

# KUMC Implements Quality by Design To Drive Efficiency Across its Organization

## KUMC Applies CTTI's Quality by Design Recommendations

### SUMMARY

The University of Kansas Medical Center (KUMC) Quality Assurance (QA) team gained leadership support to implement Quality by Design (QbD) across its organization. CTTI's QbD recommendations and principles document were foundational to the QA team's effort.

### GOAL(S)

KUMC's QA team looks for ways to provide research education and process improvement, so when KUMC's Vice Chancellor of Research passed along CTTI's QbD recommendations, it resonated as a goal the team would like to implement. While many organizations implement QbD at the study level, KUMC wanted to apply the principles across the entire organization. The team's ultimate goal was to embed QbD principles into policies, Standard Operating Procedures (SOPs), templates and training, building a QbD framework across the entire research culture at KUMC.

### CHALLENGES

The QA team knew that applying QbD broadly would improve efficiency in the long run, but there was work to be done to take QbD from concept to practice. The team needed to balance QA activities with QbD implementation. Additionally, KUMC is a large academic medical center consisting of three schools conducting research. The team needed to identify other areas within the research enterprise where QbD is applicable, starting with teaching the fundamentals: What is QbD?

### SOLUTION(S)

CTTI's QbD recommendations were developed with consideration to the fact that QbD thinking is new to most organizations. The CTTI QbD [Principles document](#) breaks down specific areas across the study lifecycle where QbD thinking could potentially be applied, including protocol design, patient safety, study execution, reporting, and more.

### TAKING ACTION

The first thing the QA team did was to gain support from leadership. The team explained CTTI's QbD concept, why it is important, and pitched ideas for how they could incorporate it into various aspects of the organization. It was helpful that the QA program at KUMC works heavily with investigators and study coordinators, allowing the team to hear what is needed and the questions being asked. During their pitch to leadership, the QA team was able to speak to how QbD could help answer those questions and address those needs. Once they had support from leadership, the QA team started incorporating CTTI's recommendations into the QA program. For example, if the QA team was reviewing an investigator-initiated protocol, it would think about some of the critical-to-quality factors and provide context in the comments provided back to the investigator and study team. The team also worked to standardize forms and templates to the process, making QbD simpler and promoting faster integration. After QbD was solidified across QA, the QA team worked to develop training to apply QbD thinking more broadly. Rather than try to teach QbD as a concept, the QA team conducted example-driven training that would resonate more strongly with employees. For example, the team would pose a hypothetical eligibility criteria situation and say, "This was the eligibility criteria, but the participant didn't meet a particular inclusion criteria and a waiver was granted by the sponsor. If you were writing this protocol, what would be the criteria necessary to determine that these parameters were too specific?" In its training, the QA team used examples like eligibility and adverse events with which investigators identify. Through these examples, they showed employees that it will not take additional time to use QbD thinking; if it is incorporated into practice as habitual thinking, you won't even realize it is happening.

### IMPACT

Once the training was complete and the process more embedded (QbD is never "done" in an organization, KUMC noted. It is always evolving.), KUMC began seeing more efficient processes across the board. For example, by writing a protocol that incorporates CTTI's QbD principles, the team is seeing fewer provisos and deviations. The organization now examines where it can add information up front to help mitigate disruption down the road, which makes working not only more efficient, but also more enjoyable.

### ADVICE

QbD is not a one-size-fits-all approach, so what works for KUMC may not be the same as what works for other organizations. For some, a study-by-study implementation may be more beneficial. Before diving into QbD, understanding your own organization, its processes, and its needs helps to drive the most effective way to incorporate QbD into your goals.

### ORGANIZATION

University of Kansas Medical Center

### CONTACT

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### ORGANIZATION TYPE

Academia

**IMPLEMENTATION DATE**

2018

**TOPIC**

Quality

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