



Collaborating for Success: Tips for Improving Partnerships Between QA and Clinical Operations at Your Site

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WHY IS A PARTNERSHIP BETWEEN QA AND CLINICAL OPERATIONS IMPORTANT?

The key to a successful clinical trial is a balance of collaboration between Quality Assurance (QA) and clinical operations. The level of collaboration between QA and clinical operations staff can vary per clinical site. In many cases, there is little to no interaction between the two departments, or relationships are strained because of the lack of communication and transparency regarding what each group is contributing to the project and organization. A Contract Research Organization (CRO) with a heavy focus on operational activities can unintentionally overlook regulatory guidelines. On the other hand, a CRO with the burden to follow regulatory guidelines can overcomplicate their routine activities which can lead to delayed timelines and an unsuccessful clinical trial. Though QA operates independently from clinical operations, the two teams must collaborate to ensure the highest level of quality deliverables for sponsors and participants. Today's culture must shift to reflect that the two departments are indeed on the same team working toward the same goal while maintaining a balance.

STRATEGIES TO IMPROVE PARTNERSHIP

- Dispel the “Police” stereotype: QA can be perceived as the “police” trying to enforce regulations. QA’s responsibility is to ensure clinical operations are complying with the regulatory, SOP, and protocol requirements however, QA is not out to get anyone. Better to have QA spot the gap than a sponsor or regulator!
- Get to know your clinical operations colleagues:
 - Getting to know each other is a great way to build trust and working relationships. Face-to-face interactions put a person behind the position/title and can aid in improving communications when conflict arises.
- Schedule live audit debriefs with clinical operations:
 - Nobody likes to receive surprise audit findings in an official report. Once an audit is concluded, QA can schedule a live debrief before finalizing observations. This opens the door for conversation and understanding of clinical processes
- Be present in the clinic during non-auditing days:
 - QA has the perspective to assist with process improvements, SOP development, training opportunities, etc. Offering help/ insight outside of audits builds trust and lets the team know we are all in this together.
- Give praise and kudos to the clinical operations colleagues for a job well done! Noting successes along with the findings helps morale!



Sponsor/regulators–QA/Ops

CHALLENGES

- Lack of clear understanding of the QA role can lead to a hostile environment during audit debriefs.
- QA must be mindful that their job is to aid clinical operations, not to impede their work. Auditors should stay out of the way as much as possible.
- QA staff are expected to be resilient. However, workload, limited resources, and high-stress levels can lead to burnout.
- Performance anxiety is an issue. Some people make more mistakes when they feel like they are being watched. Making the auditee comfortable is a very important soft skill.

SUCCESS STORIES

“My success in my journey is because of the collaboration with everyone I have ever worked with. I firmly believe that you learn something from everyone regardless of how brief or long the encounter is and whether the outcome is positive or negative. Each person and experience has shaped me into who I am today” ~ Ashley Stumbo, Associate Director, Clinical Operations

“By nature, Quality Assurance and Clinical Operations don’t always agree but if you have a good relationship and mutual respect of each other’s jobs, QA can be a great resource, and ally and can even save Clinical Operations in tricky situations and audits.” ~ Amy Denvir, Senior Director, Deployment and Integration

“I appreciate our Quality Assurance team not only because of the members but because of their impact on past and future studies. Many do not know all that is included in QA endeavors, but they are essential. After speaking with sponsors and hearing their feedback, it is evident how a QA team can also lead sponsors back to Altasciences. Thanks for your diligence. I assure you it is noted!” ~Terra Marten, Data Coordinator III, Clinical Operations