

Enhancing the Deviation and CAPA Formulation and Review Process to Improve Compliance, Quality and Principal Investigator Satisfaction

N. Ostrowsky-Fabisch

Rutgers Cancer Institute

1. Background

Deviations pose risk to the conduct of clinical trials; corrective and preventative action plans (CAPAs) are critical for future mitigation of repetitive deviations. If deviations and CAPAs are not reported in a compliant, comprehensive, and timely manner, there can be extensive internal and external ramifications. Like other cancer centers, the Rutgers Cancer Institute of New Jersey's (RCINJ) Office of Human Research Services (OHRS) has received audit findings of incomplete and poorly written deviations and CAPAs. As a result, the OHRS leadership chartered the Quality Assurance, Improvement and Compliance Committee (QuAICC) in June 2023 to provide quality assurance oversight to the department's Disease Service Groups (DSGs) for deviation composition and CAPA development.

2. Goals

To improve the investigation, documentation, and reporting of deviations and CAPAs, QuAICC is tasked with reviewing deviations and CAPAs in a collaborative, peer-review format, to ensure deviations to patient treatment are appropriately documented, and research compliance through CAPAs is maintained per regulations and institutional policies and procedures. Although Principal Investigators (PIs) are ultimately accountable and responsible for study conduct, inclusive of deviations and CAPAs, enhancing the overall support the research staff provide to the PIs is also imperative.

3. Solutions and Methods

Meetings occur biweekly at which time a sampling of deviations and CAPAs are chosen and reviewed by Clinical Operations, Regulatory, Education and Quality Assurance (QA) leadership. DSG managers attend to present background or investigatory information about the deviation and/or to justify the corresponding CAPA.

During the in-depth review of the deviations and CAPAs, the committee ascertains:

- Was a root cause analysis performed and succinctly documented?
- Was a realistic corrective action plan implemented and concisely documented? Was a systematic, measurable, and timely preventative action plan proposed, developed and/or implemented, and then properly documented?

The committee takes actions for each deviation/CAPA:

- Accept the deviation and CAPA as written
- DSG manager revises the deviation and/or CAPA based on feedback followed by resubmission and/or re-presenting to the committee and/or to the Sponsor, QA team, Institutional Review Board (IRB)

4. Outcomes

Since the implementation of this committee, a decrease in inadequately written deviations and an increase in more comprehensively, thoughtfully formulated CAPAs has been seen by OHRS QA and leadership and reported by RCINJ's Human Research Oversight Committee and IRB, as well as by industry and cooperative group sponsors (i.e., NCI, NRG) during routine monitoring visits and audits.

Category: Quality Assurance & Remote Monitoring and Auditing - Work in progress

(Specific data and metrics will be presented.) PIs have also reported greater satisfaction with the thorough formulation of CAPAs, which is testament to research staff's improved skillset and competency.

5. Lessons Learned and Future Directions

As a result of the committee's efforts, the deviation/CAPA template was revised to guide staff in incorporating all critical elements. Trends (i.e., missing labs/pill diaries/questionnaires) are identified to proactively minimize further recurrence of common deviations. Staff, instead of managers, will be encouraged to present their deviations to aid their understanding of the impact of deviations to patient and study outcomes. The ultimate goal for this committee is to evolve into a broader process improvement committee to guide re-evaluation of current, and development of new, Standard Operating Procedures.