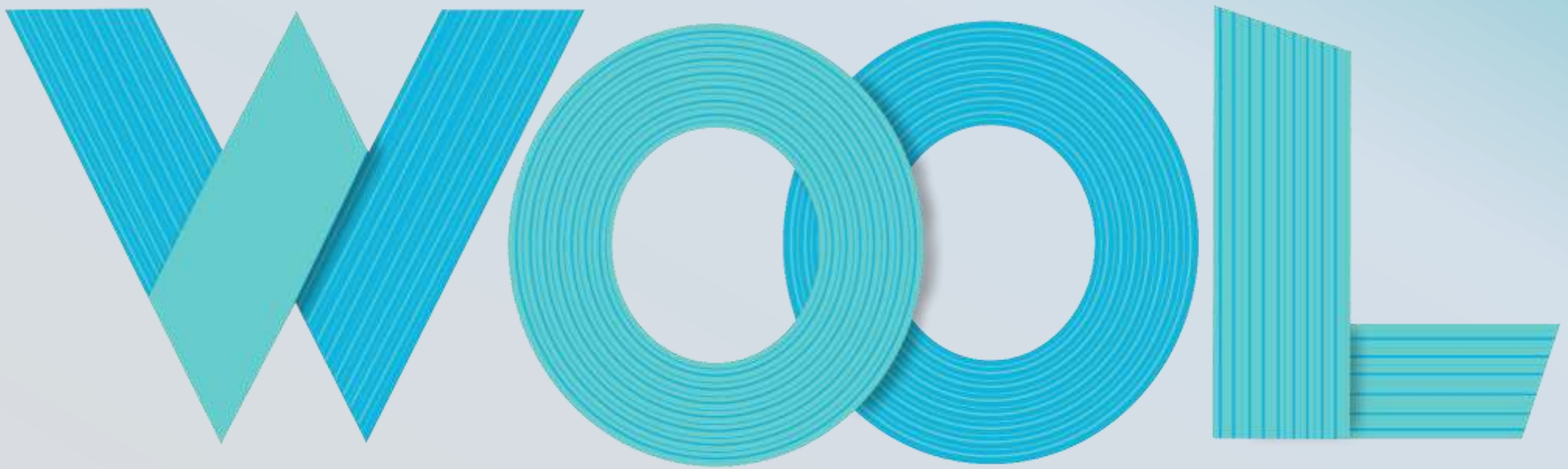

Consulting Group

Proactive quality for excellence

MEETING CRO-VENDOR OVERSIGHT REQUIREMENTS

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LIZ WOOL, RN, BSN, FACRP, CCRA, CID CMT

- **International Clinical Research Trainer and Consultant with over 25 years** experience: clinical operations, training design & delivery, training strategies and infrastructure, trial management, quality, compliance, CRO-Vendor management, procedural documents-process mapping, quality management systems, *faculty for DIA CRO-Vendor Management Workshops (DIA Annual Meeting) and DIA Courses,* international trainer and speaker **~10** conferences per year
- **President, Wool CG:** Clinical QMS, SOP Gap Analysis and Development (right fit for the organization, CRO-Vendor Oversight Framework (Governance, Plans, Lifecycle Approach: Selection to Trial Closure), Clinical Trial Risk Management, Issue Management, Auditing, Change Management, Transformation Management
- **Virtual Training Lead, Chief Learning Strategist, Wool Training Institute, Division of Wool CG:** Workforce Development, Competency Models and Framework, Basic and Advanced GCP Training, Annual GCP Training, Train-the-Trainer Programs
- **Worked With:** Start-Up – large Biotechnology & Pharmaceutical Companies, CROs, Academic Health Centers, National Institutes of Health (NIH), University Research Administrator Training Program
- **Member, Life Sciences of Tennessee, Healthcare Businesswomen's Association (HBA)**
- **Champion, Ambassador, Metrics Champion Consortium**

REGULATORY AUTHORITY COMMUNICATIONS

01.

Inadequate CRO/service provider selection process

02.

Core competencies/expertise is not ‘at the table’ to select the vendor – how do you know you are choosing a ‘qualified‘ CRO/vendor?

03.

Inadequate control - transfer of regulatory obligations

REGULATOR COMMUNICATIONS

04.

