Business Continuity for Drug Developers

Highlights:

- Responding to change in "waves" stabilizes and ensures business continuity
- Adapting to the evolution of data collection
- The importance of leveraging technology for continuity
- What the future of study delivery post-COVID-19 looks like

Introduction

From patient participation alternatives and accelerated vaccine research to operational and data management challenges, COVID-19 has proved to be a disruptive force in the clinical research space, forcing the industry to scramble to keep up — and to stay ahead.

There are never guarantees about the future. But there are ways to prepare to keep trials on track and make them flexible enough to weather outside influences that may come along in the future. Thinking ahead for business continuity sets you up for lasting success with long-term thinking and proactive planning.

Protecting patient safety is always top priority during any time but deserves specific care and focus during unforeseen events. Trial integrity, regulatory guidance compliance, and flexibility to achieve sponsor milestones also need to be given careful consideration.

Maintain Communication Pathways

During a time of abrupt transition — such as the rapid onset of COVID-19 restrictions — quickly establishing a dependable communication cadence is important for providing predictability and stability. Stakeholders can then depend on how information will flow, and that factor of uncertainty is eliminated. Keys to keep in mind:

- Establish reliable communication channels to manage the business and make decisions to align study and customer needs

- Consider flexible and creative solutions and multiple pathways among all partners such as forums, the Yammer community platform, or after-hours calls
- Provide guidance for "who, what, and when" across all impacted project teams, considering as many possible scenarios as reasonable
- Offer country-specific insights, such as closings, openings, governmental guidelines, and regulatory requirements
- Share business continuity planning, both for guidance and for documentation purposes

Response Waves

Planning a continuity strategy doesn't need to be an all-at-once proposition; rather, identifying "waves" of responses and rolling out actions at a logical, measured pace can be the difference between floundering and solid business continuity. For example:

- At the onset of a disruption, begin business continuity planning if clinical trial delivery looks to be affected, and review the landscape of studies by country as impact spreads
- As areas begin to be impacted, define what constitutes a remote site visit; offer mitigation plans for paper CRF receipt and processing if sent to offices that may be closed; and initiate discussions with sponsors on response to interruptions
- Determine the opportunity for remote visits based on the phase of the project, intended frequency of site visits, and the date of the last visit — and develop training for remote monitoring visit conduct
- Enrich processes to complete source document verification via remote monitoring visits; assess options for alternate service provisions (telemedicine platforms, eSource, etc.)
- Execute risk assessment process, update study databases to capture affected data, and determine trial modifications necessary to attain goals

The Evolution of Data Collection

The clinical research industry has adapted quickly since the onset of COVID-19. The most notable shift has been the surge of hybrid or fully virtual trials — and electronic data capture is the critical component in making them possible. Ensuring business continuity depends on adopting new models of data collection.

Data collection today and in the future relies on pivoting to new approaches such as partnering with experienced eSuite providers to optimize remote clinical trial execution, hybrid implementation alternatives, and alternate study delivery scenarios. The goal is to optimize all parts of remote clinical trial execution in a more electronic way — not only patient data collection or remote site monitoring, but the entire process.

There are various benefits of eSource. Paper source documentation is not only more expensive but comes with storage challenges and risk of loss or damage. Moving to electronic collection methods such as eCOA, ePRO, and eConsent reduce study costs and improve data quality. As the industry continues to advance, using paper methods comes with the very real risk of being left behind. eSource benefits include:

- Decrease the average time from measurement to EDC entry by more than eight days
- Eliminate the costs of usage and storage of paper by 94%
- Reduce monitoring visits by 50%
- Encourage faster adoption of protocol changes
- Ability to identify trial issues early and take quick action

eClinical technology options include electronic data capture (EDC), direct data capture (DDC), ePRO, eTMF, and eConsent. These are tools that will allow trials to continue remotely and safely while maintaining compliance with regulation.

Maintaining Continuity with Decentralized Trials

Virtual and hybrid trials also bring other advantages beyond data collection, including:

- Patient centricity; there is a reduced burden on patients, increased ease of use, and reduction of timelines, giving patients faster access to treatment
- Compliance; hybrid or decentralized trials result in a reduction of missed visits and real-time remote monitoring enables earlier intervention and better adherence to therapy
- Improved data quality
- Technology continues to improve and integrate into our lives. New generations expect convenience and modern technology; outdated technology and processes can dissuade potential patients. By adopting technology early, you can learn it, grow with it, and be prepared for any future disruptions.

Looking Forward

Maintaining business continuity during the pandemic has been an exercise in adaptation and adoption of technologies that have been around prior to COVID-19, but that are now taking on a much more impactful role. Study delivery moving forward means not only maintaining these changes but continuing to grow with them.

Telehealth will continue to grow, possibly woven together with on-site activities. Mobile nursing and home health visits will grow, possibly with call center support paradigms, meeting patients where they are in a way that they need. Investigational product delivery has much opportunity for growth and adaptation, including smart packaging and direct ship-to-patients where possible, to increase confidence that patients are compliant when they're not directly observed at a site. Virtual trial

execution will continue to evolve, as we are all increasingly experienced and familiar with telecommunication platforms that could continue to play a larger role, such as through virtual investigator meetings.

Achieving business continuity means the process itself must be flexible — just as we've shown in this crisis. The ability to pivot in a trial while still maintaining patient safety and trial integrity needs to remain top of mind moving forward.

Virtual trials won't become mainstream overnight, but ultimately the way we pull processes and technology together depends on the people who are here to help patients we're serving and to bring clinical trials to life.

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