Avoca Quality Consortium

Knowledge Center Catalog

Advance to Specific Categories: Communication | Governance/Organization Construct | Inspection | Issue Management | Leadership | Metrics/Analytics/Technology | 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
Comm Tool 01	Communication Management Plan
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Communication Resources	**18**

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
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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	Sponsor and CRO Inspection Readiness Dashboard
INSP 02a	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
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INSP 07c	Assessment of Resources and Process Operations
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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	Investigator Site Inspection Preparation Interview Question Template
INSP 14	Investigator Site Inspection Logistics and Coordination Tool
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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
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INSP 22	MHRA Blog Sponsor Oversight
INSP 23	AQC Quality Management System
INSP 24	Remote Inspection Tips for Logistics and Interviews
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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 Inspection Focus Group - October 2021
INSPA 01d	MHRA Inspection Focus Group - November 2021
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 Inspection Focus Group - 2023
INSPA 02	USA FDA Inspection Readiness Agency Resource
INSPA 03	UK MHRA Inspection Readiness Resource
INSPA 04	EU EMA Inspection Readiness Resource
INSPA 05	China NMPA Inspection Readiness Resource
INSPA 06	Japan PMDA Inspection Readiness Agency Resource
INSPA 07	Health Canada Inspection Readiness Resource
Inspection Resources	**59**

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 Tool 00	Issue Management Toolkit
ISM Tool 00a	Issue Management Process Metrics Toolkit Overview and Implementation Guide
ISM Tool 00b	Issue Management Process Metrics Toolkit Overview Slides
ISM Tool 00c	Issue Management Process Map with Metrics
ISM Tool 01	Issue Management Process Metrics Workbook
ISM Tool A	Issue Management Process Key Performance Questions to Metrics
ISM Tool B	Issue Management Process Issues to Metrics
ISM Tool C	Issue Management Process Basic Advanced Metrics to Data Elements
ISM Tool D	Issue Management Process Data Elements to Metrics
ISM Tool E	Issue Management Process Metrics Reporting Planning Worksheet
Process Tool 03h	Root Cause Analysis
Process Tool 03i	Root Cause Analysis Fishbone Diagram Template
Issue Management Resources	**11***

*Total without duplicates sitting also in other sections

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	Culture of Quality
Oversight Leadership Requirement Resources	**8**

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 and Oversight Metric Taxonomy
Met Tool 06	Strategy Maps
Met Tool 11	Development Worksheet for Special Metric Short Lists
Met Tool 18	Metrics Plan Thought Map
Met Tool 20	Metric Dashboard Example: Balanced Scorecard
Met Tool 21	AQC Catalog of Quality and Oversight Metrics
Met Tool 22	Organizational Metrics Curriculum
Metrics/Analytics/Technology Resources	**8**

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
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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**

