WCG Avoca Quality Consortium

Elevating clinical trial quality, driving efficiency, and mitigating risk through industry collaboration

AQC Knowledge Center Catalog

Category and Description of Leading Practices/Resources

1) Communication

To achieve leading practice quality oversight, an organization must proactively and clearly define required communications, the types of stakeholders who must be informed, the media, venues, or forums expected, and the style of these communications.

2) Governance/Organizational Construct

Governance leading practice concepts should apply throughout an organization. The leading practices and tools that are provided as part of this guideline should be tailored and fit-for-purpose for a specific organization based on the sourcing models that are deployed, the maturity of the Sponsor/Provider relationship, services outsourced and other considerations.

3) Inspection

As a leading practice for Inspection Readiness, the Sponsor, CRO and Clinical Sites should proactively prepare for inspections from all Health Authorities responsible for countries where Sponsors are seeking market authorization approval. Inspection Readiness is vital to ensure efficient review by Health Authorities of the clinical trial program.

4) Oversight Leadership Requirements

Leadership is essential to any group or organization. What a leader does is usually difficult to describe and is often situational. Leading practice for individuals in leadership roles that provide oversight of outsourced projects is the ability to accomplish tasks through others by providing clear direction, vision, and motivation.

5) Metrics/Analytics/Technology

Metrics and their supporting analytics seek to improve operations through oversight and management of factors that impact outcomes. Good utilization of metrics, analytics, and associated decision processes can drive efficiency, support accountability, create consistency, enhance quality, and promote an outcomes-focused culture and effective risk management.

6) Oversight Capability Maturity Model

Sponsor oversight capability, as it relates to Provider oversight, for biopharmaceutical R&D is important for the industry to drive greater efficiency and quality and reduced cycle time and risk. Advanced capability by Sponsors can offer benefits in fewer findings during audits and regulatory inspections. Sponsor capabilities also impact CROs by enabling better more effective partnerships.

7) Provider Qualification

A compilation of industry standards and tools for qualification of Clinical Service Providers. The standards are either specifically defined by health authority regulations or guidance documents, have been extrapolated based on regulations and guidance, or have become expected requirements based on leading practices, as defined by an advisory board of biopharmaceutical and Contract Research Organizations through the AQC.

8) Process Oversight

Process oversight includes the activities and behaviors necessary to manage and improve operations by overseeing process control and by surveillance of how activities are performed. Process oversight is a vital part of and is a key leading practice for Quality Oversight. Good process oversight drives quality not only in the context of operational risk, but also compliance risk.

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9) Protocol Quality

A high-quality protocol is critical not only to the full appraisal of a study's scientific objectives, but also to its proper, timely, and cost-effective implementation.

10) Patient Engagement

The use of patient input during trial design and execution can enhance the quality and efficiency of clinical development activities and results, as well as serving the patient need to be appreciated as a research partner. The following tools help support operationalizing such initiatives.

11) Quality Agreement

The Clinical Quality Agreement has been developed for use by the AQC. Clinical Quality Agreements may be composed for use at the project level, the program level, or the relationship level.

12) Quality Oversight Management Framework

The Quality Oversight Management Framework (QOMF) offers a high-level view of the AQC library of leading practices for effective Quality Oversight. This QOMF framework shares the eight elements that drive effective oversight and shows how they fit together. This framework is supported by the eight "AQC swim lane" view. The QOMF framework also includes a glossary that supports the entire AQC library, across the eight swim lanes and across the other AQC workstreams supported by the library.

13) Proactive Risk/Opportunity Management

Proactive Risk and Opportunity Management includes the coordinated activities and behaviors necessary to direct and control an organization regarding risk and opportunities. Effective proactive management of risk drives quality on many fronts, including business, operational, patient-facing, and compliance risk.

14) Risk-Based Quality Management

Regulatory authorities encourage the use of risk-based approaches in the development of clinical study design and execution in order to support Quality Management. These leading practices assist users in applying these approaches to support their compliance with regulatory authority expectations.

15) Roles/Responsibilities

Roles and Responsibilities should be understood throughout an organization and its partners to drive oversight and efficient clinical operations. Roles and Responsibilities should be proactively defined before project work begins and refined and enhanced on a periodic basis.

16) Site Quality

The AQC recognizes that the biopharmaceutical industry cannot elevate quality to the highest levels without involving sites as a critical component of the holistic clinical trial quality value system. As a result, the AQC has brought investigative site needs into the mix with Sponsors and Providers via the Site Quality Center and leading practices associated with the 12-component AQC Investigator Site Quality Management System construct.

17) Technical Oversight

Technical oversight includes the activities and behaviors necessary to manage and improve operations by overseeing the engagement and management of third parties (CROs and other third parties) that are conducting technical activities in support of clinical programs including the services that support the technologies.