Quality Management System

Published an integrated, proactive, flexible framework which organizations may use to systematically define quality objectives linked to their broader strategic goals

Initiative Status

Last Update: September 2018

Explore Design Deliver Maintain

Deliverables:

All deliverables are available for public use on the TransCelerate website, including the following:

- Clinical QMS Framework (Published in 2016)
- Issues Management Paper (Published in 2016)
- Knowledge Management Framework (Published in 2016)
- CQMS Assessment Tool (2017)

Upcoming Milestones:

- Publish Risk Management framework and Process Management methodology and supporting tools and resources later Q4 2018,
- Continue link with ICH Expert Working Group members regarding the QMS conceptual framework and alignment with ICH E6/E8 Renovations

Value for Stakeholders

- Decreased burden on Sites by streamlining clinical trial processes and focusing on measuring “Issues That Matter”; Provides consistent quality framework for Regulatory Authorities to evaluate and measure these issues
  
  “…we have seen a 70% reduction in CAPA findings by applying the "Issues that Matter" concept.” – Sponsor Company

- Increased ability for industry to proactively adapt to Regulatory changes
  
  “A new process had to be considered due to a new regulation. We were able to use the QMS Processes manuscript to assess how the new process should be implemented. We found that 90% of the process was already in place, it just needed some minor tweaks to be aligned with the new regulation.” – Sponsor Company

- Increased Patient safety during clinical trials

- Fewer study delays through reduced remediation associated with quality issues, ultimately getting drugs to market faster

- Greater ability to solve repetitive quality issues which individual companies have been unable to address