

Quality by Design Helps EMD Serono Streamline its Protocol Through Inclusion of New Perspectives

EMD Serono Applies CTTI's Quality by Design Recommendations

SUMMARY

EMD Serono applied CTTI's Quality by Design (QbD) principles in the protocol development process for a phase 3 clinical trial. This case study describes how EMD Serono used the QbD principles to bring its internal and external stakeholders together, helping to create a more streamlined protocol and more alignment across the study team. The pilot also prepared EMD Serono to kick off broader QbD implementation across its organization as part of its program for compliance with the ongoing modernization of International Council of Harmonization's E8 guideline.

GOAL(S)

The phase 3 trial EMD Serono was planning was very large and in a highly competitive research space. A lot was riding on its execution, and the study team knew that ensuring a well thought out protocol upfront was key to its later success. EMD Serono also wanted to set itself up to perform a gap analysis against the organization's existing processes for all studies to evaluate what it does well and where there was room for improvement.

CHALLENGES

EMD Serono wanted to install an approach to the trial that was risk-based and focused on aspects of the study that were critical from a patient safety and data reliability perspective. The organization also sought more opportunities for team members to provide important insights on likely challenges and strategies for improving study protocols. Specifically, as a partner in the execution of the protocol, the voice of its external Contract Research Organization (CRO) was critical to help assess the protocol from multiple perspectives, ultimately resulting in a stronger study strategy.

SOLUTION(S)

EMD Serono's head of R&D Quality participated in CTTI's QbD workstream and shared with the study team an opportunity to partner with CTTI on a pilot QbD initiative. With CTTI's support, the study team would bring QbD principles to their phase 3 trial to optimize the protocol before regulatory review. The team came away from the head of R&D Quality's presentation on CTTI and QbD with a strong impression of how it could improve the design and operation of the study, and was eager to participate.

TAKING ACTION

QbD thinking stresses cross-functional and multi-stakeholder involvement as a critical component to improved, streamlined study protocols. With that in mind, CTTI and EMD Serono began the process of putting together a cross-functional workshop when the protocol was at the blueprint phase, with patient populations, endpoints and procedures drafted, but not yet submitted for regulatory review. The workshop included representatives from teams responsible for program leadership, project management, clinical development, study management, data management, biostatistics, quality management, quality assurance, patient centricity, operational feasibility, and representatives from EMD Serono's CRO for the study.

The workshop began with CTTI introducing the core concepts of QbD and basic tools to bring it to life, including CTTI's Critical-to-Quality Factors (CTQ) Principles document. The CTQ Principles document assists study teams in surfacing the most important elements of the study protocol that, without proper planning and attention, could undermine the ability to obtain meaningful information from the trial. The workshop attendees were also provided with the latest version of the draft protocol and were asked to complete a survey as pre-work, during which they identified those factors they perceived as CTQs for safety and data reliability.

Once the workshop attendees realigned on the main goals and objectives of the trial, they jumped into a dynamic conversation around the feedback received in the pre-work surveys. As expected, themes began to emerge as the same key areas were consistently identified as CTQs. CTTI facilitated dialogue around those points with a specific focus on bringing in all the voices at the table, ensuring that all functions had an opportunity to contribute. This was important because some functions, including an external CRO, may feel hesitant to share concerns with a protocol owner. However, given CROs are on the ground dealing with sites extensively, they bring a unique and important perspective that is crucial to ensuring the protocol is pressure-tested from all angles and is operationally feasible to implement.

The cross-functional dialogue successfully helped the EMD Serono team examine its protocol and plans for study conduct through a more critical eye. For example, the original draft included a requirement for certain testing that had been incorporated based on a previous protocol for the same asset. However, the frequency of testing did not directly support the endpoints in the current study so could be removed, reducing patient burden. The consensus from the workshop was that participant retention was a clear CTQ, so the attendees looked for ways to keep the study execution as simple and accessible as possible. That included critically evaluating the number and type of required lab tests and reducing where possible.

Following the workshop, EMD Serono used CTTI's QbD Maturity Model to conduct a gap analysis across the broader organization.

IMPACT

EMD Serono credits QbD with helping the organization evolve, not only on the specific study piloted, but for future studies as well. In a post-event survey, more than 90 percent of workshop attendees said that the dialogue helped them imagine a pathway to applying QbD principles broadly across the company.

ADVICE

EMD Serono stresses that QbD is not a discrete, standalone process, but a way of thinking critically and proactively across multiple business processes to ensure study design and protocol quality is optimized from the beginning. For example, EMD Serono leverages QbD thinking in its patient centricity process as well, considering how to think critically and proactively to develop protocols that are meaningful to patients and take their perspective into account.

ORGANIZATION

EMD Serono

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ORGANIZATION TYPE

Industry

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TOPIC

Quality

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