In the absence of consistent regulatory guidance, QMS published an integrated, proactive, flexible conceptual framework, and associated operational tools, which clinical development organizations may use to systematically define quality objectives linked to their broader strategic goals.

**Benefits:**
- Supports holistic and systematic quality management across all clinical development activities; helps to move the quality issue needle from a reactive to a proactive state.
- Provides consistent conceptual quality framework to evaluate and measure “errors that matter” with increased focus on safety and getting products to market quicker.
- Supports organizations appropriately managing clinical development-related risks.
- Promotes a culture of quality, knowledge management, innovation and continuous improvement.

**Solutions:**

Describes a conceptual Clinical QMS framework (together with feedback received from Health Authorities), including the various components that comprise the cQMS, and additional detail in follow up articles describing deeper dives into specific components, Member Company implementation learnings and providing practical operational tools for advancing knowledge by users.

**Assessing a cQMS Tool (2017):**
A tool to facilitate a sponsor’s initial assessment of their own cQMS, as well as continuous improvements to their cQMS.

**Risk Management Framework (2019):**
Describes a conceptual framework for effective risk management within clinical development including tools to help develop a risk library and a detailed example of risk management.

**Processes Management Framework (2019):**
Describes a conceptual framework for effective processes management within clinical development; also includes a Process Management implementation toolkit to facilitate execution.