Avoca Quality Consortium
Knowledge Center Catalog

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Advance to Specific Categories: Communication | Governance/Organization Construct | Inspection | Issue Management | Leadership | Medical Device | Metric Toolkits | Oversight Capability Maturity Model| Pharmacovigilance | 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.

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Comm Tool 00	Communication Guideline
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Comm Tool 17	Governance Meeting Constructs and Agenda
Comm Tool 20	Setting Expectations Worksheet
Comm Tool 22	Active Lessons Learned Process and Database Construct
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Comm Tool 25	Active Lessons Learned Project Review Meeting Template
Comm Tool 26	Active Lessons Learned Review Meeting Facilitator Guide
Communication Resources	**17**

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 24	Metrics Analytics Optimization
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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 Overview
INSP 02	Inspection Readiness 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 09	QMS Annual Compliance Assessment Plan Process
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INSP 11	Investigator Site Inspector Logistics and Coordination Tool
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INSP 19	Inspection Response Guide
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INSP 25	Clinical Data Flow Tool
INSP 26a	ICH E6(R2) and ICH E6(R3) Comparison
INSP 26b	ICH E6(R3)Draft and E6(R3) Final Comparison
INSPA 00	IR Agency Resource and Member Experience
INSPA 00a	Acronyms Inspection Readiness Agency Resource Documents
INSPA 01	Member Experience Overview
INSPA 01a	Remote Inspection Focus Group - Feb 2021
INSPA 01b	eTMF Inspection Focus Group Executive Summary
INSPA 01c	FDA Member Experience
INSPA 01d	MHRA Member Experience
INSPA 01e	Health Canada Inspection Focus Group - March 2022
INSPA 01f	Swissmedic Inspection Focus Group – April 2022
INSPA 01g	EMA Inspection Focus Group – September 2022
INSPA 01h	PMDA Member Experience
INSPA 02	USA FDA Inspection Readiness Agency Resource
INSPA 03	UK MHRA Inspection Readiness Resource
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INSPA 05	China NMPA Inspection Readiness Resource
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Inspection Resources	**43**

Issue Management: A robust issue management process is critical to detect, document, report, and address non-compliance and prevent recurrence.

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ISM 02	Issue Management Process Flow
ISM 03	Issue Log Template
ISM 04	Root Cause Analysis Leading Practices
ISM Tool 00	Issue Management Toolkit
Issue Management Resources	**unique, not referenced elsewhere - 3**

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 03	Balanced vs Micromanagement
Lead Tool 04	Leadership Styles
Lead Tool 05	The Six Leadership Styles at a Glance
Lead Tool 06	Leadership Characteristics of Vendor Oversight Team
Lead Tool 07	AAAA Framework
Lead Tool 10	Vendor Oversight Interviewing Template
Lead Tool 14	Fostering a Culture of Quality in Clinical Research
Oversight Leadership Requirement Resources	**8**

Medical Device: Leading practices for the design and development of Medical Devices or Combination Products that have a device constituent.

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MedDev 01	Design Control Requirements
MedDev 01a	Design and Development Plan
MedDev 01aT	Design and Development Plan Template
MedDev 01b	User Needs
MedDev 01bT	User Needs Document Template
MedDev 01c	Design Input Requirements
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MedDev 01d	Design Output Requirements
MedDev 01e	Design Verification
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MedDev 01g	Design Transfer Requirements
MedDev 01gT	Design Transfer Template
MedDev 01h	Design Reviews
MedDev 01hT	Design Review Template
MedDev 01i	Design History File – Design and Development File
MedDev 01iT	Design History File – Design and Development File Template
MedDev 02	Medical Device Risk Management Requirements
MedDev 02a	Medical Device Risk Management Plan
MedDev 02aT	Medical Device Risk Management Plan Template
MedDev 02b	Medical Device Risk Assessment
MedDev 02bT	Medical Device Risk Assessment Template
MedDev 02c	Medical Device Assessment – Failure Modes Effects Analysis
MedDev 02cT	Medical Device Assessment – Failure Mode Effects Analysis Template
MedDev 02d	Medical Device Risk Management Report
MedDev 02dT	Medical Device Risk Management Report Template
MedDev 03	Medical Device Management Responsibility
MedDev 03a	Medical Device Management Review
MedDev 03aT	Medical Device Management Review Template
MedDev 03T	Medical Device Quality Manual Template
Med Dev Resources	**29**

