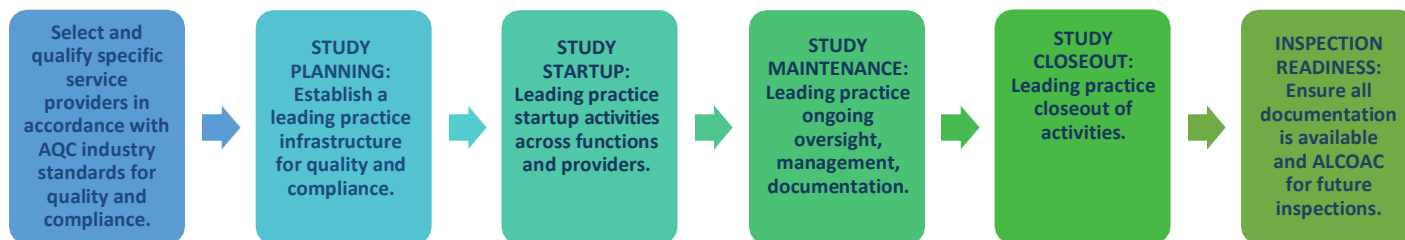


AVOCA QUALITY CONSORTIUM® SMALL COMPANY KICKSTART PACKAGE

By Clinical Trial Execution Phase

Apply tools in accordance with a Process Flow, such as the following:



1. Select and Qualify Vendors. Use appropriate tools to qualify providers you plan to use for your clinical trials (use the Core materials with the service-specific materials) and report out after completing the qualification. Periodically requalify providers.

Document ID	AQC Guides/Tools/Templates
Process Tool 01d , Process Tool 01c	CRO Qualification and Selection and CRO Scorecard
PQUAL 01a , PQUAL 01b , PQUAL 01c	Core RFI Template, Core Scorecard Template, and Core Visit Checklist Template
PQUAL 02a , PQUAL 02b , PQUAL 02c	Central Labs RFI Template, Central Labs Scorecard Template, and Central Labs Visit Checklist Template
PQUAL 03a , PQUAL 03b , PQUAL 03c	Bioanalytical Lab RFI Template, Bioanalytical Lab Scorecard Template, and Bioanalytical Lab Visit Checklist Template
PQUAL 04a , PQUAL 04b , PQUAL 04c	Biomarker Lab RFI Template, Biomarker Lab Scorecard Template, and Biomarker Lab Visit Checklist Template
PQUAL 05a , PQUAL 05b , PQUAL 05c	IxRS RFI Template, IxRS Scorecard Template, and IxRS Visit Checklist Template
PQUAL 06a , PQUAL 06b , PQUAL 06c	ECG RFI Template, ECG Scorecard Template, and ECG Visit Checklist Template
PQUAL 07a , PQUAL 07b , PQUAL 07c	Medical Imaging RFI Template, Medical Imaging Scorecard Template, and Medical Imaging Visit Checklist Template
PQUAL 08a , PQUAL 08b , PQUAL 08c	COA and eCOA RFI Template, COA and eCOA Scorecard Template, and COA and eCOA Visit Checklist Template
PQUAL 09a , PQUAL 09b , PQUAL 09c	CRO Clinical Monitoring RFI Template, CRO Clinical Monitoring Scorecard Template, and CRO Clinical Monitoring Visit Checklist Template
PQUAL 10a , PQUAL 10b , PQUAL 10c	CRO Data Management RFI Template, CRO Data Management Scorecard Template, and CRO Data Management Visit Checklist Template
PQUAL 11a , PQUAL 11b , PQUAL 11c	CRO Biostatistics RFI Template, CRO Biostatistics Scorecard Template, and CRO Biostatistics Visit Checklist Template
PQUAL 12a , PQUAL 12b , PQUAL 12c	CRO Medical Writing RFI Template, CRO Medical Writing Scorecard Template, and CRO Medical Writing Visit Checklist Template
PQUAL 13a , PQUAL 13b , PQUAL 13c	Phase I CRU RFI Template, Phase I CRU Scorecard Template, and Phase I CRU Visit Checklist Template
Process Tool 05a	Provider Assessment Report Template
Process Tool 05d	Approved Provider List Table
RnR Tool 09	Provider Onboarding Template

AVOCA QUALITY CONSORTIUM® SMALL COMPANY KICKSTART PACKAGE

By Clinical Trial Execution Phase

- 2. Study Planning.** Plan for the smooth conduct of your clinical trials: define metrics, establish communication framework, management of issues, clarify expectations and roles and responsibilities, manage quality and risk.