CRO - Vendor Selection Criteria, Selection, Qualification

05.

Changes in CRO – Vendor scope of work without changes in the contract

06.

Mergers,

Acquisitions

Due Diligence

Considerations for Picking the Right Contractor

- Have a cross functional team of staff be involved with selection criteria
- Look at internal policies
- Visit the contractor site

C Cullity, FDA, OSI, CDER, DIA Annual Meeting 2011

Ensuring Quality:

- Ensure that the contractor is qualified
  - Check that the contractor's personnel are adequately trained and licensed
- Check that employees are monitored for performance according to their quality system
- Ensure that the contractor's quality standards and yours do not conflict

C Cullity, FDA, OSI, CDER, DIA Annual Meeting 2011

Lessons Learned:

- Checking credentials
- Staff turnover
- Supervisor qualifications
- Required professional training
- Protocol training
- Closing the loop-Corrective Action Plans

Key Questions:

- Qualifications of the personnel performing the data management functions
- Other key functional roles

C Cullity, FDA, OSI, CDER, DIA Annual Meeting 2011

Key Questions:

Written SOPs identifying the **person(s)responsible** and the **procedures** for:

- Tabulating and evaluating data (domestic and foreign) for the studies as well as for all subjects who participate in each adequate and well-controlled trial
- Collecting and evaluating adverse experiences
- Statistical reviews
- Preparing reports
- Submitting data, tabulations, reports, and other materials to FDA, etc.
- Responsible for reviewing and approving study reports and data tables, and making final evaluations and decisions in reviewing adverse experiences

C Cullity, FDA, OSI, CDER, DIA Annual Meeting 2011

Key Questions:

- Integrity of the review and evaluation of evidence related to the safety and efficacy of the test article obtained from the clinical investigator
- Verification that the SOPs are followed at each stage of data handling to ensure that all data are reliable and processed without compromise of integrity

C Cullity, FDA, OSI, CDER, DIA Annual Meeting 2011

VENDOR EVALUATION AND SELECTION

- Service requires use of a new technology or methodology?
- Difficulty of vendor's services/deliverables
- Project priority
- What are their vulnerabilities? These can impact program success/quality

Critical Success Factors (CSF) – Critical to Quality (CTQ)

- First time vendor used? First time specific business unit or service used by the vendor?
- Vendor involved with data handling? Data review? Data control?
- Vendor involved with safety, efficacy data or human subject's protections?
- **RISKS:**
  - Likelihood of failure
  - Potential impact of failure
  - Detectability of failure

RFP PLANNING MEETING
Stakeholders

- What are the requirements for this protocol – are they unique? Or standard?
- Will a service be required to be ‘sub-contracted out’ by the vendor? What do we want to know about this?
  - Partnerships with specialty niche providers (Central Imaging Center)
  - Global services
- What risks or issues has the company had previously for the services and what question can we insert into the RFP to learn about this ‘early’ and explore at the bid-defense meeting?

RFP PLANNING MEETING
Stakeholders

- Identify what your company will be doing for the trial
- **Identify vendors needed for the trial**
  - How, where
  - Why?
- Have we worked with this type of vendor before?
  - Do we have RFP language and selection criteria
- **Do we have the expertise in-house**?
  - Involved with selection criteria, and expert for evaluating/scoring the RFP
  - And insight for vendor oversight during the trial

RFP CUSTOMIZATION

- **Imaging - Central Reading**
  - Strong QMS
  - Capacity and infrastructure
  - Data management systems/data transfer proficiency
  - Reader variability management
- **IRT System**
  - Ability to adapt complex algorithms
  - Part 11 compliant system
  - Handle complex randomization and IP allocation
- **Investigational Product**
  - Global distribution centers
  - Ability to successfully ship to challenging geographic locations

VENDOR EVALUATIONS

Do they answer all of the RFP questions?

Are they ‘template’ answers or detailed?

Quality of the response per Vendor

Qualified staff review their specific assignments

QMS

Infrastructure

What is not answered?

Any gaps or risks?

Any areas to clarify?