Metric Toolkits: 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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CL Tool 00	Central Labs Toolkit
CoPQ Tool 00	Cost of Poor Quality Estimator Toolkit
CP Tool 00	Cardiopulmonary Toolkit
CSMP Tool 00	Centralized and Site Monitoring Process Monitoring Metrics Toolkit
DMBios Tool 00	Data Management, Biostats and Medical Writing Toolkit
DS Tool 01	Drug Supply Metrics
DTP Tool 00	Direct to Participant Metrics
eCOA Tool 00	eCOA Metrics Toolkit

HH Tool 00	Home Healthcare Toolkit
IMG Tool 00	Imaging Toolkit
ISM Tool 00	Issue Management Toolkit
Metric Tool 00	Metric Master File Toolkit
PM Tool 01	Protocol Metrics
PVS Tool 00	Pharmacovigilance and Safety Toolkit
SAM Tool 00	Site Activation Milestone Toolkit
SC Tool 00	Site Contracting Toolkit
SED Tool 00	Screening, Enrollment and Discontinuation Toolkit
SGP Tool 00	Site Generated Performance Toolkit
SQMM Tool 00	Site Quality Management Toolkit
SSERR Tool 00	Site Selection, Ethics, Regulatory Review Toolkit
TMF Tool 00	TMF Process Toolkit
VOF Tool 00	Vendor Oversight Finance Toolkit
VOQ Tool 00	Vendor Oversight Quality Toolkit
VOR Tool 00	Vendor Oversight Relationship Assessment Toolkit
VOT Tool 00	Vendor Oversight Timeliness Metrics Toolkit
Metrics Toolkits	**25**

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 01	Oversight Capability Maturity Model
OCMM 02	Oversight Capability Maturity Model Overview
OCMM 03	Virtual and Lean Models for Oversight
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Pharmacovigilance: A compilation of Pharmacovigilance related tools to assist in qualifying PV providers, establishing a working agreement, and ensuring appropriate safety reporting. These materials have been developed based on regulations and guidance or have become leading practices based on contributions and advisement from the Avoca Quality Consortium contributing members and WCG Avoca Subject Matter Experts.

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PVSF 01	Pharmacovigilance Agreement Template
PQUAL 23	CRO Pharmacovigilance Standards

PQUAL 23a	CRO Pharmacovigilance RFI Template
PQUAL 23b	CRO Pharmacovigilance Scorecard Template
PQUAL 23c	CRO Pharmacovigilance Visit Checklist Template
Pharmacovigilance Resources	**1***

*Total without duplicates sitting also in other sections

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
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PQUAL 03	Bioanalytical Laboratory Standards
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PQUAL 04	Biomarker Laboratory Standards
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PQUAL 05	IRT Service Provider Standards
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PQUAL 06	ECG Provider Standards
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PQUAL 06c	ECG Visit Checklist Template
PQUAL 07	Medical Imaging Service Provider Standards
PQUAL 07a	Medical Imaging Service Provider RFI Template

PQUAL 07b	Medical Imaging Scorecard Template
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PQUAL 08	COA and eCOA Provider Standards
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PQUAL 08b	COA and eCOA Provider Scorecard Template
PQUAL 08c	COA and eCOA Provider Visit Checklist Template
PQUAL 09	CRO Monitoring Standards
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PQUAL 13	Phase I Clinical Research Unit Standards
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PQUAL 14	Electronic Regulatory Binders eISF Standards
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PQUAL 15	eConsent Standards
PQUAL 15a	eConsent RFI Template
PQUAL 15b	eConsent Scorecard Template
PQUAL 15c	eConsent Visit Checklist Template
PQUAL 16	Mobile Health Care Provider Visits Standards
PQUAL 16a	Mobile Health Care Provider Visits RFI Template
PQUAL 16b	Mobile Health Care Provider Visit Scorecard Template
PQUAL 16c	Mobile Health Care Provider Visits Visit Checklist Template
PQUAL 17	eHealth Record for Patient Recruitment and Feasibility Standards

