

Essential Soft Skills for Quality Leaders: Learnings from the COVID-19 Pandemic Response

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Abstract

The COVID-19 pandemic impacted multiple industries in 2020, including every part of the clinical research enterprise – patients, investigational sites, Principal Investigators, Sponsors, CROs, supporting vendors and others. Navigating the challenges of keeping business continuity during this time required many quality professionals to explore new ‘soft’ skills to add to their traditional technical expertise. Authored by an expert from Advanced Clinical, this white paper examines the soft skills that are beneficial in the development of a well-rounded, quality thinker and professional.





Introduction

As the clinical research industry navigated the challenges posed by the COVID-19 pandemic, many quality professionals turned to quality management systems, applicable regulations, and a diverse array of quality tools and experiences. In many instances, however, something was missing. The technical skills and knowledge that many had previously relied on were simply not enough to address these new challenges. Individuals who were able to think more broadly were successful in creating a collaborative, empowering experience that positively impacted all parties. This relied on solutions that worked for all stakeholders, while complying with regulations. Based on the concept of going beyond delegation to true empowerment, “multiplying”¹ is a soft skill based on using teamwork to accomplish more, grow staff, earn loyalty and create a culture of trust and support. This concept and management philosophy take into account the changed needs of individuals, teams, and businesses, proving to be highly impactful.

Response to the COVID-19 Pandemic

In response to the pandemic, the clinical research industry relied on the adaptation of existing, well-defined technical knowledge and expertise, combined with the effective application of critical soft skills to navigate changing circumstances. Organizations that valued operational adaptation and regulatory compliance equally—while also applying out-of-the box thinking and caring for everyone within the organization—typically adapted well. Specifically, communication, multiplying, and compassion were essential.

One of the hardest concepts for quality professionals is to look beyond risks and regulations in order to challenge the status quo. This was particularly important during the pandemic, when it was essential to develop innovative ways to ensure quality in the conduct of clinical trials that also factored in the human component. This is an important skill for well-rounded quality professionals.

While the International Conference for Harmonization (ICH) E6 R2 Guideline focused on the application of risk management, day-to-day interactions with sponsors before the pandemic often indicated that the concept of risk management was not fully welcomed and implemented. The need for a balance of risk and key soft skills became evident in multiple areas once the COVID-19 pandemic began.





It was critical to get sites to work in a new way – quickly adapting protocol design and study conduct to new limitations, dealing with social distancing restrictions, securely uploading source documents, and implementing telemedicine visits.

Initial Response

Unlike many previous crises faced by quality professionals, the COVID-19 pandemic did not provide a long lead time for decision making, leaving little time to draft a response plan, engage in discussions, or organize rounds of peer management review, which are processes that many quality professionals relied upon. Historically, there has been reliance on well thought-out regulations and guidance. In the pandemic, these were not initially available, because regulators were experiencing the same challenges as clinical researchers. However, it was critical to get sites to work in a new way – quickly adapting protocol design and study conduct to new limitations, dealing with social distancing restrictions, securely uploading source documents, and implementing telemedicine visits. At the same time, privacy and regulatory compliance had to be ensured. Challenges were involved in virtually all interactions between stakeholders.

Key steps in the initial response to COVID included the following activities:

- > Understanding regulatory guidance
- > Quickly determining necessary processes, procedures and other actions
- > Devising new approaches to keep research moving forward, ensuring that endpoints were met and trial closures were prevented
- > Collaborating with regulatory agencies to make necessary and compliant adaptations
- > Taking into account the effects of the pandemic on everyone, fostering strong teams and ensuring safety

