Advanced Clinical

WHITE PAPER

Hindsight Is 20/20: Effective Pharma-CRO Quality Partnerships In Turbulent Times

Stacy Powers Newalu, MPH, RQAP-GCP, CCRC
Associate Director, Compliance and Quality

Table of Contents

Abstract

The COVID-19 pandemic has reaffirmed the old saying that “the only constant in life is change.” As a mid-sized CRO providing Quality Assurance and Regulatory Compliance Services to pharmaceutical and biotechnology partners, Advanced Clinical had planned for a productive 2020, working collaboratively with partners and clients, and conducting business ‘as usual.’ Then everything changed. Authored by an expert from Advanced Clinical, this white paper provides insights into the skills and tools that build strong partnerships, as well as common misunderstandings that can lead to strained relationships. The focus is on relationships between smaller or mid-sized biotechnology or pharmaceutical companies and their CRO partners. Challenges and outcomes from navigating 2020 demonstrate how the skills that are useful during normal times become crucial during turbulent times.

Introduction

With sponsors spending over 10 years and spending billions of dollars to develop each new drug through the approval process to market, choosing the right partner for a development program is critical. As a result, sponsors take caution in identifying and evaluating potential CRO partners, a process that starts with early discussions of capabilities, proposals, bid defenses, and qualification audits. The sponsor investigates and gets to know the potential partners' company culture, capabilities, processes, quality management systems, electronic systems, and everything else to be offered to the sponsor to support the planned studies. During this process, the sponsor gains insights into intangible factors, such as personality matches, organizational fit, and quality philosophies.

However, even with the most rigorously qualified CROs, things do not always go smoothly, and issues can arise. Bumps in the road can occur and threaten even the most promising relationships. Tools that establish a strong foundation and foster collaboration allow us to overcome these challenges and ensure business continuity and strengthening of partnerships.

Starting Off on the Right Foot

First impressions matter. Sponsors who are seeking help need to feel that they have found the right CRO for the job and have identified a trusted advisor to support their program. It is essential to listen to and understand the sponsor's needs, challenges, preferences, and to relate to any concerns. The CRO must show it can provide expertise and consultative input at the level required, building mutual respect from the start.

Setting the Tone for Success

To set the tone for success, a strong kick-off meeting is essential. This is the starting point for getting to know all team members, starting knowledge transfer and reviewing contractual obligations. Expectations are aligned, deliverables reviewed, and communication pathways for issue escalation established. This sets up all parties for a productive and successful relationship.

Bumps in the road can occur and threaten even the most promising relationships. Tools that establish a strong foundation and foster collaboration allow us to overcome these challenges and ensure business continuity and strengthening of partnerships.

Ongoing Temperature Checks

Ongoing temperature checks are also important. These require open lines of communication between all parties. Depending on client preference and work volume, this may involve regularly scheduled virtual or in-person meetings, ad hoc phone calls, or one-on-one meetings with management. The frequency can change during the engagement as needs evolve.

Last year, audit capabilities changed rapidly, and ongoing communications needed to be reactive and adjust. Providing more frequent and short updates allowed everyone to be equally informed - email and ad hoc phone calls became more commonplace to help with the frequent status updates. A teamwork attitude and trust in one another are cornerstones to successful partnerships. Honest and open conversations when challenges arise will further build a strong relationship.

Navigating Bumps in the Road

When bumps in the road occur, proactive, direct, and transparent communication is vital to address the issue and to stop it from spinning out of control. Being open minded to all opinions on how to address an issue is vital, while the escalation process that was established at the kick-off meeting provides the tools and direction needed to ensure everyone's voices are being heard.

2020: The Year That Tested Us

In January 2020, Advanced Clinical anticipated a normal year. The annual audit plan had been executed, audits were underway, and auditors were out in the field. Audit dates had been confirmed months in advance, and audits planned and assigned for the year. Then in March 2020, everything changed. All essential travel was halted immediately, and all onsite audits were indefinitely postponed. Immediate communication was needed with auditors, clients, and auditees. In this period of rapid change, it was challenging to anticipate immediate and long-term needs.

A teamwork attitude and trust in one another are cornerstones of successful partnerships. Honest and open conversations when challenges arise will further build a strong relationship.

Keys to Success

Several areas were key to success against this backdrop. Ongoing communication and check-ins were critical with the rapidly changing environment, enabling support of the client, auditors and auditees. Even when the answers to questions were not yet known, it was important to share current knowledge. One positive outcome was to add COVID-related topics to the kick-off meeting agenda, so that when challenges arose, rapid action could be taken. Tools used include: a communication plan; brief, scheduled status meetings; email updates; sharing of industry intelligence; establishment of a central information portal; development of a COVID-19 protocol/process information package; as well as COVID-related training sessions.

Teams Were Adaptive

The teams at Advanced Clinical and our clients were adaptive, using a rapid deployment model to address changes in schedules and processes. We developed new processes to address COVID challenges, addressed travel concerns, and navigated the demands for personal protective equipment (PPE). Tools employed included active calendars, flexible processes and procedures to allow for COVID-required modifications, a framework for rapid implementation, resources and new technology to support our teams, identification of a PPE provider for staff that needed to visit sites, and a toolkit to help our team when travel resumed.

New Requests Were Accommodated

Teams worked together to accommodate new requests, rapid turnaround times, changes in staffing, and technology challenges. Tools employed included a “get it done” attitude, a willingness to think outside-the-box for problem solving, an openness to new ways of doing things, brainstorming sessions, and extensive use of online meeting tools, video tours for remote auditing, and novel processes.

Unknowns Were Successfully Handled

Initially, there were many unknowns. There were questions about how long work might be impacted, what elements of an audit could be done virtually, what technology was needed, what regulators would expect, and when “normal” might return. Tools used to address the unknowns and rapid changes included a disruptive event protocol to direct teams on how to manage the variables, auditee COVID policy requests to understand our auditee and vendor limitations, team member support programs and additional trainings to help ease the challenges everyone was facing.

Conclusion

Positive Takeaways

While COVID was hard on everyone involved in the clinical trials enterprise, there were three, key positive takeaways:

1. Greater acceptance of virtual approaches to all activities, including work, auditing, and meetings
2. Improved technology is now more readily available, enabling virtual tours, document sharing, and communication
3. Teams and partnerships are now stronger, with deeper connections, based on having weathered the pandemic together

Stacy Newalu, MPH, RQAP-GCP, CCRC

Associate Director, Compliance and Quality

Stacy has over 20 years of experience in the pharmaceutical industry. She is a former Food and Drug Administration Regulatory Project Manager and has held senior management positions at an Institutional Review Board (IRB) and an academic outpatient clinical research center. Stacy manages contracted Quality Service projects as well as conducts a variety of quality assessments and related activities, including gap assessments, site audits, TMF audits, vendor audits and inspection readiness activities including inspection preparation and mock inspections. Stacy has extensive experience in developing and delivering training programs in the areas of regulatory inspection readiness, research regulations, compliance and quality, and administering and overseeing the regulatory aspects of clinical research. Stacy holds a Master of Public Health Degree in Communicable Diseases, and Bachelor of Science degrees in both Microbiology and Medical Technology.