The article, "TransCelerate's Clinical Quality Management System: From a Vision to a Conceptual Framework," has been published in the June 2016 issue of Therapeutic Innovation & Regulatory Science (TIRS) and chronicles the evolution of a TransCelerate concept paper describing a proposed Clinical QMS Framework.

To read more about the findings, as well as review feedback from varied global clinical trial stakeholders during the socialization of the concept paper, visit the TransCelerate website at http://www.transceleratebiopharmainc.com/assets/quality-management-system/

WHERE do Health Authorities Stand on the Clinical QMS Conceptual Framework?

Health authorities across the globe identified many benefits of the conceptual framework, including:

- Its strong focus on patients, including through more efficient development of new treatments.
- Its flexibility and tailoring to organizations both large and small, multi-national or local implementation.
- Its value for organizations in managing quality holistically and consistently.
- Its value for regulators in potentially reducing review resources and regulatory timelines.

Ultimately, a Clinical QMS will help expedite the drug development process so that patients can receive novel treatments in a shorter amount of time.

WHAT does TransCelerate Hope to Achieve with its QMS Initiative?

The TransCelerate Quality Management System Initiative has identified potential benefits that could be captured from the development of a proactive and flexible conceptual framework focused on assisting an organization in creating a quality management system (QMS) designed to better manage and navigate its complex clinical trial environment.

The Clinical QMS Conceptual Framework will ultimately serve as a resource to help expedite the clinical development process and improve quality across the spectrum of clinical activities by:

- Accelerating delivery of new products to patients
- Reducing delays in clinical development
- Improving issue management across the enterprise
- Assuring data integrity
- Encouraging an “Get it Right the First Time” approach to avoid preventable re-work

Why is a Clinical QMS Needed?

Currently, organizations struggle to deliver promising treatments to patients quickly and economically because of sub-optimal approaches to clinical quality management across a drug development enterprise.

A Clinical QMS provides an integrated and harmonized system throughout an organization- and better enables quality. Most importantly, a Clinical QMS can improve performance within an organization.

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