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Perspectives for QbD Discussions and Potential Champions

These tables below are not intended to serve as a checklist. Consider if these perspectives are important for your program or trial. Perspectives not listed here may also be important to include depending on the situation.

Senior Advocate	Identify institutional sponsor(s) at the executive leadership level who can advocate for QbD, communicate its importance across the organization, and ensure that appropriate resources (time, money, people) are dedicated to establishing and sustaining QbD. Examples include: Chief Medical Officer, Executive VPs for R&D, Clinical Development and/or Clinical Operations, and the Vice Provost for Research.
Key QbD Champions	Consider both: 1. Individuals who lead functions within companies (e.g. Clinical Operations, Clinical Quality, Biostatistics, Data Management, Regulatory); departments within an academic medical center; or departments within a regulatory agency who can ensure the leadership vision for QbD is translated into day to day operations. These leaders are also well-positioned to directly reward proactive management of quality, driving behavioral change. 2. Staff who are well-regarded by peers and are "connectors" and unofficial leaders across the organization who can help shape a proactive culture and who can advocate for QbD through informal channels.

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Internal Organizational Perspectives

- While all of these perspectives may be important, ten different individuals may not be needed to represent all of the listed perspectives; one person may be able to appropriately provide multiple perspective (e.g both biostatistics and data management).
- Contract Research Organizations (CROs) are not discretely listed here; however, CRO representatives should be included in the QbD process to the extent they perform listed roles. If a CRO is engaged after the initial protocol development and QbD process have occurred, the study sponsor should share decisions made about critical to quality trial aspects and what will be considered "errors that matter" for the trial.

Key Perspectives for QbD Discussions	Typical Study Responsibility	Representative Title(s)
Clinical/Medical	Design of clinically relevant protocol; medical oversight and decision-making during study	Clinician, Study Physician, Medical Monitor, Global Clinical Lead
Biostatistics	Development of statistical analysis and implementation of statistical analysis plan	Study statistician, Statistical programmer
Clinical Operations	Operationalize program and trial globally. Oversee operational aspects of trial. Interact with and manage study vendors.	Clinical Program Operations Lead, Clinical Trial Manager, Study Team Lead, Clinical Project Manager
Clinical Data Management	Design and implementation of trial-specific data collection tools; ongoing data monitoring, querying, and cleaning.	Clinical Data Manager, IT/database architect
Safety / Pharmacovigilance	Safety surveillance, medical review of adverse events for reporting, review and approval of safety sections of protocol and other trial documents	Safety Physician, Global Safety Officer
Medical Writing	Manage drafting and review of protocol, study report, and other trial related publications	Medical Writer, Lead Author
Regulatory Affairs	Manage interactions with HA on trial design and approval	Regulatory Strategist, Global Regulatory Lead
Clinical Supply Chain	Clinical trial supply forecasting and management	Trial Supply Manager
Clinical Quality Management	Provide day-to-day GCP guidance to team; provide quality control for internal activities; report on Quality metrics	Quality Manager
Clinical Quality Assurance	Develop and implement independent QA audit plan for study;	Clinical QA Lead, Clinical QA Manager; Clinical QA

External Perspectives

- External perspectives can be invaluable to understand real-world application of the protocol.
- Resources for collaborating with patients, patient groups and advocacy organizations are available as part of the CTTI Patient Groups in Clinical Trials Project. Collaborating with organizations or individuals *external to your organization* may require the collaboration of a variety of departments *within your organization*. For example, prior to beginning an external collaboration, it may be beneficial to ensure alignment with Legal, Privacy, and Procurement representatives.

Key Perspectives for QbD Discussions	Typical Study Responsibility	Representative Title(s)
Patient	Validation of clinically relevant protocol with meaningful endpoints to patients, feasibility assessment, accrual strategy, informed consent review	Patient, Patient Surrogate, Patient Advocate, Parent
Investigative Site Staff	Feasibility assessment, accrual strategy	Principal Investigator, Clinical Research Coordinator, Study Nurse, Site Operations Director
CRO	Varies by sponsor, from full study outsourcing to select activities. May include study feasibility, site selection, monitoring, data management, statistical support, medical writing, regulatory affairs, medical monitoring, or any of a sponsor's responsibilities.	See "Key Perspectives" table above.