Ongoing Challenges

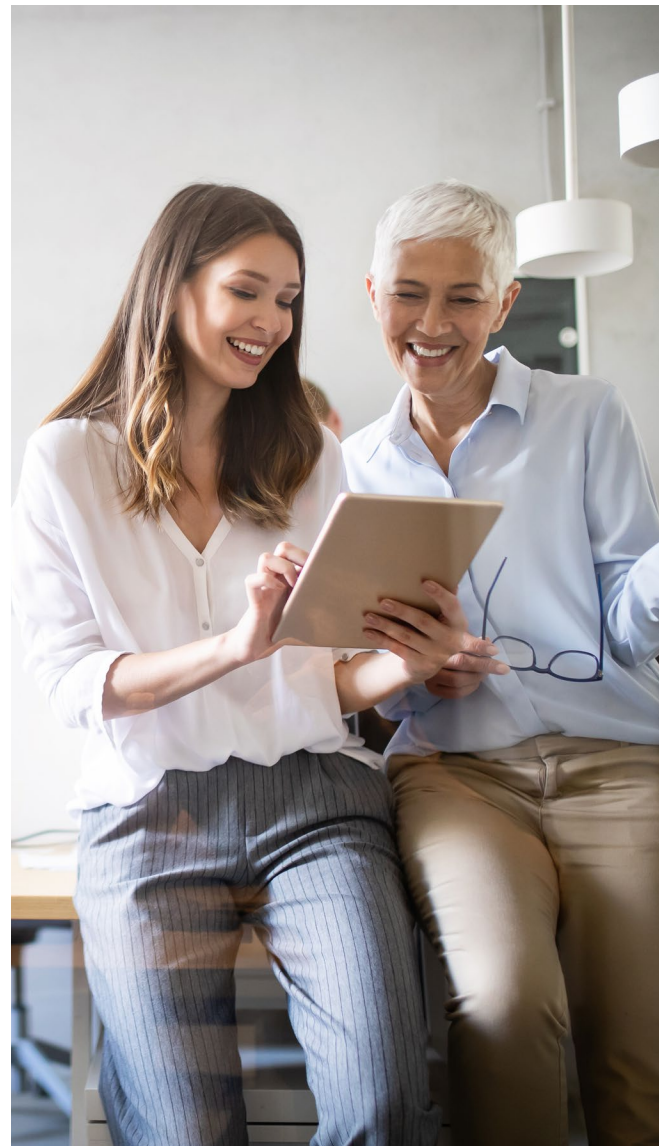
Once the initial, process-related challenges posed by COVID-19 were addressed, new challenges arose. Ongoing monitoring of updates to regulatory guidance was essential, with continued efforts to overcome operational hurdles. The human cost of the pandemic began to be fully felt.

Nonetheless, it was often possible to keep trials going by using remote approaches, addressing budgetary issues to reflect the changed work being performed. Careful documentation of what was done and why was more important than ever, as was frequent communication.

Long-Term Response

Reflecting on experiences and learnings will be helpful in continuing operations during any future disruptions. This will involve adapting and innovating processes permanently to allow for changes while following regulations, and the development or refining of a holistic mindset. Deliverables from this exercise will be defined processes that can adapt to disruptions of any kind, and ongoing monitoring of the wellbeing of all stakeholders.

Critical soft skills that were emphasized from the pandemic are the critical importance of internal and external communication, multiplying, compassion (or emotional intelligence) and grace.





Internal Communication

Pre-COVID internal communication methods applied by Advanced Clinical included:

- > Weekly email updates from the company President on functional accomplishments, customer feedback, and sales
- > Monthly company town hall calls with senior management
- > A monthly company newsletter on current events and business status
- > A quarterly all-staff meeting on the state of the business, including highlights and accolades

During the COVID pandemic, these methods were supplemented with the following:

- > Additional efforts to support staff and keep the organization engaged
- > Frequent email updates from HR and executive management on plans for business continuity, and ultimately, return to normalcy
- > The establishment of a COVID regulatory reference portal that included resources and topics were shared related to working remotely, staying connected, and inclusion
- > Frequent messages from the CEO, sharing thoughts and inspiration, and emphasizing that this was a shared experience
- > Wellbeing listening and sharing sessions, which were especially valuable for those who had not previously worked remotely
- > Human Resources surveys on staff wellbeing, carried out several times during 2020 and 2021, with the goal of staying connected with all staff

External Communication

External communication efforts, involving sites and sponsors, were also increased with the goal of introducing efficiencies such as telemedicine visits and new remote monitoring procedures at sites. New collaborations were established, including open industry sharing to provide support through the challenges of COVID. Examples of initiatives are shown in Figure 1.

