Beyond Audits: DCRI Uses CTTI's Quality by Design Recommendations to Expand its Quality Assurance Program to Holistic, Proactive Quality Oversight

DCRI Applies CTTI's Quality by Design Recommendations

SUMMARY

The Duke Clinical Research Institute's (DCRI) Quality Assurance (QA) group in 2016 was largely reactive and audit-focused. In an effort to integrate quality more broadly into the organization, the QA team trained a cross-functional group of 25 individuals in Quality by Design thinking using CTTI's recommendations as a guide.

GOAL(S)

In the DCRI's early days, its QA team was unofficially nicknamed "the audit group." They were seen as the team on a mission to find what other DCRI teams were doing wrong and enforce corrective action -- not an ideal image. The directors of DCRI's QA group found this understanding of QA problematic. From their perspective, audits are only a very small component of an organization's overall quality system, and there was work to be done to make quality a partnership across the DCRI. DCRI's QA leadership set out on a mission to drive ownership for quality deep into the organization by teaching DCRI's functional teams that a good quality management must be proactive and holistically applied across all functions.

CHALLENGES

From the outset, the QA team had a steep hill to climb to overcome their stereotype as reactive auditors and rule enforcers. Many of the functional areas they wanted to educate were embedded with employees who had no previous exposure to Quality by Design (QbD) principles, which emphasize building quality into the outset of every clinical study through collaborative work across functions and keeping the focus on those errors that matter to decision-making or trial outcomes. Many DCRI employees worried that the additional efforts required to implement QbD would ultimately lead to a loss of time and increase costs. Clinical research, they reasoned, is a competitive market, and keeping budgets lean is the only way to compete.

SOLUTION(S)

CTTI's QbD suite of resources offer evidence-driven answers and tools for countering the narrative that QbD is costly and time-consuming. On the contrary, many QbD-driven studies enjoy efficiency and cost savings through well-designed protocols with fewer protocol amendments. The QbD recommendations from CTTI offer tips for bringing together stakeholders and building quality into clinical trial protocols from the outset. CTTI's QbD principles document illustrates in detail how the likelihood of a successful, quality, efficient trial can be dramatically improved through prospective attention to preventing important errors that could undermine the ability to obtain meaningful information from the trial.

TAKING ACTION

The QA team began building a program comprised of about 25 diverse, cross-functional individuals in the DCRI organization who had an interest in quality. The group included people from information technology, mega-trials, statistics, clinical operations, and data management. These individuals met monthly and were soon anointed as being a QbD ambassador across the organization. These meetings had several goals. First, QA leadership wanted to build a sense of community and collaboration within the QbD ambassador group, breaking down silos that can often limit traditional clinical research. Instead, QA leadership wanted these 25 individuals to rely on one another. Even though solutions were not one-size-fits-all, different functional areas quickly found there were similar experiences that could support one another. For example, someone in statistics offered insight to how to solve an issue the mega-trials team had encountered. Knowledge sharing across the organization took off, and once that trust was built, the groups collaborated on how to intervene proactively to address potential quality issues before they arose. The group began to challenge themselves on how they might work together as a team to get things right the first time, every time. The second goal of the QA leaders was to train these 25 individuals to be a resource for QbD within the organization. That training included educating them on root cause analysis, helping them identify and solve issues proactively. The QbD ambassadors rose to the challenge and became very interested in making DCRI's Standard Operating Procedures (SOPs) more meaningful as opposed to a checklist or document that employees rarely looked at.

IMPACT

Four years later, the QA group's old "audit group" stigma is gone, and employees are much more familiar with the DCRI QA director’s favorite saying: "Quality is the right relationship." The notion of interconnectedness across functions to deliver quality trials is central to QbD and now at the core of the DCRI QA team's remit. Although DCRI's QbD workgroup has since disbanded, the effort was successful in integrating QbD thinking into the organization, with individuals in the original QbD cross-functional group continuing to implement its tenets individually into each functional area. DCRI's QA team is currently exploring ways to formally track progress of QbD thinking via trends on audit findings, SOPs, and budget.

ADVICE

CTTI's recommendations and evidence-based resources were valuable to DCRI because they provided organizational examples where implemented QbD processes and methodologies brought real, tangible value. The QA team credits CTTI's efforts as helping change hearts and minds across its organization in relation to QbD. For teams unsure where to start with QbD, DCRI recommends using CTTI's QbD resources as a gold standard. Their philosophy: "If you are afraid to make a misstep, you will never make progress. Dive in!"

ORGANIZATION

Duke University

CONTACT

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ORGANIZATION TYPE

Academia

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TOPIC

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