*Key to address at bid-defense meeting

If a perfect score – why and document thoughts

If not a perfect score – why and document thoughts

Consistent approach for all vendors ‘same robustness’

Ensure comparisons are equivalent

Revise Bid-Defense Meetings to Address: Issues, Risks, Gaps, Concerns

BID-DEFENSE MEETINGS

NOT ONLY about financial negotiations

Bus Dev people only?

Functional leads/representatives

Develop targeted questions for issues, risks, gaps, concerns

- Areas requested more information after the RFP evaluations
- Understand ‘what is an acceptable answer’?

Culture of the organization matches your culture

*Internal understanding of a ‘culture’ fit

*Define and agree before bid – defense meeting

Internal capabilities, expertise and talent at the meeting

- Specialty area
- Computerized systems – data sharing, transparency

Look For:

Vendor addresses YOUR needs, and agrees to any changes, mitigations/remediations to fulfill the needs of the protocol/program requirements- GAP ANALYSIS

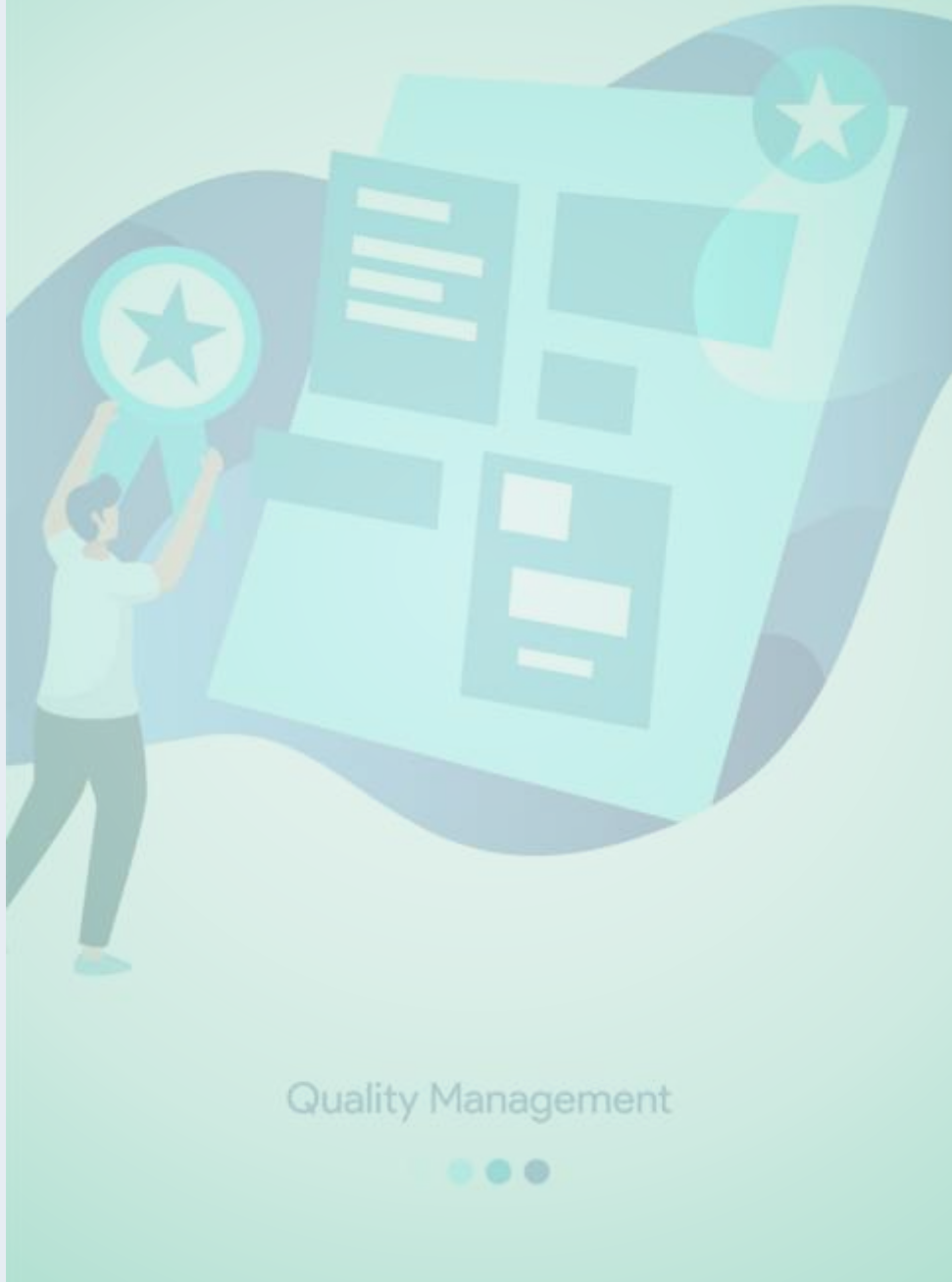
TIPS: VENDOR SELECTION

