

# AQC Knowledge Center Catalog

**Advance to Specific Categories:** [Communication](#) | [Governance/Organization Construct](#) | [Inspection](#) | [Leadership](#) | [Metrics/Analytics/Technology](#) | [Oversight Capability Maturity Model](#) | [Provider Qualification](#) | [Process Oversight](#) | [Protocol Quality](#) | [Patient Engagement](#) | [Quality Agreement](#) | [Quality Oversight Management Framework](#) | [Risk](#) | [Risk-based Quality Management](#) | [Roles and Responsibilities](#) | [Site Quality](#) | [Technical Oversight](#) | [Summary of Knowledge Center Documents](#) | [New Documents in Development](#)

**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.

[Return to Top](#)

Comm Tool 00	Communication Guideline
Comm Tool 01	Communication Matrix
Comm Tool 02	Communication Management Plan
Comm Tool 03	Issue Escalation Process Tool
Comm Tool 04	Escalation Pathways
Comm Tool 05	Risk Issue Triggers RACI Matrix Template
Comm Tool 06	Decision Escalation Process
Comm Tool 07	Risk or Issue Communication Template
Comm Tool 08	Governance Key Contacts List
Comm Tool 09	Team Contact List
Comm Tool 10	Communication Planning and Targeting Checklist
Comm Tool 11	Meeting Minutes Template
Comm Tool 12	Action Item Template
Comm Tool 13	Meeting Agenda Template
Comm Tool 14	Issue Log Template
Comm Tool 15	Leading Practices for Meetings
Comm Tool 16	Email Leading Practices
Comm Tool 17	Governance Meeting Constructs
Comm Tool 18	Governance Committee Standing Agendas
Comm Tool 19	Communication Barriers and Enablers
Comm Tool 20	Setting Expectations Worksheet
Comm Tool 21	Project Status Report
Comm Tool 22	Active Lessons Learned Process
Comm Tool 23	Active Lessons Learned Database Construct
Comm Tool 24	Active Lessons Learned Capture Template
Comm Tool 25	Active Lessons Learned Project Review Meeting Template
Comm Tool 26	Active Lessons Learned Review Meeting Facilitator Guide
Comm Tool 27	Communication Systems and Technologies
Comm Tool 28	Communication Standardized Tools and Templates
Comm Tool 29	Communication Regularly Scheduled Meetings
Comm Tool 30	Communication Standard Reports
Comm Tool 31	Subject Matter Expert Contact List Template

# AQC Knowledge Center Catalog

Number of Communication Resources	32
-----------------------------------	----

**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.

[Return to Top](#)

Gov Tool 00	Governance and Organizational Construct Guideline
Gov Tool 01	Governance Structure and Objectives
Gov Tool 02	Governance Charters
Gov Tool 02a	Template for a Governance Charter
Gov Tool 02b	Sample Executive Committee Charter
Gov Tool 02c	Sample Operations Mgmt Comm Charter
Gov Tool 02d	Sample Business Mgmt Comm Charter
Gov Tool 03	Decision Making Models
Gov Tool 04	Types of Decisions
Gov Tool 05	Simple Decision Making Process
Gov Tool 05a	Complex Decision Making Process
Gov Tool 06	Rational vs Intuitive Decision Making
Gov Tool 07	Proactive Governance Decision Making
Gov Tool 07a	Template Governance Decision Making
Gov Tool 07b	Sample Governance Decision Making
Gov Tool 07c	Project Risk Opportunity Template
Gov Tool 08	Decision Trees
Gov Tool 08a	Decision Scorecard
Gov Tool 08b	Decision Scorecard Instructions
Gov Tool 08c	Sample Decision Scorecard
Gov Tool 09	Constraints on Decision Making
Gov Tool 10	Good Decision Making
Gov Tool 11	Centers of Excellence
Gov Tool 11a	Template for Functional Model Governance
Gov Tool 12	Quality Units
Gov Tool 13	Business Objectives and Needs
Gov Tool 13a	Template for Business Objectives and Needs
Gov Tool 14	Preparing a Governance Plan
Gov Tool 15	Governance Plan Accountabilities Tool
Gov Tool 16	Change Management
Gov Tool 17	Risk and Issue Triggers
Gov Tool 18	Risk Assessment and Mitigation Tool
Gov Tool 19	Governance Planning Timeline and Milestones
Gov Tool 20	Opportunity Assessment Tool
Gov Tool 21	Measures to Track Governance Success

## AQC Knowledge Center Catalog

<b>Gov Tool 22</b>	Sourcing Models Definitions and Characteristics	
<b>Number of Governance/Organizational Construct Resources</b>		<b>36</b>

**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.

[Return to Top](#)

