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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.

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Comm Tool 00	Communication Guideline
Comm Tool 01	Communication Matrix
Comm Tool 02	Communication Management Plan
Comm Tool 03	Issue Escalation Process
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
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Comm Tool 14	Issue Log Template
Comm Tool 15	Leading Practices for Meetings
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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

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.

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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
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Gov Tool 07c	Project Risk Opportunity Template
Gov Tool 08	Decision Trees
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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

Gov Tool 22	Sourcing Models Definitions and Characteristics	
Governance/Organizational Construct Resources		**36**

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.

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

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.

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

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.

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Met Tool 00	Metrics/Analytics/Technology Guideline
Met Tool 01	Quality Metrics Taxonomy
Met Tool 03	Metrics Categories and Review Accountabilities
Met Tool 05	Decision Trees
Met Tool 06	Strategy Maps
Met Tool 07	Decision Biases
Met Tool 08	Summary Guide to Optimization
Met Tool 09	Data Visualization
Met Tool 10	Measurement Focus
Met Tool 11	KPI Development Worksheet
Met Tool 12	Metrics Planning

Met Tool 13	Cost Benefit Analysis
Met Tool 13a	Cost Benefit Analysis - Complex Example
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 Quality 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
Metrics/Analytics/Technology Resources	**26**

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.

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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
Oversight Capability Maturity Model Resources	**15**

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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 Avoca Quality Consortium.

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

PQUAL 09b	CRO Monitoring Scorecard Template
PQUAL 09c	CRO Monitoring Visit Checklist Template
PQUAL 10	CRO Data Management Standards
PQUAL 10a	CRO Data Management RFI Template
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PQUAL 10c	CRO Data Management Visit Checklist Template
PQUAL 11	CRO Biostatistics Standards
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PQUAL 11c	CRO 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
PQUAL 14	Electronic Regulatory Binder-eISF Standards
PQUAL 14a	Electronic Regulatory Binder-eISF RFI Template
PQUAL 14b	Electronic Regulatory Binder-eISF Scorecard Template
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PQUAL 15	eConsent Standards
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PQUAL 16	Mobile Health Care Provider Visits Standards
PQUAL 16a	Mobile Health Care Provider Visits RFI Template
PQUAL 16b	Mobile Health Care Provider Visits Visit Scorecard Template
PQUAL 16c	Mobile Health Care Provider Visits Visit Checklist Template
PQUAL 17	eHealth Records for Patient Recruitment and Feasibility Standards
PQUAL 17a	eHealth Records for Patient Recruitment and Feasibility RFI Template
PQUAL 17b	eHealth Records for Patient Recruitment and Feasibility Scorecard Template
PQUAL 17c	eHealth Records Patient Recruitment and Feasibility Visit Checklist Template
Provider Qualification Resources	**68**

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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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
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
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Process Tool 04h	QbD Leading Practices when Outsourcing
Process Tool 04i	QbD Provider Risk Assessment
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Process Tool 05	Joint Quality Management Plans
Process Tool 05a	Provider Assessment Report Template
Process Tool 05b	Central Provider Assessments Tracking Table
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Process Tool 05d	Approved Provider List Table
Process Tool 05e	jQMP (Joint Quality Management Plan) 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
Process Oversight Resources	**48**

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.

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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
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.

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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
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.

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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
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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
QAGR 21	Pharmacovigilance
Quality Agreement Resources	**35**

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.

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QOMF 01	Proactive Quality Oversight Management
QOMF 02	Avoca Quality Consortium Glossary
Quality Oversight Management Framework Resources	**2**

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.

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Risk Tool 00	Proactive Risk and Opportunity Management Guideline
Risk Tool 01	Elements of Risk Management
Risk Tool 02	Elements of Opportunity Management
Risk Tool 03	Risk Management Tools
Risk Tool 03a	Risk Matrix with Instructions

Risk Tool 03b	FMECA Tool
Risk Tool 03c	Fault Tree Analysis Template
Risk Tool 03d	Risk Ranking and Filtering
Risk Tool 03e	Sample Risk Matrix
Risk Tool 03f	Risk Ranking Template
Risk Tool 03g	Risk Matrix Template
Risk Tool 04	Opportunity Matrix with Instructions
Risk Tool 05	Provider Risk Assessment and Mitigation
Risk Tool 06	Risk Assessment Control and Review
Risk Tool 06a	Risk Prevention and Detection Controls
Risk Tool 06b	Risk Plan with Bubble Plot
Risk Tool 06c	EMA Risk Identification Template
Risk Tool 07	Risk Management Plan Template
Risk Tool 07a	Risk Oversight Table
Risk Tool 07b	Key Risk Indicators and Central Statistical Monitoring
Risk Tool 08	Opportunity Management Plan Template
Risk Tool 08a	Opportunity Tracking Template
Risk Tool 09	Project Warning Signs and Recovery
Risk Tool 09a	Project Transition Practices
Risk Tool 09b	Project Transition Plan Template
Risk Tool 09c	Project Recovery Plan Template
Risk Tool 10	Measures of Risk and Opportunity Mgmt Success
Risk Tool 11	Problems Risk Opportunities Dilemma
Risk Tool 12	Risk Evaluation of Wearable Devices
Proactive Risk/Opportunity Management Resources	**29**

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.