- Are you really assessing your vendors or 'just completing a checklist'?
- Organizational structure and responsibilities
- Acquisitions, Mergers, Due Diligence

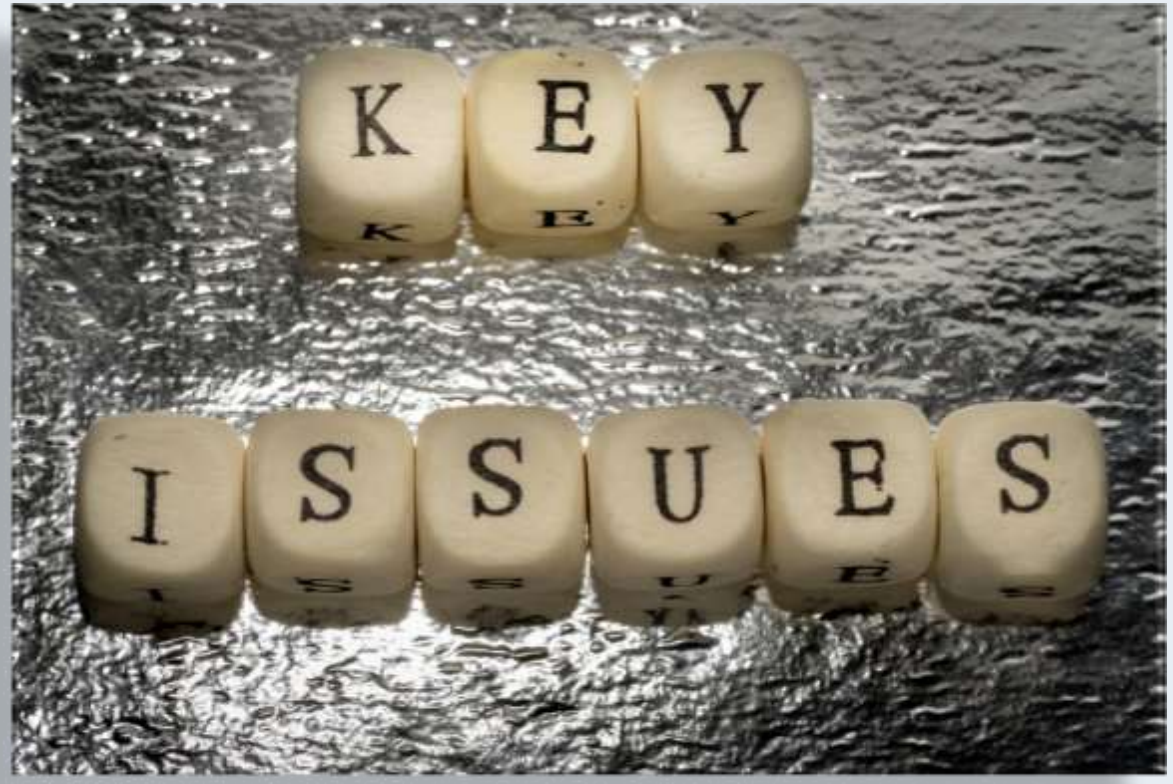
- **Vendor selection criteria** and methods, scoring tools –DETAILED
- **RFP Review Meeting**: Focus on GAPS AND RISKS

Your Team:

Have the *expertise, including QA,* to '*select' the vendor* – *if not* – how can you tell the regulator that your company selected a qualified CRO – Vendor *(FDA)*



VENDOR SELECTION



Select vendor based on expected standards-criteria, program requirements and risk assessment and *ability for vendor to address* concerns, risks, gaps and this is documented and forwarded to study team members for their oversight of the vendor (to the agreements)

- Focus: Identify gaps and risks during the selection phase in partnership with GCP QA Qualification Assessment/Audit
- Assess your current approaches and modify accordingly
- Identify a ‘process owner’ for this activity
- Qualified staff involved in all aspects for the Vendor Selection process
- Document!