<b>INSP 00</b>	Inspection Readiness Guideline	
<b>INSP 00a</b>	Inspection Readiness Agency Grid Instructions	
<b>INSP 01</b>	Inspection Readiness Agency Grid	
<b>INSP 02</b>	Sponsor and CRO Functional Inspection Preparation Checklist	
<b>INSP 03</b>	Inspection Preparation Kickoff Meeting Presentation Template	
<b>INSP 03a</b>	Inspection Preparation Kickoff Email Template	
<b>INSP 03b</b>	Inspection Preparation Timeline Template	
<b>INSP 04</b>	Inspection Preparation Storyboard Template	
<b>INSP 04a</b>	Inspection Preparation Most Challenging Questions	
<b>INSP 05</b>	Sponsor and CRO Inspection Logistics and Coordination Tool	
<b>INSP 05a</b>	Dos and Do Nots During Inspection Interviews	
<b>INSP 06</b>	Inspection Preparation Logistics Presentation Template	
<b>INSP 07</b>	ICH E6 (R2) Landscape Map	
<b>INSP 08</b>	Sponsor and CRO Inspection Preparation Tool	
<b>INSP 09</b>	QMS Annual Compliance Assessment Plan Process	
<b>INSP 09a</b>	QMS Compliance Assessment Plan Schedule Template	
<b>INSP 09b</b>	QMS Assessment Findings and Resolutions Template	
<b>INSP 11</b>	Investigator Site Inspection Preparation Tool	
<b>INSP 12</b>	Investigator Site Functional Inspection Preparation Checklist	
<b>INSP 13</b>	Clinical Investigator Inspection Preparation- Interview Template and Learning Tool	
<b>INSP 14</b>	Investigator Site Inspection Logistics and Coordination Tool	
<b>INSP 15</b>	Clinical Site Inspection Follow up	
<b>INSP 16</b>	Investigator Site Inspection Preparation Most Challenging Questions	
<b>INSP 17</b>	PMDA Required Foreign Investigative Site Inspection Documents Tool	
<b>INSP 18</b>	Pharmacovigilance Areas of Focus	
<b>INSP 19</b>	Inspection Response Guide	
<b>INSP 20</b>	Inspection Response Checklist	
<b>INSP 21</b>	Inspection Response Tool	
<b>INSP 22</b>	MHRA Blog Sponsor Oversight	
<b>INSP 23</b>	AQC Quality Management System	
<b>Number of Inspection Resources</b>		<b>30</b>

**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

# AQC Knowledge Center Catalog

oversight of outsourced projects is the ability to accomplish tasks through others by providing clear direction, vision, and motivation.

[Return to Top](#)

<b>Lead Tool 00</b>	Oversight Leadership Guideline
<b>Lead Tool 01</b>	Rules of Leadership
<b>Lead Tool 02</b>	Delegation
<b>Lead Tool 03</b>	Balanced vs Micromanagement
<b>Lead Tool 04</b>	Leadership Styles
<b>Lead Tool 05</b>	The Six Leadership Styles at a Glance
<b>Lead Tool 06</b>	Leadership Characteristics
<b>Lead Tool 07</b>	AAAA Framework
<b>Lead Tool 08</b>	Cultural Attributes
<b>Lead Tool 09</b>	Emotional Intelligence
<b>Lead Tool 10</b>	Behavioral Interviewing
<b>Lead Tool 10a</b>	Interview Template
<b>Lead Tool 10b</b>	Sample Behavioral Interview Questions
<b>Lead Tool 11</b>	Competency Model
<b>Lead Tool 12</b>	Characteristics of a Well Functioning Team
<b>Lead Tool 13</b>	RISE Self Development Model
<b>Lead Tool 14</b>	Culture of Quality
<b>Number of Oversight Leadership Requirement Resources</b>	
	<b>17</b>

**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.

[Return to Top](#)

<b>Met Tool 00</b>	Metrics/Analytics/Technology Guideline
<b>Met Tool 01</b>	Quality Metrics Taxonomy
<b>Met Tool 03</b>	Metrics Categories and Review Accountabilities
<b>Met Tool 05</b>	Decision Trees
<b>Met Tool 06</b>	Strategy Maps
<b>Met Tool 07</b>	Decision Biases
<b>Met Tool 08</b>	Summary Guide to Optimization
<b>Met Tool 09</b>	Data Visualization
<b>Met Tool 10</b>	Measurement Focus
<b>Met Tool 11</b>	KPI Development Worksheet
<b>Met Tool 12</b>	Metrics Planning
<b>Met Tool 13</b>	Cost Benefit Analysis
<b>Met Tool 13a</b>	Cost Benefit Analysis - Complex Example

## AQC Knowledge Center Catalog

Met Tool 14	System Scorecard	
Met Tool 14a	System Scorecard Template	
Met Tool 15	Determining Measurement Strategy	
Met Tool 16	Metrics Focus Areas and Sub Areas	
Met Tool 17	Risk Framing Analysis and Aggregation	
Met Tool 18	Metrics Plan Thought Map	
Met Tool 19	Pursuing Optimization Within Your Organization	
Met Tool 20	Metric Dashboard Template	
Met Tool 21	Catalog of Oversight Metrics	
Met Tool 22	Organizational Metrics Curriculum	
Met Tool 23	Functional and Technical Provider Services Metrics	
Met Tool 25	Risk Metric Framework	
Met Tool 25a	Identification and Review of Risk Drivers and Risk Metrics	
<b>Number of Metrics/Analytics/Technology Resources</b>		<b>26</b>