PQUAL 17a	eHealth Record for Patient Recruitment and Feasibility RFI Template
PQUAL 17b	eHealth Record for Patient Recruitment and Feasibility Scorecard Template
PQUAL 17c	eHealth Record Patient Recruitment and Feasibility Visit Checklist Template
PQUAL 18	TMF Standards
PQUAL 18a	TMF RFI Template
PQUAL 18b	TMF Scorecard Template
PQUAL 18c	TMF Visit Checklist Template
PQUAL 19	Telemedicine Telehealth Standards
PQUAL 19a	Telemedicine Telehealth RFI Template
PQUAL 19b	Telemedicine Telehealth Scorecard Template
PQUAL 19c	Telemedicine Telehealth Visit Checklist Template
PQUAL 20	General Digital Health Technology Standards
PQUAL 20a	General Digital Health Technology RFI Template
PQUAL 20b	General Digital Health Technology Scorecard Template
PQUAL 20c	General Digital Health Technology Visit Checklist
PQUAL 21	eHealth Record to EDC Connector Apps Standards
PQUAL 21a	eHealth Record to EDC Connector Apps RFI Template
PQUAL 21b	eHealth Record to EDC Connector Apps Scorecard Template
PQUAL 21c	eHealth Record to EDC Connector Apps Checklist Template
PQUAL 23	CRO Pharmacovigilance Standards
PQUAL 23a	CRO Pharmacovigilance RFI Template
PQUAL 23b	CRO Pharmacovigilance Scorecard Template
PQUAL 23c	CRO Pharmacovigilance Visit Checklist Template
PQUAL 24	CRO Investigator Site Budget Contract Payment Standards
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PQUAL 24c	CRO Investigator Site Budget Contract Payment Visit Checklist Template
PQUAL 26	Provider Selection Rationale Template
PQUAL 27	High Level CRO Qualification Scorecard
PQUAL 28	Provider Assessment Report Template
PQUAL 29	Central Provider Assessments Tracking Table
PQUAL 30	Approved Provider List Table
PQUAL 31	Provider Qualification and Selection
PQUAL 32	Participant Feasibility Recruitment Retention Standards
PQUAL 32a	Participant Feasibility Recruitment Retention RFI Template
PQUAL 32b	Participant Feasibility Recruitment Retention Scorecard Template
PQUAL 32c	Participant Feasibility Recruitment Retention Visit Checklist
PQUAL 33	Investigational Product Management Standards
PQUAL 33a	Investigational Product Management RFI

PQUAL 33b	Investigational Product Management Score Card Template
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PQUAL 36	CRO Project Management Standards
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PQUAL 39b	Electronic Data Capture Scorecard Template
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PQUAL 40	CRO Medical Monitoring Standards
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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 03	Process Document Control
Process Tool 03b	Joint Process Development
Process Tool 03e	Process Development Document
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Process Tool 03g	Lean and Kaizen Events
Process Tool 05e	Joint Quality Management Plan
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 Tool 08	Functional Service Provider Quality Oversight Plan
Process Tool 09	Kick Off Meeting Agenda
Process Tool 10	Study Closeout Study Level Checklist
Process Tool 11	Study Closeout Investigator Site Checklist
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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 00b	Patient Engagement Reading List
PTEN 00c	Definitions and Considerations for Patient Engagement Strategy
PTEN 00d	Business Objectives for Patient Engagement
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 09	Innovative Approaches to Patient-Centric Protocol Design
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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
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
QAGR 21	Pharmacovigilance
QAGR 22	Essential Documents/Trial Master File (TMF)
Quality Agreement Resources	**36**

