Avoca Quality Consortium Leading Change Collaborative Forum

Meeting Highlights

Topic: Provider Qualification Workstream Updates

Meeting Date: August 17, 2021

Background Information

The emergence of the COVID-19 pandemic has caused the pharmaceutical industry to rapidly adapt its processes and technologies, including clinical trials. The AQC Leading Change Collaborative Forum features compelling topics designed to encourage provocative discussion. The priority is providing practical and actionable support and having immediate "peer-to-peer" benchmarking about how other organizations are managing the topic at hand, all while ensuring prioritization of patient safety, data integrity, and regulatory compliance.

Discussion Summary

The AQC is finalizing five new Provider Qualification (PQUAL) standards and the accompanying resources. Because so many new Member companies have joined the AQC over the last few months, Janis Hall, Senior Consultant at WCG Avoca, began the discussion with a basic overview. The vision is to transform the way the industry qualifies clinical service providers. The standards are designed to:

- Enhance regulatory compliance
- Reduce costs
- Shorten timeframes for onboarding clinical service providers
- Drive efficiency through information sharing
- Reduce risk
- Drive technology adoption

As of August 2, 2021, the AQC has established 1,938 PQUAL standards. The standards have been defined by health authority regulations or guidance documents, extrapolated based on regulations and guidance, or have become expected requirements based on leading practices. Before going into detail about the new standards, Janis provided a regulatory overview.

Regulatory Context

The regulatory landscape for provider qualification has crystallized over the last several years. One example is the ICH E6(R2) Guideline for Good Clinical Practice. Janis explained that ICH E6(R2) calls for written documentation of all of the responsibilities that are being delegated, making clear that the ultimate responsibility always resides with the sponsor.

ICH E6(R2) includes an addendum stating that the sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including those that are subcontracted to another party by the sponsors' CRO. “That makes it even more challenging for sponsors to provide that effective oversight.”

Janis then paused to define terms that are frequently misunderstood and misapplied across the industry:

- **First party** refers to the sponsor.
- **Second party** refers to entities that directly contract with the sponsor (e.g., CROs and labs).
- **Third party** refers to subcontracted providers. These third parties, subcontracted by the CRO on behalf of the sponsor, creates that additional risk addressed in the ICH E6(R2) guidance.

Another key piece of regulatory guidance, the MHRA Good Clinical Practice Guide-Clarification for Industry states that “the process of vendor oversight begins with the selection of a suitable vendor,” and lists assessment methods that can be considered, many of which align to existing PQUAL tools:

- Qualification questionnaires
- Assessment of CVs and previous experience
- Obtaining suitable references
- Referring to prior knowledge of the vendor from use in other clinical trials
- Assessing quality system/written procedures
- Conducting audits

Janis also shared what she learned from her experience with inspections regarding provider qualification. What are they asking for?

- Provider list for clinical program
- Provider contracts (redacted content)
- Provider qualification SOPs
- Preferred or approved provider list
- Qualification summary reports (including selection criteria)

AQC Provider Qualification Process

Janis then shared the AQC’s recommended provider qualification process, mapping many of the steps to existing tools.

- Assess and document provider risk
- Assign a qualification team leader and members who will identify standards against which the providers are going to be evaluated
- Identify, review, and document your own selection criteria, including dealbreakers
- Send out the RFIs, review responses, and interview vendors; score them against AQC standards
- When possible, conduct on-site assessment visits
- Document selection decision making
- Track provider assessment activity

Overview: AQC Provider Qualification Standards

The current 1,938 AQC PQUAL standards are across four categories:

- Core requirements
- Technical services
- eClinical and decentralized clinical trials
- Functional services

Each category includes several sets of standards. For each standard, the AQC team develops four tools. “So, it's not just developing the standards, it's also creating tools that go with the standards.”

Newer AQC Members may be unfamiliar with what the standards look like, so she provided a primer. Each set of standards looks the same. They're set up in a table with taxonomy that tracks each standard allowing it to be mapped through the accompanying tools -- templates, scorecards, and checklists.

Janis then went on to review the new sets of standards, some of which are in draft form.

- Pharmacovigilance
- Investigator budgets, contracts, payments
- Mobile Cardiac Monitoring
- Feasibility Recruitment Retention
- Investigational Product Management

AQC members have the opportunity to review all standards before they are published, and they can stay current on changes and updates through the *AQC Express* newsletter or the member-only online community, *Aha!* For more information on the qualification standards, contact Lisa.McKay@theavocagroup.com.

If you are interested in learning more about the WCG Avoca Quality Consortium (AQC) or its Leading Change series, please contact Dawn.Auerbach@theavocagroup.com.