**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.

[Return to Top](#)

OCMM 00a	Oversight Strategy	
OCMM 00b	Governance/Organization Construct	
OCMM 00c	Oversight Leadership	
OCMM 00d	Process Oversight	
OCMM 00e	Metrics/Analytics/Technology	
OCMM 00f	Proactive Risk and Opportunity Management	
OCMM 00g	Budget, Sourcing, Contractual, Financial Oversight	
OCMM 00h	Communication Associated with External Party Oversight	
OCMM 00i	Roles and Responsibilities within Oversight Landscape	
OCMM 00j	Technical Oversight	
OCMM 02	Oversight Capability Maturity Model Worksheet	
OCMM 03	Oversight Capability Maturity Model Instructions	
OCMM 04	Conceptual Foundation	
OCMM 05	Oversight Capability Maturity Model Image	
OCMM 06	Virtual and Lean Models for Oversight	
<b>Number of Oversight Capability Maturity Model Resources</b>		<b>15</b>

**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

## AQC Knowledge Center Catalog

defined by an advisory board of biopharmaceutical and Contract Research Organizations through the Avoca Quality Consortium.

[Return to Top](#)

<b>PQUAL 01</b>	Core Standards
<b>PQUAL 01a</b>	Core RFI Template
<b>PQUAL 01b</b>	Core Scorecard Template
<b>PQUAL 01c</b>	Core Visit Checklist Template
<b>PQUAL 02</b>	Central Labs Standards
<b>PQUAL 02a</b>	Central Labs RFI Template
<b>PQUAL 02b</b>	Central Labs Scorecard Template
<b>PQUAL 02c</b>	Central Labs Visit Checklist Template
<b>PQUAL 03</b>	Bioanalytical Lab Standards
<b>PQUAL 03a</b>	Bioanalytical Lab RFI Template
<b>PQUAL 03b</b>	Bioanalytical Lab Scorecard Template
<b>PQUAL 03c</b>	Bioanalytical Lab Visit Checklist Template
<b>PQUAL 04</b>	Biomarker Lab Standards
<b>PQUAL 04a</b>	Biomarker Lab RFI Template
<b>PQUAL 04b</b>	Biomarker Lab Scorecard Template
<b>PQUAL 04c</b>	Biomarker Lab Visit Checklist Template
<b>PQUAL 05</b>	IxRS Provider Standards
<b>PQUAL 05a</b>	IxRS RFI Template
<b>PQUAL 05b</b>	IxRS Scorecard Template
<b>PQUAL 05c</b>	IxRS Visit Checklist Template
<b>PQUAL 06</b>	ECG Provider Standards
<b>PQUAL 06a</b>	ECG RFI Template
<b>PQUAL 06b</b>	ECG Scorecard Template
<b>PQUAL 06c</b>	ECG Visit Checklist Template
<b>PQUAL 07</b>	Medical Imaging Provider Standards
<b>PQUAL 07a</b>	Medical Imaging RFI Template
<b>PQUAL 07b</b>	Medical Imaging Scorecard Template
<b>PQUAL 07c</b>	Medical Imaging Visit Checklist Template
<b>PQUAL 08</b>	COA and eCOA Provider Standards
<b>PQUAL 08a</b>	COA and eCOA RFI Template
<b>PQUAL 08b</b>	COA and eCOA Scorecard Template
<b>PQUAL 08c</b>	COA and eCOA Visit Checklist Template
<b>PQUAL 09</b>	CRO Monitoring Standards
<b>PQUAL 09a</b>	CRO Monitoring RFI Template
<b>PQUAL 09b</b>	CRO Monitoring Scorecard Template
<b>PQUAL 09c</b>	CRO Monitoring Visit Checklist Template
<b>PQUAL 10</b>	Data Management Standards

## AQC Knowledge Center Catalog

PQUAL 10a	Data Management RFI Template
PQUAL 10b	Data Management Scorecard Template
PQUAL 10c	Data Management Visit Checklist Template
PQUAL 11	Biostatistics Standards
PQUAL 11a	Biostatistics RFI Template
PQUAL 11b	Biostatistics Scorecard Template
PQUAL 11c	Biostatistics Visit Checklist Template
PQUAL 12	CRO Medical Writing Standards
PQUAL 12a	CRO Medical Writing RFI Template
PQUAL 12b	CRO Medical Writing Scorecard Template
PQUAL 12c	CRO Medical Writing Visit Checklist Template
PQUAL 13	Phase I Unit Standards
PQUAL 13a	Phase I Unit RFI Template
PQUAL 13b	Phase I Unit Scorecard Template
PQUAL 13c	Phase I Unit Visit Checklist Template
<b>Number of Prequalification Resources</b>	
	<b>52</b>

**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.

[Return to Top](#)