Figure 1: Clinical trial industry collaborations during COVID-19





Multiplying

The practice of multiplying enabled managers to invoke each team member's unique skills/abilities and create an atmosphere of innovation, productive effort, and collective intelligence. This contrasts with delegation, which shifts authority and responsibility for particular functions, tasks or decisions from one person to another, but prevents broad organizational benefit in comparison to multiplying.

Giving grace – or ‘courteous goodwill’ – proved to be particularly helpful in addressing situations that seemed insurmountable.

methodologies critical to wellbeing. Leaders have a particular responsibility to take care of their direct reports, colleagues and themselves. A key learning has been the importance of asking for assistance when it is needed – recognizing that these unusual circumstances took virtually everyone outside their comfort zone and beyond their knowledge base.

Grace

Giving grace – or ‘courteous goodwill’ – proved to be particularly helpful in addressing situations that seemed insurmountable. 2020 proved to be a time of much self-reflection related to the limitations of all stakeholders, and giving grace helped in navigating these in a compassionate way. This will continue to be important in the future, to build on the unifying common experience of COVID.

Compassion (Emotional Intelligence)

Another soft skill that was embraced more than ever was compassionate inclusion of all team members, regardless of location, culture, or individual responses to change. Everyone experienced some degree of isolation, fear, uncertainty, and obstacles to daily life during the pandemic. Many approaches and resources were available, with the application of proven





Conclusion

Key takeaways from COVID

Four key takeaways from the pandemic were:

1. Utilization of only technical (hard) skills will limit productivity, innovation and growth.
2. Soft skills were essential to building teams and to business continuity – as in all situations that involve major change.
3. Soft skills can be challenging to learn and apply in a work environment. The pandemic has shown that individuals with solid soft skills stand out as true leaders (and admirable people) and strengthen teams and companies.
4. Soft skills are in high demand during the disruptive periods that inevitably occur in an ever-changing industry, and these should be a focus of development throughout a quality professional's career.

“What we need to do is learn to work in the system, by which I mean that everybody, every team, every platform, every division, every component is there not for individual, competitive profit or recognition, but for contribution to the system as a whole on a win-win basis.”

**William Edwards Deming
(1900-1993)**

REFLECTION QUESTIONS FOR QUALITY PROFESSIONALS

Quality professionals wishing to focus on personal development should consider these questions:

- > How can you ensure to take a comprehensive approach in your role in clinical research (regulations, innovation, compassion, leadership)?
- > How do you react to unanticipated situations? Do you develop short- and long-term plans?
- > How do you ensure you are leading rather than policing?
- > How can you challenge yourself to think differently and still follow regulations?
- > How do you incorporate soft skills into your interactions with people to make you (and others) more effective and better positioned as a leader?
- > What is the level of communication and compassion between yourself and your team? Could it be improved?





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Kimberly has over 20 years of experience developing and implementing quality infrastructure and SOPs across multiple organizations in various management roles with increasing levels of responsibility. Kimberly has directed, planned, and conducted many type audits and quality service support to include sponsor audits, FDA inspections, international health regulatory readiness inspections, ISO 9001:2008 inspections, investigator site audits, TMF audits, for-cause audits, vendor audits, gap assessments, and internal audits. Kimberly holds a Master of Science Degree in Pharmaceutical Science with a Specialization in Drug Development from the University of Cincinnati and a Bachelor of Science Degree in Biological Sciences from Colorado State University.

Resources

1. Multipliers: How the Best Leaders Make Everyone Smarter, Liz Wiseman, 2017

ABOUT ADVANCED CLINICAL

Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research—approaching each opportunity with foresight, character, resilience and innovation. Based on decades of experience, we help our clients achieve better outcomes by conducting candid conversations and anticipating potential issues through our customized solutions.

Visit our website to learn more: www.advancedclinical.com