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RBQM 01	Development of a Risk-Based Monitoring Plan
RBQM 01a	Risk-Based Monitoring Plan Template
RBQM 01b	Risk-Based Monitoring Framework
RBQM 02	Centralized Monitoring Procedural Standards
Risk-Based Quality Management Resources	**4**

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.

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

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)).

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SQMS 01	Proactive Quality Framework for Sites - Quality Culture and Practices
SQMS 02	Introduction to Quality Management Systems for the Clinical Trial Site
SQMS 03	Proactive Quality Framework for Sites - Investigator Responsibilities
SQMS 04	Personnel Selection for the Trial
SQMS 05	Investigator Site Onboarding and Training of Trial Staff
SQMS 05a	Clinical Site Training Matrix
SQMS 05b	Site Staff Qualifications Assessment and Onboarding Plan
SQMS 05c	Site Staff Orientation Agenda and Schedule
SQMS 05d	Site Staff Training Plan
SQMS 05e	Site Staff Sample On-the-Job Training Form
SQMS 05f	Site Staff Training File Review Form
SQMS 05g	Site Staff Procedural Document Review Training Form
SQMS 05h	Site Staff Remote Training Attendance Form
SQMS 05i	Site Staff Group Training Attendee Form
SQMS 05j	Site Staff Protocol Training Form
SQMS 05k	Site Staff External Training
SQMS 05l	Investigator Site Staff Onboarding and Training Glossary
SQMS 06	Site and Team Management Tool: RACI Model
SQMS 06a	Sample Clinical Site RACI Chart
SQMS 07	Clinical Site Standard Operating Procedures Management Standards for SOP Development
SQMS 07a	Clinical Site SOP Management Log

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SQMS 08	Clinical Site Investigator Trial Oversight-Supervision Procedural Document Standards
SQMS 08a	Clinical Site Investigator Trial Oversight Supervision Template
SQMS 09	Clinical Site Investigator Delegation of Duties and Tasks Procedural Document Standards for SOP and Policy Development
SQMS 09a	Clinical Site Investigator Master Delegation Matrix
SQMS 10	Clinical Site Source Document Management Procedural Standards for SOP and Policy Development
SQMS 10a	Clinical Site Source Document Location Log
SQMS 11	Clinical Site IP Mgmt Accountability Procedural Doc Standards for SOP and Policy Development
SQMS 11a	Clinical Site Investigational Product Temperature Log
SQMS 12	Clinical Site Handling of Protocol Amendments New Study Information Procedural Standards for SOP and Policy Development
SQMS 12a	Clinical Site Protocol Amendment Tracking Log
SQMS 12b	Clinical Site New Study Information Tracking Log
SQMS 13	Clinical Site Protocol Deviation Management Procedural Document Standards for SOP and Policy Development
SQMS 13a	Clinical Site Protocol Deviation Tracking Log
SQMS 14	Clinical Site Users of Electronic Systems Log Template
SQMS 15	Clinical Site Risk-based Quality Management of Informed Consent Process
SQMS 15a	Basic Clinical Site Informed Consent Process Illustration Tool
SQMS 16	Clinical Site Risk-based Quality Management of IRB and EC Responsibilities
SQMS 16a	Clinical Site IRB and EC Interaction Compliance Priorities Identification Tool
SQMS 17	Role of Audits and Inspections in Clinical Site Risk-based Quality Management
SQMS 17a	Clinical Site Guidelines for Internal Audits
SQMS 17b	Outline for Clinical Site Yearly Audit Plan
SQMS 18	Clinical Site Risk-based Quality Management of the Safety and Adverse Event Reporting Process
SQMS 18a	Clinical Site Adverse Event Definitions, Recording, and Reporting Requirements Tool
SQMS 18b	Clinical Site Adverse Event Log Template
SQMS 19	Clinical Site Risk-based Quality Management of Root Cause Analysis
SQMS 22	Overview Clinical Site Procedures and Policies Development Guide
SQMS 24	Clinical Site Risk Assessment Tools
SQMS 25	Clinical Site Risk Prevention and Detection Controls
SQMS 26	Clinical Site Risk Management Plan Template
SQMS 27	Site Quality Agreement Template
SQMS 28	Clinical Site Risk and Issues Triggers
Site Centricity Resources	**52**

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.