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CONTACT INFORMATION

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ADDITIONAL SLIDES

VENDOR LIFECYCLE MANAGEMENT

RFP Success Factors

- RFP Planning Meeting
- Vendor Criteria
- Map Criteria to Scoring Tool
- Map Criteria to Risk Tools

RFP Template

RFP Review Scoring Tool

- Vendor Criteria Review
- Scoring Tool
- Weighted
- Outcome – Risk Score
- Outcome- strengths and weaknesses

RFP Review Meetings

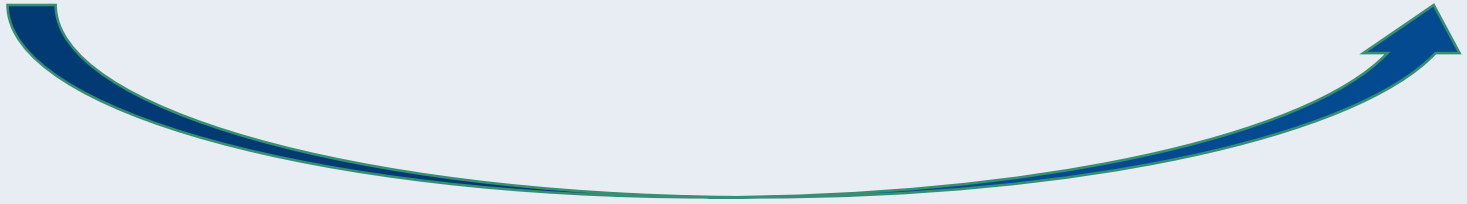
- Scores – Individuals and Total for Team Review
- Weaknesses
- Strengths
- Risks
- Drives feedback to Vendor
  - Gaps
  - **QMS** robustness

Feedback to Vendor to present **on QMS,** identified weaknesses and risks perceived by the RFP Review Team

- Present remediation plans
- Present risk management plan

Bid Defense Meeting – present on

- **QMS** remediation plans, risk management plan, and remediation plans
- Methods and timelines
- Verification step of **QMS**



VENDOR LIFECYCLE MANAGEMENT

Review, re-score the RFP, confirm and approve Vendor RM method and RMP

- Final Vendor Selection

CRO-Vendor Plans:

- Metrics
- Quality Management Plan
- Risk Management Plan

CRO-Vendor Governance Committee (s)

- Review of Study Issues, Vendor Issues, Sponsor Issues, Quality Metrics for both the study and CRO-Vendor performance

Continuous Monitoring and Feedback Loop on Performance – real time – to modify practices, documents to impact change

Feedback to CRO or Sponsor failures in RMP, QMS to rectify for the study and the business enterprise