Document ID	AQC Guides/Tools/Templates
Tech Tool 01b	Kick Off Meeting Agenda
Comm Tool 11, Comm Tool 12, Comm Tool 13	Meeting Minutes Template, Action Item Template, and Meeting Agenda Template
Process Tool 02a	Template Transfer of Obligations
Process Tool 01b	Template Task Ownership Matrix
Comm Tool 20	Setting Expectations Worksheet
QAGR 01	AQC Quality Agreement Template
Met Tool 21	Catalog of Quality Metrics
Met Tool 23	Functional and Technical Provider Services Metrics
Met Tool 11	KPI Development Worksheet
Comm Tool 01	Communication Matrix
Comm Tool 02	Communication Management Plan
Comm Tool 03	Issue Escalation Process
Comm Tool 05	Risk Issue Triggers RACI Matrix Template
Comm Tool 07	Risk or Issue Communication Template
Comm Tool 14	Issue Log Template
Process Tool 05e	jQMP Template
Process Tool 07a, Process Tool 07b, Process Tool 07c	Quality Audit Plan Template, Quality Audit Agenda and Checklist, Quality Audit Schedule Template
PROQ 01	Protocol Quality Review Checklist
Risk Tool 03a, Risk Tool 03e	Risk Matrix with Instructions* and Sample Risk Matrix*
Risk Tool 07	Risk Management Plan Template
Tech Tool 01c	Provider Oversight Plan Template
Process Tool 05c	Project Provider Tracking Table
Tech Tool 02a	Project Management Status Report

*Introductory level risk tools. For intermediate level tools, use Risk Tools 06a ([Risk Prevention and Detection Controls](#)) and/or 06b ([Risk Plan with Bubble Plot](#)). For advanced level tools, use Risk Tool 03d ([Risk Ranking and Filtering](#)) and 03f ([Risk Ranking Template](#)).

- 3. Study Start Up.** These guides enable users to provide effective oversight based on what CRO and other technical services are being outsourced. Select only those that are for services outsourced.

Document ID	AQC Guides/Tools/Templates
Tech Tool 01	Core Oversight Practices
Tech Tool 03	Study Start Up Oversight
Tech Tool 04	Monitoring Oversight
Tech Tool 05	Enrollment Oversight
Tech Tool 06	Data Management Oversight
Tech Tool 07	Biostatistics Oversight
Tech Tool 08	Medical Writing Oversight
Tech Tool 09	Regulatory Oversight
Tech Tool 10	CTMS Oversight
Tech Tool 11	Third Party Organization Start Up and Oversight

AVOCA QUALITY CONSORTIUM® SMALL COMPANY KICKSTART PACKAGE

By Clinical Trial Execution Phase

Document ID	AQC Guides/Tools/Templates
Tech Tool 12	Central Lab Oversight
Tech Tool 13	IxRS and IRT Provider Oversight
Tech Tool 14	ECG Provider and Reader Oversight
Tech Tool 15	Imaging Provider and Reader Oversight
Tech Tool 16	Biomarker Lab Oversight
Tech Tool 17	Clinical Supply Management Provider Oversight
Tech Tool 18	TMF eTMF Oversight
Tech Tool 19	Bioanalytical Lab Oversight
Tech Tool 20	COA Provider Oversight
Tech Tool 21	Pharmacovigilance Oversight
Tech Tool 22	IDMC Oversight
Tech Tool 23	Pt Recruitment Retention Oversight
Tech Tool 25	Clinical Trial Home Nursing Provider Oversight

4. Study Maintenance. Leading practice oversight, management, and documentation. Evaluate quality on an ongoing basis.

Document ID	AQC Guides/Tools/Templates
INSP 09	QMS Annual Compliance Assessment Plan Process
INSP 09a	QMS Compliance Assessment Plan Schedule Template
INSP 09b	QMS Assessment Findings and Resolutions Template
Process Tool 07	Quality Audit Process
Process Tool 07d	Site Quality Audit Report Template
Process Tool 07e	Provider Quality Audit Report Template
Tech Tool 24	Quality Assurance Audits Oversight

5. Study Closeout. Leading practice closeout of activities.

Document ID	AQC Guides/Tools/Templates
Tech Tool 26	Study Closeout Process Oversight
Tech Tool 26a	Study Closeout Study Level Checklist
Tech Tool 26b	Study Closeout Investigator Site Checklist

6. Inspection Preparation. Ensure all documentation is available and ALCOAC for future inspections.

Document ID	AQC Guides/Tools/Templates
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