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Tech Tool 00	Technical Oversight Guideline
Tech Tool 01	Core Oversight Practices
Tech Tool 01a	Provider Selection Rationale Template
Tech Tool 01b	Kick Off Meeting Agenda
Tech Tool 01c	Provider Oversight Plan Template
Tech Tool 02	Project Management Oversight
Tech Tool 02a	Project Management Status Report
Tech Tool 03	Study Start Up Oversight
Tech Tool 03a	Study Start Up Experience
Tech Tool 03b	Study Start Up Feedback
Tech Tool 04	Monitoring Oversight
Tech Tool 04a	Monitoring Experience
Tech Tool 04b	Monitoring Feedback
Tech Tool 05	Enrollment Oversight
Tech Tool 05a	Enrollment Experience
Tech Tool 05b	Enrollment Feedback
Tech Tool 06	Data Management Oversight
Tech Tool 06a	Data Management Experience
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Tech Tool 07	Biostatistics Oversight
Tech Tool 07a	Biostatistics Experience
Tech Tool 07b	Biostatistics Feedback
Tech Tool 08	Medical Writing Oversight
Tech Tool 08a	Medical Writing Experience
Tech Tool 08b	Medical Writing Feedback
Tech Tool 09	Regulatory Oversight
Tech Tool 09a	Regulatory Experience
Tech Tool 10	CTMS Oversight
Tech Tool 11	Third Party Organization Start Up and Oversight
Tech Tool 12	Central Lab Oversight
Tech Tool 12a	Central Lab Experience
Tech Tool 12b	Central Lab Feedback
Tech Tool 13	IxRS and IRT Provider Oversight
Tech Tool 13a	IxRS and IRT Experience
Tech Tool 13b	IxRS and IRT Feedback
Tech Tool 14	ECG Provider and Reader Oversight

Tech Tool 14a	ECG Provider and Reader Experience
Tech Tool 14b	ECG Provider and Reader Feedback
Tech Tool 15	Imaging Provider and Reader Oversight
Tech Tool 15a	Imaging Provider and Reader Experience
Tech Tool 15b	Imaging Provider and Reader Feedback
Tech Tool 16	Biomarker Lab Oversight
Tech Tool 16a	Biomarker Lab Experience
Tech Tool 16b	Biomarker Lab Feedback
Tech Tool 17	Clinical Supply Management Provider Oversight
Tech Tool 17a	Clinical Supply Experience
Tech Tool 17b	Clinical Supply Feedback
Tech Tool 18	TMF eTMF Oversight
Tech Tool 18a	TMF eTMF Industry and Regulatory Landscape
Tech Tool 19	Bioanalytical Lab Oversight
Tech Tool 19a	Bioanalytical Lab Experience
Tech Tool 19b	Bioanalytical Lab Feedback
Tech Tool 20	COA Provider Oversight
Tech Tool 20a	COA Experience
Tech Tool 20b	COA Feedback
Tech Tool 21	Pharmacovigilance Oversight
Tech Tool 21a	Pharmacovigilance Experience
Tech Tool 21b	Pharmacovigilance Feedback
Tech Tool 22	IDMC Oversight
Tech Tool 22a	IDMC Experience
Tech Tool 22b	IDMC Feedback
Tech Tool 23	Pt Recruitment Retention Oversight
Tech Tool 23a	Pt Recruit Retention Experience
Tech Tool 23b	Pt Recruit Retention Feedback
Tech Tool 24	Quality Assurance Audits Oversight
Tech Tool 24a	Quality Assurance Audit Experience
Tech Tool 24b	Quality Assurance Audit Feedback
Tech Tool 25	Clinical Trial Home Nursing Provider Oversight
Tech Tool 25a	Clinical Trial Home Nursing Provider Experience
Tech Tool 25b	Clinical Trial Home Nursing Provider Feedback
Tech Tool 26	Study Closeout Process Oversight
Tech Tool 26a	Study Closeout Study Level Checklist
Tech Tool 26b	Study Closeout Investigator Site Checklist
Technical Oversight Resources	**73**

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Summary of Knowledge Center Resources

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Category of Leading Practices/Resources	Total Number
Communication	32
Governance/Organizational Construct	36
Inspection	30
Oversight Leadership	17
Metrics/Analytics/Technology	26
Oversight Capability Maturity Model	15
Provider Qualification	68
Process Oversight	48
Protocol Quality	7
Patient Engagement	35
Quality Agreement	35
Quality Oversight Management Framework	2
Proactive Risk and Opportunity Management	29
Risk-Based Quality Management	4
Roles/Responsibilities	11
Site Quality	52
Technical Oversight	73
Total Available Knowledge Center Resources:	**520**

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New Documents in Development	
PQUAL 18	eTMF Standards
PQUAL 18a	eTMF RFI Template
PQUAL 18b	eTMF Scorecard Template
PQUAL 18c	eTMF Checklist Template
PQUAL 19	Telemedicine Standards
PQUAL 19a	Telemedicine RFI Template
PQUAL 19b	Telemedicine Scorecard Template
PQUAL 19c	Telemedicine Visit Checklist Template
PQUAL 20	Actigraphy Motion Sensors Standards
PQUAL 20a	Actigraphy Motion Sensors RFI Template
PQUAL 20b	Actigraphy Motion Sensors Scorecard Template
PQUAL 20c	Actigraphy Motion Sensors Visit Checklist Template
PQUAL 21	Electronic Data Pipes Standards
PQUAL 21a	Electronic Data Pipes RFI Template
PQUAL 21b	Electronic Data Pipes Scorecard Template
PQUAL 21c	Electronic Data Pipes Checklist Template
RBQM 03	Subject Data Sampling Methods for Risk-Based Monitoring
SQMS 21	Clinical Investigator Tool List