Process Tool 00	Process Oversight Guideline
Process Tool 01	Elements of Process Oversight
Process Tool 01a	Task Ownership Matrix
Process Tool 01b	Template Task Ownership Matrix
Process Tool 01c	CRO Scorecard
Process Tool 01d	CRO Qualification and Selection
Process Tool 02	Transfer of Obligations
Process Tool 02a	Template Transfer of Obligations
Process Tool 03	Process Document Control
Process Tool 03a	Process Tracking Table
Process Tool 03b	Joint Process Development
Process Tool 03c	Six Sigma SIPOC Tool
Process Tool 03d	Six Sigma Swim Lane Tool
Process Tool 03e	Template Joint Process Document
Process Tool 03f	Process Improvement
Process Tool 03g	Lean and Kaizen Events
Process Tool 03h	Root Cause Analysis
Process Tool 03i	Template RCA Fishbone Diagram
Process Tool 03j	Statistical Process Control



## AQC Knowledge Center Catalog

Process Tool 03k	Process Mapping Instructions
Process Tool 03l	Process Improvement Table Template
Process Tool 04	Quality by Design Principles
Process Tool 04a	QbD for Pharma GMP Activities
Process Tool 04b	QbD for Pharma GCP Activities
Process Tool 04c	Operationalizing QbD for Clinical Trials
Process Tool 04d	QbD Template CTQ Table
Process Tool 04e	QbD Template IMP Intervention Risk
Process Tool 04f	QbD Template Design and Methods Risk
Process Tool 04g	QbD Template FMEA
Process Tool 04h	QbD Leading Practices when Outsourcing
Process Tool 04i	QbD Provider Risk Assessment
Process Tool 04j	History of QbD for Pharma GCP Activities
Process Tool 04k	QbD Risk Assessment and Prioritization
Process Tool 05	Joint Quality Management Plans
Process Tool 05a	Provider Assessment Report Template
Process Tool 05b	Central Provider Assessments Tracking Table
Process Tool 05c	Project Provider Tracking Table
Process Tool 05d	Approved Provider List Table
Process Tool 05e	jQMP Template
Process Tool 06	Change Management Leading Practices
Process Tool 06a	Change Management Plan Template
Process Tool 06b	Organizational Change Management Presentation Template for a New QMS
Process Tool 07	Quality Audit Process
Process Tool 07a	Quality Audit Plan Template
Process Tool 07b	Quality Audit Agenda and Checklist
Process Tool 07c	Quality Audit Schedule Template
Process Tool 07d	Site Quality Audit Report Template
Process Tool 07e	Provider Quality Audit Report Template
<b>Number of Process Oversight Resources</b>	
	<b>48</b>

**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.

[Return to Top](#)

PROQ 01	Protocol Quality Review Checklist
PROQ 02	Leading Practices in Quality Protocol Development
PROQ 02a	Defining Meaningful Scientific Questions
PROQ 02b	Developing Rigorous Feasible Attractive Study Designs
PROQ 02c	Protocol Authoring with Functional Input
PROQ 02d	Protocol Review QC and Approval
PROQ 02e	Assess Implementation Experience and Measure Performance



# AQC Knowledge Center Catalog

Number of Protocol Quality Resources	7
--------------------------------------	---

**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.

[Return to Top](#)

PTEN 00	Patient Engagement Playbook
PTEN 00a	Business Objectives for Patient Engagement
PTEN 00b	Patient Engagement Reading List
PTEN 00c	Definitions and Considerations for Patient Engagement Strategy
PTEN 00d	Patient Engagement for Market and Scientific Strategy of Clinical Development Programs
PTEN 00e	Patient Engagement for Operational Strategy for Clinical Trials
PTEN 00f	Patient Engagement for Enhancement of Positive Public Perception
PTEN 00g	Timepoints of Entry for Patient Engagement
PTEN 00h	Patient Engagement from Patient Perspective
PTEN 01	Trial Participant Survey Guidance
PTEN 01a	Trial Participant Survey at Enrollment
PTEN 01b	Trial Participant Survey at Mid-Study
PTEN 01c	Trial Participant Survey at End of Study
PTEN 01d	Mock Survey Enrollment Report for Patients
PTEN 01e	Mock Survey Enrollment Report for Sites Sponsor CRO
PTEN 01f	Mock Survey End of Study Report for Patients
PTEN 01g	Mock Survey End of Study Report for Sites Sponsor CRO
PTEN 01h	Study Participant Letter
PTEN 02	Online Patient Communities What Why When How
PTEN 02a	Patient Insights and Benefits
PTEN 02b	Online Community Moderation Primer
PTEN 02c	Online Community Set Up Checklist
PTEN 02d	Online Focus Groups and Surveys
PTEN 02e	Virtual Patient Advisory Boards
PTEN 02f	Private Clinical Trial Communities
PTEN 02g	Trial Alumni Communities and Long Term Relationships
PTEN 03	Use of Disease Information and Clinical Trial Participation Opinion Surveys
PTEN 03a	Sample Disease Information Survey
PTEN 03b	Sample Clinical Trial Participation Opinion Survey
PTEN 04	Sample Patient Survey Objectives and Information for IRB Submission
PTEN 05	Evaluation Tool for Patient Centricity at Sites
PTEN 06	Evaluation Tool for Patient Centricity at Sponsor or CRO
PTEN 07	Patient Engagement Program Key Success Factors
PTEN 08	Leveraging Existing Real World Data to Design Patient Centric Clinical Trial Protocols
PTEN 09	Innovative Approaches to Patient-Centric Protocol Design

# AQC Knowledge Center Catalog

Number of Patient Engagement Resources	35
--	----

**Quality Agreement:** The Clinical Quality Agreement has been developed for use by The Avoca Group Quality Consortium. Clinical Quality Agreements may be composed for use at the project level, the program level, or the relationship level.

