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A New Remote Reality

Despite the many innovations and brilliant scientific and medical advances, the life-sciences industry is still fairly risk averse. Graham Belgrave, senior VP, European Operations at Advanced Clinical, says one potentially positive outcome is that companies will be “encouraged,” or perhaps forced would be more accurate to consider, to deploy and use the plethora of elegant and functional e-solutions and remote capabilities, some of which have been around for some time. “The pandemic also has kick-started many other potential solutions to access, treat, evaluate, and manage research subjects and as the new normal takes shape, I think we can expect to see some, perhaps radical, alternatives come to the forefront,” he says.

Managing a widely dispersed global team based in offices is normal business for many organizations, and yet what occurred upon lockdown is anything but normal. “We are fortunate to have superb business technology and platforms in use throughout the company; these are designed to protect both our client’s confidential information and to also be GDPR compliant,” Graham says. “Following FDA guidance to ensure explanations relating to COVID-19 of missing data, our biostatistics and data management team developed a COVID-19 Impact EDC page to capture all relevant data in one place. This will dramatically reduce the number and need for mid-study updates and provide all this data in one place.”

Graham says Advanced Clinical is working with sites and clients to transition whenever possible to virtual patient visits, while some sites are also minimizing patient’s on-site attendance through home visits or telehealth. “What has clearly become perhaps self-evident is the absolute need for processes that match the new normal, for timely, frequent communications, robust and compliant systems, and perhaps most importantly, collaboration,” he says. “I believe that this spirit of collaboration, communication, and thinking outside the box will prevail and a return to the status quo would indeed be a retrograde step. I strongly believe that remote working, RBM, and tele visits will continue as will the ongoing innovation associated with Internet-based applications that increase the speed and utility for all parties to communicate and safely and compliantly share information from remote locations. In addition, risk assessment and mitigation steps for new study protocols as well as new or modified requirements for SQV and SIV will continue.”

Graham says, perhaps, more radically, there will be a “blurring” of the CRA and DM roles, perhaps in some instances a blended role within these new paradigms. “I do not see the removal of the need for face-to-face and on-site visits, albeit perhaps at a reduced level, after all I would submit that the establishment of effective working relationships is far easier, at least initially, face to face,” he says. “Overall, I do believe as an industry we have improved many of our processes as a result of COVID-19, which is a definite positive.”

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