

Background

The Quality Assurance and Safety Monitoring (QASM) team is responsible for auditing investigator-initiated studies at Siteman Cancer Center. Study teams are often uneasy or even fearful about an upcoming audit.

“My study is being audited next week, I can’t wait!” Let’s be honest, those words have most certainly never been spoken! Most of us are not excited at the notion of having our study looked at with a magnifying glass, data and case report forms sifted through with a fine-tooth comb, and our hard work critiqued and evaluated.

As auditors, it can be discouraging to hear that the audit process is considered burdensome, awkward, or punitive. QASM is taking steps to strengthen the auditor/research team relationship.

Goals to be Achieved

In the past several years, our QA team has grown from a team of one to a team of four. As our team grew, we set forth on a path of bolstering a positive image and shifting how auditors and the audit process are viewed.

Our goal is to help teams to ensure the rights and welfare of research study patients are protected. We want to be seen as a source of support and knowledge, a partner to the research team.



Methods and Materials

We rolled out 4 new initiatives:

Weekly team meetings

With a growing team it became evident that a weekly auditor meeting would be beneficial. With a team of 1 and even 2, a routine meeting was not necessary. But as the team grew we realized that having a weekly meeting with a set agenda was what we needed to work through issues and questions and help with consistency and keep us on track as a team.

A QASM team communication plan

New information was communicated to teams in a variety of ways but we realized that communications from our team didn’t always reach all who needed the information. We concluded that email was the best route for communicating with our teams and developed an email template that is short and simple and highlights to whom the information is most important (i.e. regulatory, clinical coordinator).

An audit working group

Team discussions about common audit findings and mining audit data revealed teams who excelled at certain aspects of study management and had great processes. We convened an audit working group composed of auditors, team leaders, and managers to connect groups and improve working processes. We planned quarterly meetings with this group to discuss our data and ideas for improvement. The group was very interested to see how they compared to each other and to learn from each other. Groups that excelled in a particular area provided insight to the group on processes that were successful.

Specific multi-step audit training

We developed individualized and study-specific audit training for teams to prepare them for what to expect from the audit process. We became aware that in our efforts to improve relationships with teams we should be involved with the education and training leading up to the actual audit of the study. Though our department had always provided a new team member training which touched on audit and audit prep; the training was more of an overview of the process and did not often touch of study specifics. We determined that team members could be more prepared for what to expect from the audit process and how they could be more in tune with what would take place in the weeks leading up to the audit, the audit week(s), and the post-audit processes

Outcomes

- Our weekly team meeting has made it possible for our team to thrive and generate new ideas.
- As new information becomes available we are now better equipped to communicate to all study team members due to our communication plan. This greatly improves our ability to level the playing field when everyone receives the same information at the same time.
- Our audit working group attendees were interested in learning from each other. This opened the lines of communication, giving us a platform for sharing information and collaboration and allowing teams to discuss common roadblocks.
- Our multi-step process for audit education helps team members become comfortable with the process by knowing what to expect.

Lessons Learned and Future Directions

Our team realized that each of us brings to the table a wealth of information and opinions, and we sometimes disagree. We discussed in detail how we would conduct our meetings, where each team member has a voice and a listening ear. Our team meetings and discussion guidelines have strengthened our team due to our ability to discuss ideas freely and to truly work together.

Our next steps are to create an internal intranet where educational communications can be stored and accessed by our teams, to continue our audit working group not only in an effort for us to collaborate more with our teams but to also provide an opportunity for teams to collaborate with each other, and to assess how our new training plan affects audit findings and teams’ connection to the process.



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