[Return to Top](#)

QAGR 01	AQC Quality Agreement Template
QAGR 02	Table of Contents and Acronyms
QAGR 03	Scope
QAGR 04	Standards
QAGR 04a	Standard Processes
QAGR 04b	Standards Review and Oversight
QAGR 05	Governance
QAGR 05a	Governance Benefits
QAGR 06	Communication
QAGR 07	Risk Management
QAGR 08	Protocol and Process Deviation
QAGR 09	Quality Metrics
QAGR 10	Selection and Training of Personnel
QAGR 11	Third Party Vendors and Suppliers
QAGR 12	Audits and Issue Resolution
QAGR 12a	Lead Auditor
QAGR 12b	SOPs and Findings Definitions
QAGR 12c	General Audit Strategy
QAGR 12d	Audits Initiated by CRO
QAGR 12e	Audits by Sponsor of CRO
QAGR 12f	Audit Follow Up
QAGR 12g	Audit of Sites by Sponsor
QAGR 13	Inspections
QAGR 13a	Inspection Readiness Plan
QAGR 13b	Unannounced Inspections
QAGR 13c	QA Support of Inspections
QAGR 13d	Inspection Follow Up
QAGR 14	Performance Control
QAGR 15	Biostatistics and Programming
QAGR 16	Data Management
QAGR 17	Investigator Selection and Training
QAGR 18	Investigator Site Watch and Deviation Management
QAGR 19	Medical Writing of Trial Documents
QAGR 20	Monitoring

# AQC Knowledge Center Catalog

<b>QAGR 21</b>	Pharmacovigilance
<b>Number of Quality Agreement Resources</b>	
<b>35</b>	

**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.

[Return to Top](#)

<b>QOMF 01</b>	Proactive Quality Oversight Management
<b>QOMF 02</b>	Avoca Quality Consortium Glossary
<b>Number of Quality Oversight Management Framework Resources</b>	
<b>2</b>	

**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.

[Return to Top](#)

<b>Risk Tool 00</b>	Proactive Risk and Opportunity Management Guideline
<b>Risk Tool 01</b>	Elements of Risk Management
<b>Risk Tool 02</b>	Elements of Opportunity Management
<b>Risk Tool 03</b>	Risk Management Tools
<b>Risk Tool 03a</b>	Risk Matrix with Instructions
<b>Risk Tool 03b</b>	FMECA Tool
<b>Risk Tool 03c</b>	Fault Tree Analysis Template
<b>Risk Tool 03d</b>	Risk Ranking and Filtering
<b>Risk Tool 03e</b>	Sample Risk Matrix
<b>Risk Tool 03f</b>	Risk Ranking Template
<b>Risk Tool 04</b>	Opportunity Matrix with Instructions
<b>Risk Tool 05</b>	Provider Risk Assessment and Mitigation
<b>Risk Tool 06</b>	Risk Assessment Control and Review
<b>Risk Tool 06a</b>	Risk Prevention and Detection Controls
<b>Risk Tool 06b</b>	Risk Plan with Bubble Plot
<b>Risk Tool 06c</b>	EMA Risk Identification Template
<b>Risk Tool 07</b>	Risk Management Plan Template
<b>Risk Tool 07a</b>	Risk Oversight Table
<b>Risk Tool 07b</b>	Key Risk Indicators and Central Statistical Monitoring
<b>Risk Tool 08</b>	Opportunity Management Plan Template
<b>Risk Tool 08a</b>	Opportunity Tracking Template
<b>Risk Tool 09</b>	Project Warning Signs and Recovery
<b>Risk Tool 09a</b>	Project Transition Practices

# AQC Knowledge Center Catalog

<b>Risk Tool 09b</b>	Project Transition Plan Template	
<b>Risk Tool 09c</b>	Project Recovery Plan Template	
<b>Risk Tool 10</b>	Measures of Risk and Opportunity Mgmt Success	
<b>Risk Tool 11</b>	Problems Risk Opportunities Dilemma	
<b>Risk Tool 12</b>	Risk Evaluation of Wearable Devices	
<b>Number of Proactive Risk/Opportunity Management Resources</b>		<b>28</b>

## Risk-based Quality Management:

[Return to Top](#)

<b>RBQM 02</b>	Centralized Monitoring Procedural Standards	
<b>Number of Risk-based Quality Management Resources</b>		<b>1</b>

**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.

[Return to Top](#)