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

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
PQUAL 03b	Bioanalytical Lab Scorecard Template
PQUAL 03c	Bioanalytical Lab Visit Checklist Template
PQUAL 04	Biomarker Lab Standards
PQUAL 04a	Biomarker Lab RFI Template
PQUAL 04b	Biomarker Lab Scorecard Template
PQUAL 04c	Biomarker Lab Visit Checklist Template
PQUAL 05	IxRS Provider Standards
PQUAL 05a	IxRS RFI Template
PQUAL 05b	IxRS Scorecard Template
PQUAL 05c	IxRS Visit Checklist Template
PQUAL 06	ECG Provider Standards
PQUAL 06a	ECG RFI Template
PQUAL 06b	ECG Scorecard Template
PQUAL 06c	ECG Visit Checklist Template
PQUAL 07	Medical Imaging Provider Standards
PQUAL 07a	Medical Imaging RFI Template
PQUAL 07b	Medical Imaging Scorecard Template
PQUAL 07c	Medical Imaging Visit Checklist Template
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
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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
PQUAL 14c	Electronic Regulatory Binder-eISF Visit Checklist Template
PQUAL 15	eConsent Standards
PQUAL 15a	eConsent RFI Template
PQUAL 15b	eConsent Scorecard Template
PQUAL 15c	eConsent 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 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
PQUAL 18	eTMF Standards
PQUAL 18a	eTMF RFI Template
PQUAL 18b	eTMF Scorecard Template
PQUAL 18c	eTMF 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 Wearable Sensor Device Standards
PQUAL 20a	General Wearable Sensor Device RFI Template
PQUAL 20b	General Wearable Sensor Device Scorecard Template
PQUAL 20c	General Wearable Sensor Device Visit Checklist Template
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 22	Actigraphy Motion Sensors Standards
PQUAL 22a	Actigraphy Motion Sensors RFI Template
PQUAL 22b	Actigraphy Motion Sensors Scorecard Template
PQUAL 22c	Actigraphy Motion Sensors Visit 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
PQUAL 24a	CRO Investigator Site Budget Contract Payment RFI Template
PQUAL 24b	CRO Investigator Site Budget Contract Payment Scorecard Template
PQUAL 24c	CRO Investigator Site Budget Contract Payment Checklist Template
PQUAL 25	Mobile Cardiac Monitoring Standards
PQUAL 25a	Mobile Cardiac Monitoring RFI Template
PQUAL 25b	Mobile Cardiac Monitoring Scorecard Template
PQUAL 25c	Mobile Cardiac Monitoring 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	Patient Feasibility Recruitment Retention Standards
PQUAL 32a	Patient Feasibility Recruitment Retention RFI Template
PQUAL 32b	Patient Feasibility Recruitment Retention Scorecard Template
PQUAL 32c	Patient Feasibility Recruitment Retention Checklist Template
PQUAL 33	Investigational and Medicinal Product Management Standards
PQUAL 33a	Investigational and Medicinal Product Management RFI Template
PQUAL 33b	Investigational and Medicinal Product Management Scorecard Template
PQUAL 33c	Investigational and Medicinal Product Management Visit Checklist Template
PQUAL 34	Mobile Biomarker Sensors Standards
PQUAL 34a	Mobile Biomarker Sensors RFI Template
PQUAL 34b	Mobile Biomarker Sensors Scorecard Template
PQUAL 34c	Mobile Biomarker Sensors Visit Checklist Template
PQUAL 35	Mobile Respiratory Sensors Standards

PQUAL 35a	Mobile Respiration Sensors RFI Template
PQUAL 35b	Mobile Respiratory Sensors Scorecard Template
PQUAL 35b	Mobile Respiratory Sensors Visit Checklist Template
PQUAL 36	CRO Project Management Standards
PQUAL 36a	CRO Project Management RFI Template
PQUAL 36b	CRO Project Management Scorecard
PQUAL 36c	CRO Project Management Visit Checklist
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PQUAL 38	Risk-Based Provider Qualification and Oversight
Provider Qualification Resources	**131**

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
Process Tool 03f	Process Improvement
Process Tool 03g	Lean and Kaizen Events
Process Tool 03h	Root Cause Analysis
Process Tool 03i	Root Cause Analysis Fishbone Diagram Template
Process Tool 03j	Statistical Process Control
Process Tool 04b	Industry Resources for Applying QbD in Clinical Trials
Process Tool 04c	Operationalizing QbD for Clinical Trials
Process Tool 04g	QbD Template FMEA
Process Tool 04h	QbD Leading Practices when Outsourcing
Process Tool 04k	QbD Risk Assessment and Prioritization
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
Process Oversight Resources	**29**

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**
Patient Engagement Resources	**31**

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 00	Proactive Risk and Opportunity Management Guideline
Risk Tool 02	Elements of Opportunity Management
Risk Tool 03b	FMECA Tool
Risk Tool 03g	Risk Matrix Template
Risk Tool 04	Opportunity Management Plan, Matrix and Tracking Template
Risk Tool 07	Risk Management Plan Template
Risk Tool 07b	Key Risk Indicators and Central Statistical Monitoring
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 13	Value Risk Framing Analysis and Aggregation
Risk Tool 14	Risk Metric Framework
Risk Tool 14a	Identification and Review of Risk Drivers and Risk Metrics
Proactive Risk/Opportunity Management Resources	**16**

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
RBQM 03	Subject Data Sampling Methods for Risk Based Source Data Monitoring
RBQM 04	Process for Establishing Critical to Quality (CTQ) Factors and Quality Tolerance Limits (QTLs)
RBQM 04a	Critical to Quality (CTQ) Factors Template
RBQM 05	Process for De-Risking Protocols
RBQM 05a	Protocol De-Risking Checklist
RBQM 06	Integrated Quality Risk Management Plan (IQRMP)
RBQM 07	Provider Risk Rating and Comparison Workbook