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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INNO 01	DCT Risk Evaluation	
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	
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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	Considerations for Development of the Monitoring Plan	
RBQM 03	Participant Data Sampling Methods for Risk Based Source Data Monitoring	
RBQM 06	Risk Management Plan (RMP) Template	
RBQM 07	Provider Risk Rating and Comparison Workbook	
RBQM 08	Study Risk Assessment Template	
RBQM 08a	Study Risk Assessment Example Entries	
RBQM 09	Specifications for Risk-based Systems for Digital Oversight of Risk	
RBQM 10	Risk-Based Trial Master File (TMF) Review	
RBQM 12	Centralized Monitoring Guide	
RBQM 13	ICH E8 R1 RBQM Change Toolkit	
RBQM 14	RBQM in Data Management SOPs and Data Management Plan	
RBQM 16	Key Risk Indicators (KRI) Guidance Document	
RBQM 17	CTQ Guidance	
RBQM 18	QbD_RBQM Overview	
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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 04	RACI Analysis and Template
RnR Tool 05	Performance Management Initiatives for Outsourcing Oversight
RnR Tool 07	Personnel Performance Measurement
RnR Tool 08	SMART Goals
RnR Tool 09	Service Provider Onboarding Template
RnR Tool 10	Core Competency Decision Tool
RnR Tool 11	Task Ownership Matrix
RnR Tool 12	Transfer of Obligations
RnR Tool 13	Role-Based Transition Plan Template
RnR Tool 14	Service Provider Oversight Plan Template
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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 AQC Investigator Site Quality Management System construct. (See also Investigator Site Inspection Readiness leading practices. (INSP 11, 13, 16, 17)

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IQUAL 01	Investigator Site Qualification Standards
SDEI 01	Clinical Research Site Diversity, Equity, and Inclusion Standards
SFS 01	Clinical Research Site Feasibility and Selection Solution Overview
SFS 01a	Clinical Research Site Profile Content Standard
SFS 01b	Site Diversity Profile Form
SFS 01c	Trial Specific Interest and Feasibility Form
SFS 01d	Virtual Site Tour Content Checklist
SFS 01e	Use of Virtual Site Tours and Videoconferencing-Telephone Capabilities
SQMS 01	QMS Framework for Sites
SQMS 03	Proactive Quality Framework for Sites - Investigator Responsibilities
SQMS 04	Investigator Site Personnel Onboarding Training and Selection to a Study Team

SQMS 05a	Clinical Site Investigator Master Delegation and Training Matrix
SQMS 05b	Site Staff Qualifications Assessment, Onboarding, Training Plans and Documentation
SQMS 05c	Site Staff Orientation Agenda and Schedule
SQMS 05f	Site Staff Training File Review Form
SQMS 06	Site and Team Management Tool RACI Model
SQMS 06a	Sample Clinical Site RACI Chart
SQMS 07	Clinical Site Standard Operating Procedure Development and Management
SQMS 07a	Clinical Site SOP Management Log
SQMS 08	Clinical Site Investigator Trial Oversight Standards
SQMS 08a	Clinical Site Investigator Trial Oversight Template
SQMS 10	Clinical Site Source Record Management Standards
SQMS 10a	Clinical Site Source Record Location Log
SQMS 11	Clinical Site Investigational Product Management Standards
SQMS 11a	Clinical Site Investigational Product Temperature Log
SQMS 12	Clinical Site Protocol Amendments and New Study Information Standards
SQMS 12a	Clinical Site Protocol Amendments and New Study Information Tracking Log
SQMS 13	Clinical Site Protocol Deviation Management Standards
SQMS 13a	Clinical Site Protocol Deviation Tracking Log
SQMS 14	Clinical Site Users of Electronic Systems Log Template
SQMS 15	Clinical Site Informed Consent Process Guidelines
SQMS 17	Role of Audits and Inspections in Clinical Site Quality Management (QMS)
SQMS 17a	Clinical Site Guidelines for Internal Audits
SQMS 17b	Outline for Clinical Site Yearly Audit Plan
SQMS 18	Clinical Site Safety and Adverse Event Reporting Process
SQMS 18b	Clinical Site Adverse Event Log Template
SQMS 20	Business Impact Analysis Template
SQMS 21	Business Continuity Plan Template
SQMS 23	Clinical Research Site General Role Ladder, Profile, and Training Resource
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
SQMS 29	Clinical Site Communication Plan Template
SQMS 30	Site FAQ Reference Document
SQMS 32	Site Study Team Meetings Agenda and Minutes Template
SQMS 33	Site Protocol Transition Form for Change in Research Coordinator
SQMS 34	Site SOP Abbreviations and Glossary
SQMS 35	General Administration SOP - Site GA-100
SQMS 36	Regulatory Affairs SOP - Site RA-200