<b>RnR Tool 00</b>	Roles and Responsibilities Guideline	
<b>RnR Tool 01</b>	Sourcing Models and Oversight	
<b>RnR Tool 02</b>	Core Competency	
<b>RnR Tool 03</b>	Core Competency Chart	
<b>RnR Tool 04</b>	Using RACI Charting and Analysis	
<b>RnR Tool 05</b>	Performance Management Initiatives for Outsourcing Oversight	
<b>RnR Tool 06</b>	Template RACI Chart	
<b>RnR Tool 07</b>	Leading Practices in Performance Measurement	
<b>RnR Tool 08</b>	SMART Goals	
<b>RnR Tool 09</b>	Provider Onboarding Template	
<b>RnR Tool 10</b>	Core Competency Decision Tool	
<b>Number of Roles/Responsibilities Resources</b>		<b>11</b>

**Site Quality:** The Avoca Quality Consortium (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. (See also Investigator Site Inspection Readiness leading practices (INSP 11-17)).

[Return to Top](#)

<b>SQMS 01</b>	Proactive Quality Framework for Sites - Quality Culture and Practices
<b>SQMS 02</b>	Introduction to Quality Management Systems for the Clinical Trial Site
<b>SQMS 03</b>	Proactive Quality Framework for Sites - Investigator Responsibilities
<b>SQMS 04</b>	Personnel Selection for the Trial
<b>SQMS 05</b>	Investigator Site Onboarding and Training of Trial Staff

## AQC Knowledge Center Catalog

<b>SQMS 05a</b>	Clinical Site Training Matrix
<b>SQMS 05b</b>	Site Staff Qualifications Assessment and Onboarding Plan
<b>SQMS 05c</b>	Site Staff Orientation Agenda and Schedule
<b>SQMS 05d</b>	Site Staff Training Plan
<b>SQMS 05e</b>	Site Staff Sample On-the-Job Training Form
<b>SQMS 05f</b>	Site Staff Training File Review Form
<b>SQMS 05g</b>	Site Staff Procedural Document Review Training Form
<b>SQMS 05h</b>	Site Staff Remote Training Attendance Form
<b>SQMS 05i</b>	Site Staff Group Training Attendee Form
<b>SQMS 05j</b>	Site Staff Protocol Training Form
<b>SQMS 05k</b>	Site Staff External Training
<b>SQMS 05l</b>	Investigator Site Staff Onboarding and Training Glossary
<b>SQMS 06</b>	Site and Team Management Tool: RACI Model
<b>SQMS 06a</b>	Sample Clinical Site RACI Chart
<b>SQMS 07</b>	Clinical Site Standard Operating Procedures Management Standards for SOP Development
<b>SQMS 07a</b>	Clinical Site SOP Management Log
<b>SQMS 08</b>	Clinical Site Investigator Trial Oversight-Supervision Procedural Document Standards
<b>SQMS 08a</b>	Clinical Site Investigator Trial Oversight Supervision Template
<b>SQMS 09</b>	Clinical Site Investigator Delegation of Duties and Tasks Procedural Document Standards for SOP and Policy Development
<b>SQMS 09a</b>	Clinical Site Investigator Master Delegation Matrix
<b>SQMS 10</b>	Clinical Site Source Document Management Procedural Standards for SOP and Policy Development
<b>SQMS 10a</b>	Clinical Site Source Document Location Log
<b>SQMS 11</b>	Clinical Site IP Mgmt Accountability Procedural Doc Standards for SOP and Policy Development
<b>SQMS 11a</b>	Clinical Site Investigational Product Temperature Log
<b>SQMS 12</b>	Clinical Site Handling of Protocol Amendments New Study Information Procedural Standards for SOP and Policy Development
<b>SQMS 12a</b>	Clinical Site Protocol Amendment Tracking Log
<b>SQMS 12b</b>	Clinical Site New Study Information Tracking Log
<b>SQMS 13</b>	Clinical Site Protocol Deviation Management Procedural Document Standards for SOP and Policy Development
<b>SQMS 13a</b>	Clinical Site Protocol Deviation Tracking Log
<b>SQMS 14</b>	Clinical Site Users of Electronic Systems Log Template
<b>SQMS 15</b>	Clinical Site Risk-based Quality Management of Informed Consent Process
<b>SQMS 15a</b>	Basic Clinical Site Informed Consent Process Illustration Tool
<b>SQMS 16</b>	Clinical Site Risk-based Quality Management of IRB and EC Responsibilities
<b>SQMS 16a</b>	Clinical Site IRB and EC Interaction Compliance Priorities Identification Tool
<b>SQMS 17</b>	Role of Audits and Inspections in Clinical Site Risk-based Quality Management
<b>SQMS 17a</b>	Clinical Site Guidelines for Internal Audits

## AQC Knowledge Center Catalog

<b>SQMS 17b</b>	Outline for Clinical Site Yearly Audit Plan
<b>SQMS 18</b>	Clinical Site Risk-based Quality Management of the Safety and Adverse Event Reporting Process
<b>SQMS 18a</b>	Clinical Site Adverse Event Definitions, Recording, and Reporting Requirements Tool
<b>SQMS 18b</b>	Clinical Site Adverse Event Log Template
<b>SQMS 19</b>	Clinical Site Risk-based Quality Management of Root Cause Analysis
<b>SQMS 22</b>	Overview Clinical Site Procedures and Policies Development Guide
<b>Number of Site Centricity Resources</b>	
	<b>47</b>