RBQM 08	Integrated Risk Tool
RBQM 09	Specifications for Risk-based Systems for Digital Oversight of Risk
RBQM 10	Guidance for Risk-Based Trial Master File (TMF) Review
RBQM 12	Risk-based Centralized Monitoring Guidance
RBQM 11	Site Diversity Recruitment and Comparison Workbook
RBQM 13	ICH E8 R1 RBQM Change Toolkit
RBQM 14	RBQM in Data Management SOPs and Data Management Plan
Risk-Based Quality Management Resources	**18**

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	Leading Practices in Performance Measurement
RnR Tool 08	SMART Goals
RnR Tool 09	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	Provider Oversight Plan Template
Roles/Responsibilities Resources	**13**

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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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	Use of Virtual Site Tours and Video Conferencing – Telephone Capabilities to Qualify Research
SFS 01e	Virtual Site Tour Content Checklist
SQMS 02	Introduction to Quality Management Systems for the Clinical Trial Site
SQMS 03	Proactive Quality Framework for Sites - Investigator Responsibilities
SQMS 04	Investigator Site Personnel Onboarding Training and Selection to a Trial 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 06	Site and Team Management Tool: RACI Model
SQMS 06a	Sample Clinical Site RACI Chart
SQMS 07	Clinical Site Standard Operating Procedures Overview and Management Standards for SOP Development
SQMS 07a	Clinical Site SOP Management Log
SQMS 08	Clinical Site Investigator Trial Oversight-Supervision Procedural Document Standards
SQMS 08a	Clinical Site Investigator Trial Oversight Supervision Template
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 and 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 20	Business Impact Analysis Template
SQMS 21	Business Continuity Plan Template
SQMS 23	Clinical Research Site General Role Ladder, Profile, and Training Resource
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
SQMS 29	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
Site Quality Resources	**60**

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 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
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Tech Tool 08	Medical Writing Oversight
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Tech Tool 11	Provider Start Up and Oversight
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Tech Tool 12a	Central Lab Experience
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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
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Tech Tool 16	Biomarker Lab Oversight
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Tech Tool 17	Clinical Supply Management Provider Oversight
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Tech Tool 18	TMF eTMF Oversight
Tech Tool 18a	TMF eTMF Industry and Regulatory Landscape
Tech Tool 19	Bioanalytical Lab Oversight
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Tech Tool 20	COA-eCOA and DHT Provider Oversight Provider Oversight
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Summary of Knowledge Center Resources

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Category of Leading Practices/Resources	Total Number
Communication	**18**
Governance/Organizational Construct	**19**
Inspection	**59**
Issue Management	**11**
Oversight Leadership	**8**
Metrics/Analytics/Technology	**8**
Oversight Capability Maturity Model	**15**
Pharmacovigilance	**1**
Provider Qualification	**131**
Process Oversight	**29**
Protocol Quality	**7**
Patient Engagement	**31**
Quality Agreement	**36**
Quality Oversight Management Framework	**2**
Proactive Risk and Opportunity Management	**16**
Risk-Based Quality Management	**18**
Roles/Responsibilities	**13**
Site Quality	**60**
Technical Oversight	**67**
Total Available Knowledge Center Resources:	**549**

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New Documents in Development	
ISM 03	Issue Management Effectiveness Checks
ISM 04	Issue Management Investigation and Root Cause Analysis
ISM 05	Issue Management Escalation Pathways
PQUAL 39	Electronic Data Capture Standards
PQUAL 39a	Electronic Data Capture RFI
PQUAL 39b	Electronic Data Capture Scorecard
PQUAL 39c	Electronic Data Capture Visit Checklist
PQUAL 40	Medical Monitoring Standards
PQUAL 40a	Medical Monitoring RFI
PQUAL 40b	Medical Monitoring Scorecard
PQUAL 40c	Medical Monitoring Visit Checklist

PQUAL 41	Third Party Subcontracted Vendor Qualification and Oversight
RBQM 15	Risk-based Approaches to Audits
RBQM 15a	Risk-based Audit Selection Tool
RBQM 15b	Process Maturity Scorecard
RBQM 16	Standard list of defined KRIs with purpose and definition commonly used for Centralized Monitoring
RBQM 17	Guidance on determining Critical to Quality Factors
SQMS 42	Competency Model/Framework (Nurse vs. Non-Nurse vs. PI vs. Sub-I)
SQMS 43	Guidance and Checklist for Site Qualification and Oversight of DCT Service Providers
SQMS 44	Guidance and Checklist or Evaluating Protocols or Impact on Site Operations
SQMS 45	Guidance and Checklist on Taking a Risk-based Approach to Evaluating Electronic Systems and Tools used by Sites