

Let It Go! One Strategy to Maximize Limited QA Resources

A. Gateman, E. Smas

Yale Cancer Center, Yale School of Medicine

1. Background

The Yale Center for Clinical Investigation (YCCI) Quality Assurance (QA) team conducts internal reviews of clinical research across the Yale School of Medicine, including the Yale Cancer Center. Balancing resources between conducting internal reviews and working with investigators and research staff on corrective and preventative actions (CAPAs) is critical to ensuring a robust quality assurance program. The QA team found that trials with significant observations and more extensive CAPAs were consuming greater QA resources than originally allocated. This was hindering the QA team's ability to conduct routine reviews and support the broader portfolio.

2. Goals

To balance the QA team's time spent between conducting reviews across the entire research portfolio and overseeing the execution of trial specific CAPAs, a more efficient use of available systems, resources, and trainings was instituted.

3. Solutions and Methods

Upon identification of a review with significant observations, the QA team works with the Principal Investigator (PI) and research team to identify the root causes. Once the root causes are determined, a CAPA is developed. Ideally, the CAPA items are matched to existing and/or new internal systems and resources available. Instead of implementing, executing, and tracking the CAPA within the QA team, the QA team now works collaboratively to pair the PI and research team with Subject-Matter Experts (SME) and system resources. For example, if an observation related to managing essential documents is found, and the root cause identified is lack of systems or process to maintain regulatory files, the internal team who supports Forte's eReg®, the electronic regulatory file maintenance system used at Yale, and the YCCI Director of Training are paired with the PI and research team to assist with education, training and eReg system implementation.

4. Outcomes

Extending beyond the QA team and utilizing existing SMEs and system resources has multiple benefits. The QA team has created a clear process for hand-offs and completion of reviews, allowing allocation of more time to review trials across the School. Also, by pairing PIs and research teams with support systems, researchers have gained an awareness of available resources for not only their current studies but for future studies as well. The PIs and research teams are more aware of who to contact and system supports are established prospectively at study startup versus deficiencies being discovered and addressed at the time of quality reviews. Researchers now are more aware of their access to receive answers, guidance, and education directly from SMEs.

5. Lessons Learned

Category: Training and Quality Assurance – Work In Progress

Establishing clear communication is essential for a smooth, coordinated team approach of support when involving multiple stakeholders. The QA team remains involved and works closely with collaborators to track the process, ensuring that work is completed and delivered in a timely manner.

Both methods have been successful in providing reviews and addressing CAPA plans but letting go and collaborating with SMEs is much more efficient for the QA team and, ultimately, the PIs and research teams.