**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.

[Return to Top](#)

<b>Tech Tool 00</b>	Technical Oversight Guideline
<b>Tech Tool 01</b>	Core Oversight Practices
<b>Tech Tool 01a</b>	Provider Selection Rationale Template
<b>Tech Tool 01b</b>	Kick Off Meeting Agenda
<b>Tech Tool 01c</b>	Provider Oversight Plan Template
<b>Tech Tool 02</b>	Project Management Oversight
<b>Tech Tool 02a</b>	Project Management Status Report
<b>Tech Tool 03</b>	Study Start Up Oversight
<b>Tech Tool 03a</b>	Study Start Up Experience
<b>Tech Tool 03b</b>	Study Start Up Feedback
<b>Tech Tool 04</b>	Monitoring Oversight
<b>Tech Tool 04a</b>	Monitoring Experience
<b>Tech Tool 04b</b>	Monitoring Feedback
<b>Tech Tool 05</b>	Enrollment Oversight
<b>Tech Tool 05a</b>	Enrollment Experience
<b>Tech Tool 05b</b>	Enrollment Feedback
<b>Tech Tool 06</b>	Data Management Oversight
<b>Tech Tool 06a</b>	Data Management Experience
<b>Tech Tool 06b</b>	Data Management Feedback
<b>Tech Tool 07</b>	Biostatistics Oversight
<b>Tech Tool 07a</b>	Biostatistics Experience
<b>Tech Tool 07b</b>	Biostatistics Feedback
<b>Tech Tool 08</b>	Medical Writing Oversight
<b>Tech Tool 08a</b>	Medical Writing Experience
<b>Tech Tool 08b</b>	Medical Writing Feedback
<b>Tech Tool 09</b>	Regulatory Oversight
<b>Tech Tool 09a</b>	Regulatory Experience

## AQC Knowledge Center Catalog

<b>Tech Tool 10</b>	CTMS Oversight
<b>Tech Tool 11</b>	Third Party Organization Start Up and Oversight
<b>Tech Tool 12</b>	Central Lab Oversight
<b>Tech Tool 12a</b>	Central Lab Experience
<b>Tech Tool 12b</b>	Central Lab Feedback
<b>Tech Tool 13</b>	IxRS and IRT Provider Oversight
<b>Tech Tool 13a</b>	IxRS and IRT Experience
<b>Tech Tool 13b</b>	IxRS and IRT Feedback
<b>Tech Tool 14</b>	ECG Provider and Reader Oversight
<b>Tech Tool 14a</b>	ECG Provider and Reader Experience
<b>Tech Tool 14b</b>	ECG Provider and Reader Feedback
<b>Tech Tool 15</b>	Imaging Provider and Reader Oversight
<b>Tech Tool 15a</b>	Imaging Provider and Reader Experience
<b>Tech Tool 15b</b>	Imaging Provider and Reader Feedback
<b>Tech Tool 16</b>	Biomarker Lab Oversight
<b>Tech Tool 16a</b>	Biomarker Lab Experience
<b>Tech Tool 16b</b>	Biomarker Lab Feedback
<b>Tech Tool 17</b>	Clinical Supply Management Provider Oversight
<b>Tech Tool 17a</b>	Clinical Supply Experience
<b>Tech Tool 17b</b>	Clinical Supply Feedback
<b>Tech Tool 18</b>	TMF eTMF Oversight
<b>Tech Tool 18a</b>	TMF eTMF Industry and Regulatory Landscape
<b>Tech Tool 19</b>	Bioanalytical Lab Oversight
<b>Tech Tool 19a</b>	Bioanalytical Lab Experience
<b>Tech Tool 19b</b>	Bioanalytical Lab Feedback
<b>Tech Tool 20</b>	COA Provider Oversight
<b>Tech Tool 20a</b>	COA Experience
<b>Tech Tool 20b</b>	COA Feedback
<b>Tech Tool 21</b>	Pharmacovigilance Oversight
<b>Tech Tool 21a</b>	Pharmacovigilance Experience
<b>Tech Tool 21b</b>	Pharmacovigilance Feedback
<b>Tech Tool 22</b>	IDMC Oversight
<b>Tech Tool 22a</b>	IDMC Experience
<b>Tech Tool 22b</b>	IDMC Feedback
<b>Tech Tool 23</b>	Pt Recruitment Retention Oversight
<b>Tech Tool 23a</b>	Pt Recruit Retention Experience
<b>Tech Tool 23b</b>	Pt Recruit Retention Feedback
<b>Tech Tool 24</b>	Quality Assurance Audits Oversight
<b>Tech Tool 24a</b>	Quality Assurance Audit Experience
<b>Tech Tool 24b</b>	Quality Assurance Audit Feedback



