Webinar Q&A

"Employing Strategies for Effective Risk and Capability Assessments When Choosing a Clinical Vendor"

Recorded Wednesday, February 21, 2018
Presented by Dennis Salotti, Vice President, Operations, The Avoca Group
Answers by Dennis Salotti

Q) It may be just semantics, but is there a difference between "qualification" and "prequalification"?

A) The short answer is no. They are essentially synonymous in use and practice.

Avoca has found that the terms are used interchangeably, however 'qualification' is more commonly used than 'prequalification'.

Avoca, in its origination of standards, RFIs, and other tools in the Avoca Quality Consortium Knowledge Center, used the term prequalification because the scope of this initiative excluded qualification audit deliverables (audit plan, agenda, report, etc.).

The vendor qualification process, in many, but not all contexts, involves a form of audit or otherwise-termed assessment of evidence of compliance with standards and requirements. This is contingent upon the particular procedures, company risk tolerance, and risk classification for a given category and/or company. Avoca is using the term 'Qualification' in reference to Diligent™, since it is a more commonly understood term.

Q) What suggestions do you have for incorporating quality requirements into legal contracts with vendors – i.e., negative consequences (usually financial) if quality measures are not met?

A) I personally do not favor this approach. In the context of a quality issue where this would apply, I do not think that enforcing financial consequences furthers the common goal of resolving the cause of the quality issue – after the financial penalty, the quality issue still remains.

It may be more effective to outline how responses to quality issues will be communicated, escalated, and resolved – at an appropriate level of detail given the context of the engagement. Quality Agreements make excellent tools to use in this capacity.

A few further considerations:

- Does the presence of a negative consequence (financial or otherwise) adversely influence open and timely communication of risks and issues? Punitive levers – real or perceived – may introduce unwanted behavior.
- Issues are inevitable. Navigating the resolution of an issue with a Provider is an opportunity to better understand their performance capability both in the resolution to the issue and the preventative actions that follow as a result of learning from that quality issue. This is valuable intelligence that can be used in future provider selections. As a Provider in my former life, I can share that the worst consequence of mismanaged issues is the loss of the opportunity for repeat business.

Q) Does Avoca have the basic pre-qualification standards available for each different type of service?

A) Avoca maintains a set of Core Standards that apply to all Providers/service categories.

Additionally, we maintain technical standards in seven (7) endpoint generating categories:

- ECG
- IRT
- COA
- Medical Imaging
- Central Labs
- Bioanalytical Labs
- Biomarker Labs

By June 2018, five (5) additional functional service categories will be added, including:

- Clinical Monitoring
- Data Management
- Biostatistics
- Medical Writing
- Phase I Units

Avoca is in active conversations with Sponsor companies that are participating in Diligent™ to identify further service categories to include.

Q) What type of supplier qualification evidence is expected to be in the TMF? ALL documents? Or is a summary acceptable?

A) From Avoca's observation, there is a challenge within the industry with maintaining consistency and completeness with vendor qualification documentation. We have observed that consistency and completeness of the filing of documentation in the TMF is a separate challenge.

The documentation gathered in the course of qualifying a vendor serves the purpose of evidence when the story of how evaluation and decision around a vendor needs to be reconstructed, typically in the event of an inspection (also for internal audit or Sponsor audits for CROs subcontracting to third-parties). Thus, the best way to identify what is relevant is to establish what was used in making the decision.

In my recent attendance at ExL's European Clinical Quality Oversight Forum, a panel of inspectors from EMA and MHRA commented specifically that documentation should be maintained in a way that is quickly and easily available to an inspector – and that this may be in file repositories other than "the TMF" for the trial – as some documentation (e.g., legal contracts) may be necessarily stored in these other repositories.

So, while it is prudent to think through the documentation necessary to recreate the story of events and decisions, this can be done in such a manner that documentation residing elsewhere than the TMF may be referenced and summarized, so long as the document name, location and availability can be readily provisioned for the inspector.

Q) How often are qualifications in the centralized model updated? I.e., every 24 months, etc.?

A) The RFI documentation was originally planned to be updated on a chronological basis – every 6 months. What we have observed in practice, however, is that upon request from a Sponsor, the Provider reviews and often makes minor update to their RFI documentation prior to granting approval for Avoca to release the materials.

Q) What group typically coordinates the qualification process?

A) Avoca's experience is that this can vary by organization and is influenced by factors including, but not limited to, size, structure, outsourcing model, and maturity with vendor qualification practices. We have seen the process driven by clinical project management, category management/sourcing, procurement, and by dedicated third-party quality and oversight groups.