencies and potential risks that can be addressed with role-specific education and training. This proactive approach not only strengthens compliance but also builds a resilient, learning-oriented research environment.