## AQC Knowledge Center Catalog

<b>Tech Tool 25</b>	Clinical Trial Home Nursing Provider Oversight
<b>Tech Tool 25a</b>	Clinical Trial Home Nursing Provider Experience
<b>Tech Tool 25b</b>	Clinical Trial Home Nursing Provider Feedback
<b>Tech Tool 26</b>	Study Closeout Process Oversight
<b>Tech Tool 26a</b>	Study Closeout Study Level Checklist
<b>Tech Tool 26b</b>	Study Closeout Investigator Site Checklist
<b>Number of Technical Oversight Resources</b>	<b>73</b>

### Summary of Knowledge Center Resources

[Return to Top](#)

<b>Number of Communication Resources</b>	<b>32</b>
<b>Number of Governance/Organizational Construct Resources</b>	<b>36</b>
<b>Number of Inspection Resources</b>	<b>30</b>
<b>Number of Oversight Leadership Requirement Resources</b>	<b>17</b>
<b>Number of Metrics/Analytics/Technology Resources</b>	<b>26</b>
<b>Number of Oversight Capability Maturity Model Resources</b>	<b>15</b>
<b>Number of Prequalification Resources</b>	<b>52</b>
<b>Number of Process Oversight Resources</b>	<b>48</b>
<b>Number of Protocol Quality Resources</b>	<b>7</b>
<b>Number of Patient Engagement Resources</b>	<b>35</b>
<b>Number of Quality Agreement Resources</b>	<b>35</b>
<b>Number of Quality Oversight Management Framework Resources</b>	<b>2</b>
<b>Number of Proactive Risk/Opportunity Management Resources</b>	<b>28</b>
<b>Number of Risk-based Quality Management Resources</b>	<b>1</b>
<b>Number of Roles/Responsibilities Resources</b>	<b>11</b>
<b>Number of Site Quality Resources</b>	<b>47</b>
<b>Number of Technical Oversight Resources</b>	<b>73</b>
<b>Total Available Knowledge Center Resources:</b>	<b>495</b>

### New Documents in Development

[Return to Top](#)

<b>INSP 10</b>	Electronic Data Audit Trail Review Guide
<b>PQUAL 14</b>	Electronic Regulatory Binder Standards
<b>PQUAL 14a</b>	Electronic Regulatory Binder RFI Template
<b>PQUAL 14b</b>	Electronic Regulatory Binder Scorecard
<b>PQUAL 14c</b>	Electronic Regulatory Binder Visit Checklist

## AQC Knowledge Center Catalog

<b>PQUAL 15</b>	Electronic Informed Consent Standards
<b>PQUAL 15a</b>	Electronic Informed Consent RFI Template
<b>PQUAL 15b</b>	Electronic Informed Consent Scorecard
<b>PQUAL 15c</b>	Electronic Informed Consent Visit Checklist
<b>PQUAL 16</b>	Mobile Health Care Provider Visits Standards
<b>PQUAL 16a</b>	Mobile Health Care Provider Visits RFI Template
<b>PQUAL 16b</b>	Mobile Health Care Provider Visits Scorecard
<b>PQUAL 16c</b>	Mobile Health Care Provider Visits Visit Checklist
<b>PQUAL 17</b>	eHealth Records Standards for Patient Recruitment and Feasibility
<b>PQUAL 17a</b>	eHealth Records for Patient Recruitment and Feasibility RFI Template
<b>PQUAL 17b</b>	eHealth Records for Patient Recruitment and Feasibility Scorecard
<b>PQUAL 17c</b>	eHealth Records Patient Recruitment and Feasibility Visit Checklist
<b>PQUAL 18</b>	Electronic Health Records for eCRF Population and QC Standards
<b>PQUAL 18a</b>	Electronic Health Records for eCRF Population and QC RFI Template
<b>PQUAL 18b</b>	Electronic Health Records for eCRF Population and QC Scorecard
<b>PQUAL 18c</b>	Electronic Health Records for eCRF Population and QC Visit Checklist
<b>PQUAL 19</b>	Telemedicine Standards
<b>PQUAL 19a</b>	Telemedicine RFI Template
<b>PQUAL 19b</b>	Telemedicine Scorecard
<b>PQUAL 19c</b>	Telemedicine Visit Checklist
<b>PQUAL 20</b>	Actigraphy Motion Sensors Standards
<b>PQUAL 20a</b>	Actigraphy Motion Sensors RFI Template
<b>PQUAL 20b</b>	Actigraphy Motion Sensors Scorecard
<b>PQUAL 20c</b>	Actigraphy Motion Sensors Visit Checklist
<b>RBQM 01</b>	Development of a Risk-Based Monitoring Plan
<b>RBQM 01a</b>	Risk-based Monitoring Plan Template
<b>SQMS 21</b>	Clinical Investigator Tool List
<b>SQMS 23</b>	Clinical Site Highly Probable/High Impact Risks and Mitigation Options
<b>SQMS 24</b>	Clinical Site Risk Assessment Tool
<b>SQMS 25</b>	Clinical Site Risk Prevention and Detection Controls
<b>SQMS 26</b>	Clinical Site Risk Management Plan