

Quality oversight of clinical R&D vendors is becoming more complex and increasingly important. Carefully crafted quality agreements, routine review of site monitoring visit reports, investigator site co-monitoring visits, vendor audits, corrective and preventive action programs — these are the common tools for clinical trial vendor oversight. Yet, recent industry experience shows that these tools are not adequate to ensure that vendors are complying with basic Good Clinical Practice (GCP) requirements that protect clinical trial subjects and maintain integrity of patient data in outsourced clinical trials.

CIS OFFERS VENDOR OVERSIGHT SOLUTIONS

Clinical trial vendor oversight is a topic that generates significant interest from our clients. The questions are about how to maintain quality while also meeting competitive demands of the industry and remaining compliant with government regulations.

CIS offers consulting services in the following areas to help sponsors implement effective vendor oversight programs and meet current GCP compliance requirements, as defined by the International Conference on Harmonization (ICH), the FDA and other relevant government agencies:

PROGRAM	DESCRIPTION
Outsourcing Strategy	Evaluate current or proposed sponsor strategy for outsourcing clinical trial activity. Provide recommendations to align the outsourcing strategy with sponsor's strategic goals. Include company-specific processes and guidelines for vendor qualification, selection, and oversight.
Vendor Assessments	Plan and conduct vendor assessments for clinical trial services and provide recommendations for vendor qualification and selection.
Vendor Audits	Plan and conduct audits of vendor practices and procedures as they relate to clinical services provided to the sponsor. Develop a vendor qualification program.
Key Performance Indicators (KPIs)	Evaluate sponsor's current vendor oversight systems and collaborate to identify key metrics related to vendor effectiveness. Develop and implement a KPI program for routinely collecting and reporting vendor performance data. Use data to define targets for improvement and implement corrective actions to address non-compliance issues.
Standard Operating Procedures (SOPs)	Develop business processes that address vendor selection, staff training, vendor oversight and issue escalation; document those processes as SOPs or Work Instructions (WIs).
Training	Provide sponsor or CRO staff with monitoring training, focusing on specific monitoring issues that agencies have identified in recent 483 observations. Include training on the sponsor's process for escalating issues for prompt resolution.
Quality Monitoring	Collaborate with the sponsor of outsourced clinical trial activities to design a quality monitoring program. Provide experienced site monitors to review a large percentage of monitoring trip reports in an effort to readily identify issues, trends and corrective actions across investigative sites for an outsourced clinical trial.

Recent FDA 483s were issued due to a lack of oversight of clinical trials, including monitoring activities.

PARTNERING AND ADAPTING

At CIS, we partner with a wide array of investigational product sponsors across the pharmaceutical industry, and we take responsibility for ensuring that our clients are prepared to adapt to the shifting needs of the industry. We accomplish this by implementing strategies designed specifically to the needs of our clients, and through translating and applying regulations and guidelines into daily activities across the organization. We are committed to staying on top of the latest industry developments and ensuring that our clients are equipped with the knowledge and necessary tools to survive in this challenging, diverse, ever-changing industry.

ABOUT CIS

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for the pharmaceutical industry, from Global Clinical Research and Development, through Manufacturing, U.S. Commercial Compliance, and Government Programs. Founded in 2004, CIS provides its clients with a deep understanding of industry laws and regulations, innovative and practical applications, and custom solutions to establish a “Culture of Compliance” that is both meaningful and sustainable.

Our experts identify, assess and prioritize your organization’s exposure to compliance risks, subsequently developing and implementing risk evaluation and mitigation techniques to ensure adherence to legal and regulatory requirements.

SERVICE AREAS

CIS provides solutions that span across all phases of the product compliance lifecycle.