SQMS 37	Project Management SOP - Site PM-300
SQMS 38	Trial Participant Management SOP - Site TPM-400
SQMS 39	Data Management SOP - Site DM-500
SQMS 40	Quality Assurance SOP - Site QA-600
SQMS 41	Site SOP Related Resources
SQMS 42	Evaluating Computerized Systems and Electronic Tools
SQMS 42a	eISF Implementation Guide
SQMS 43	Principal Investigator Oversight Responsibilities and Plan Template for Decentralized Clinical Trials
SQMS 44	Evaluating a Protocol and its Impact on Operations and Potential Participants at an Investigator Site
SQMS 45	Guidance for Instructing Participants on the Completion of Trial-Required Records
SQMS 45a	Participant PRO Checklist
SQMS 48	Site Study Diversity Action Plan Template
Site Quality Resources	**62**

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 01	Core Oversight Practices
Tech Tool 02	Project Management Oversight
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
Tech Tool 06b	Data Management Feedback
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 12	Central Laboratory Oversight
Tech Tool 12a	Central Laboratory Experience
Tech Tool 12b	Central Laboratory Feedback
Tech Tool 13	IRT Provider Oversight
Tech Tool 13a	IRT Experience
Tech Tool 13b	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	Medical Imaging Provider and Reader Oversight
Tech Tool 15a	Medical Imaging Provider and Reader Experience
Tech Tool 15b	Medical Imaging Provider and Reader Feedback
Tech Tool 16	Biomarker Laboratory Oversight
Tech Tool 16a	Biomarker Laboratory Experience
Tech Tool 16b	Biomarker Laboratory 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 Oversight
Tech Tool 19	Bioanalytical Laboratory Oversight
Tech Tool 19a	Bioanalytical Laboratory Experience
Tech Tool 19b	Bioanalytical Laboratory Feedback
Tech Tool 20	COA-eCOA and DHT Provider Oversight Provider Oversight
Tech Tool 20a	COA-eCOA and DHT Experience
Tech Tool 20b	COA-eCOA and 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	Participant Recruitment and Retention Oversight
Tech Tool 23a	Participant Recruitment and Retention Experience

Tech Tool 23b	Participant Recruitment and 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	Mobile Healthcare Provider Oversight
Tech Tool 25a	Mobile Healthcare Provider Experience
Tech Tool 25b	Mobile Healthcare Provider Feedback
Technical Oversight Resources	**63**

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Summary of Knowledge Center Resources	
Category of Leading Practices/Resources	**Total Number**
Communication	17
Governance/Organizational Construct	18
Inspection	45
Issue Management	3
Oversight Leadership	8
Medical Device	29
Metrics Toolkits	25
Oversight Capability Maturity Model	3
Pharmacovigilance	1
Provider Qualification	124
Process Oversight	21
Protocol Quality	7
Patient Engagement	31
Quality Agreement	36
Quality Oversight Management Framework	2
Proactive Risk and Opportunity Management	8
Risk-Based Quality Management	15
Roles/Responsibilities	13
Site Quality	62
Technical Oversight	63
Total Available Knowledge Center Resources:	**531**

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New Documents in Development	
ISM 05	Issue Management Escalation Pathways
ISM 06	Issue Management Decision Trees
ISM 07	Effectiveness Checks Leading Practice
ISM 08	Issue Management Framework
RBQM 15	Risk-based Approaches for Audits
RBQM 15a	Risk-based Audit Selection Tool
RBQM 15b	Process Maturity Scorecard
SQMS 46	Site Source Document Creation Guidance and AQC Template Listing
SQMS 47	Site Remediation Plan Template