THIRD-PARTY ENGAGEMENT

Factor	Description/Rationale	Potential Considerations in Evaluating Relative Importance of CTQ Factor	Examples of Issues to Consider in Evaluating Risks to CTQ Factor
Delegation of Sponsor Responsibilities	Sponsors are increasingly reliant on third-party service providers (e.g., CROs, AROs, and other study-specific vendors) to assist with activities, from designing a study through reporting its results. As a result, multiple parties have or share responsibility for study conduct and/or oversight at different points of the study. To ensure oversight of third parties, sponsors should have appropriate levels of internal governance and oversight when engaging third parties in the design, conduct, and reporting of clinical trials. The sponsor should ensure that CROs/AROs and other study vendors are (and remain) qualified to carry out contracted activities. Sponsors must also consider appropriate controls to ensure, in an ongoing manner, that CROs/AROs and vendors are carrying out these activities appropriately and in accordance with contractual requirements or other defined quality expectations.	1. What activities will be delegated to a CRO/ARO or conducted by another third party? 2. Which of these are CTQ activities? 3. Will the entire activity be delegated, or will the sponsor retain responsibility for some aspects? 4. Are there unique risks that matter to the trial inherent in this partnership? 5. What infrastructure and capabilities are required to manage the relationship and provide appropriate oversight of the deliverables from the third party? 6. Is there clarity of what needs to be escalated and when? Is there a clear escalation pathway for all parties? Do all parties understand escalation pathways?	1. Are there available data on prior performance by the third party that might inform decision making about whether to use a particular vendor? 2. By what mechanisms will the sponsor and third party ensure there is agreement on what elements of the vendor's performance are critical? 3. How will potential conflicts between standard operating procedures of the sponsor and the third party be resolved prior to study initiation? 4. How will system access be handled to ensure timely and appropriate access to information for all parties? 5. What is the nature of the contractual relationship between the sponsor and third parties responsible for CTQ activities — is there shared risk, or is it a strictly fee-for-service relationship? 6. Is there the need to establish quality parameters to measure performance? Is there a defined function or individual(s) at the sponsor with responsibility for monitoring performance of third parties? 7. How will roles be clearly defined, such that clinical investigators and site staff know with whom they need to interact and when? 8. Is performance by one third party dependent upon inputs from another? Are there mechanisms planned to ensure appropriate communication between third parties? 9. Are there defined plans to manage mergers and acquisitions that may occur during study conduct? 10. Can the DMC access a third party for data while maintaining masking of sponsor? 11. Are all relevant decisions and agreements regarding the relationship between the parties accurately reflected in the contract?

Vendor Management Program

Staff Training and Development

Risk Management Methods, Templates

Vendor Governance Structure
(Monthly/Quarterly Meetings) EC, JOC, Functional Departments, Vendor Monitoring Program Metrics, Dashboards Etc.

Vendor and Preferred Providers
Selection
and
Qualification
Includes Quality Attributes/QMS Assessments

Methods to Oversee
Vendor
'sub-contractors'

On-gong Appraisal
Quality Indicators and Attributes
Individual/All Studies
- Tracking
- Trending
- Patterns
- Issue Escalation

Inadequate Performance
- Defined
- Identified
- Escalation
- Investigation
- CAPAs
- Withhold payment
- Etc

Vendor Identification
Vendor Selection
Request for Proposals
Contract Awards
(All Standardized Methods, Templates, Rating Scales [with definitions/parameters], Risk Assessment of Vendor who does not meet your requirements, and RMP)

- Template includes request for quality attribute and QMS assessment for each department
- Each department develops template for questions to enter into the RFI/RFP (e.g. detailed selection criteria): qualifications, experience, training for each duty/activity/function,
- Experience in Therapeutic Area, Region, Countries and use of sub-contractors & their management
- Customize for protocols as required

Review of RFPs submitted for quality attributes and departmental requirements, company requirements and robust QMD

Bid Defense Meetings:
- Include Quality Attributes
- Qualifications, Experience, Training
- Company Representatives possess the SME competency to assess the CRO-Vendor
- Performance Criteria
- Performance Metrics

Contract Award:
Quality Management Approach
and
Quality Agreements

Contract Terms

Reference or Include as an Exhibit
- Quality Agreement
- Joint Quality Management Plan
- Transfer of Obligations (detailed list for each activity, duty, function)

- Payment Terms for each Deliverable
- Performance Metric
- Quality

Project Kick-Off Meetings

Quality and Performance
- Criteria
- Quality Metrics
- Vendor Quality Management and Oversight Approach

Vendor Management Plan
(Template)
One per Study
One Per Vendor

Risk Management Plan

Standardized for Each Department/Duty Function

*Issue Escalation Plan

*Communication Plan (Meetings, Standard Reports)

Vendor Management Plan
- Each Outsourced Activity, Duty, Function *(e.g. site monitoring, drug safety, CDM, ePRO, IVRS, EDC)*

Supporting Quality Standards, Procedures, Tools, Performance Criteria, Non-Performance Management and Feedback, and Documentation
**ex: Monitoring Assessment Visits with Report and Feedback to Vendor (SOP is needed)*
**ex: Monitoring Visit Report Review*
**ex: TMF Review*

Routine Meetings:
- Project Review
- Financials
- Quality - Performance Review
- Monthly/Quarterly

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***Gold Standard: Vendor Qualification – Due Diligence Audits include GCP-QA and the Functional Area** (identify gaps to SOPs, training that is required etc.)*