

The Avoca Group is a life sciences consulting firm dedicated to improving quality and compliance in the clinical trial execution process. Integrating deep subject matter expertise with industry-leading approaches and technology, we tailor solutions that help companies build quality management, inspection readiness, and effective oversight systems into new or existing processes.

## Industry Solutions by The Avoca Group

Our products and services are based on The Avoca Group's 20+ years of experience in building quality and compliance into the execution process of clinical trials.

### **Avoca Quality Consortium<sup>®</sup> (AQC)**

Collaborative comprised of nearly 100 pharma, biotech, CRO, and clinical service provider companies with the shared objective of elevating clinical trial quality and compliance. Members receive access to over 400 leading practices and guidelines, tools, templates, and process documents, as well as AQC research and archived webinars.

### **Quality Management System Design, Gap Analysis, Implementation, and Improvement**

Advising sponsors and CROs on developing a culture of risk prevention to ensure patient safety, improve data quality, provide data integrity, and increase inspection preparedness. Our 12-component construct facilitates comprehensive, robust gap assessments of existing Quality Management Systems (QMS) to ensure compliance with regulatory guidelines (e.g., ICH E6 (R2)) and leading industry practices and standards.

### **Inspection Readiness Assessment, Training, and Mock Inspections**

Helping sponsors and CROs develop a culture and mindset committed to quality through proactive risk management, ensuring an inspection readiness state throughout the entire clinical program. Our agile inspection preparation process is based on industry-leading practices and tools developed in collaboration with AQC Member companies.

### **Quality Tolerance Limits and Quality Metrics Consulting Support**

Guiding sponsors and CROs on compliance with ICH E6 (R2) by providing study teams with training and comprehensive support for planning and implementing Quality Tolerance Limits (QTLs), either as individualized study QTL support or as part of overall Quality Management System (QMS) implementations.

### **eLuminate<sup>™</sup> Online Learning Platform**

Educational training tool providing clinical research professionals with key insights from industry leaders, built from AQC leading practices and delivered via self-paced courses and interactive, engaging lessons.

# The Avoca Group Advantage

## Who We Serve



### Sponsors

- Clinical Operations/Management/Research/Development
- Clinical Quality Management/Clinical Quality Assurance
- Clinical Outsourcing/Procurement
- Vendor Management/Alliance Management
- Company Executives
- Good Clinical Practice/GCP



### CROs



### Clinical Service Providers

- Clinical Innovation
- Patient Engagement
- Site Level Managers
- Monitoring/Site Management/Study Management
- Regulatory Affairs
- Heads of Business Development and Marketing



### Investigative Sites

## The Challenges We Help Solve

**ICH E6 (R2) compliance**

**Quality management systems**

**Inspection readiness**

**Risk management**

**Provider qualification**

**Vendor management and oversight**

Companies also benefit from The Avoca Group's Research Services that provide high-quality, actionable quantitative and qualitative data collected through telephone interviews and online surveys.

Our mission is to have a positive impact on all clinical trials by helping clinical research companies increase quality, ensure compliance, and improve efficiency so that medicines can reach patients faster.

