In the absence of consistent regulatory guidance, 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.

**Initiative Status:**
Last Update: September 2019

**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
- Promote a culture of quality, knowledge management, innovation and continuous improvement

**Solutions:**

**Clinical QMS Conceptual Framework (2016):**
Describes a conceptual Clinical QMS (cQMS) framework within clinical development, reviews feedback received from Health Authorities

**Clinical QMS vs. Good Manufacturing Practice QMS Infographic (2016):**
Infographic describing the differences between QMS types and why the TransCelerate cQMS is fit for purpose for clinical development

**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 (Q1 2019):**
Describes a conceptual framework for effective risk management within clinical development

**Processes Management Framework (Q1 2019):**
Describes a conceptual framework for effective processes management within clinical development