Impact of COVID-19 on Clinical Trials

Executive Summary

The social-distancing restrictions of the COVID-19 pandemic, in addition to the redirection of hospital resources, may pose extensive burdens on clinical trials. The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have issued new guidance for sponsors to continue research while protecting patients and healthcare workers. In addition to adjusting trial protocols to continue research, it’s also important to consider ways in which manufacturers’ relationships (with trial sites and patients) can be buttressed, groundwork can be laid for future trials, and public education can help build the reputation of pharmaceutical brands and the industry as a whole.

Situation

Due to the COVID-19 pandemic, clinical-trial sponsors, patients, researchers, and healthcare professionals (HCPs) can have concerns that initiating trials or following trial protocols may put them in jeopardy. Trials normally require HCPs and researchers to have frequent in-person, in-office contact with enrolled subjects, but coronavirus-mitigation efforts direct people to self-isolate and avoid nonessential activities like these. The efforts and newly instituted regulations that have been put in place to stop the spread of COVID-19 have halted many clinical trials and could threaten future pharmaceutical innovations.

Challenge

The number of clinical-trial delays and suspensions is difficult to quantify, but many companies have made announcements about pausing existing trials or delaying new trials in order to protect patients in these days of social distancing. These changes, as well as corresponding delays in clinical-trial recruitment, and an inability to comply with protocol in existing trials, can cost the life-sciences industry tens or even hundreds of millions of dollars in unrealized revenue, and prevent lifesaving treatments from reaching patients.

Physicians report that clinical-trial enrollment is already being impacted across all specialties: patients are skipping follow-up appointments, and some clinical-trial sites are shutting down.

The FDA released this guidance to emphasize that at all times, patients’ safety should continue to be at the forefront of considerations. We want to support the continuance of these clinical trials in compliance with good clinical practice and minimizing risks to trial integrity, while also safeguarding the health and well-being of study participants.

– ANAND SHAH, M.D., FDA DEPUTY COMMISSIONER FOR MEDICAL AND SCIENTIFIC AFFAIRS
Opportunity

New guidance from the FDA and EMA has opened the door to protocol flexibility in order to maintain the integrity of the research currently underway. There is an opportunity to use the disruption caused by the global COVID-19 pandemic to adapt and evolve for the future. Practices are changing because of COVID-19 and will likely continue to change; healthcare will be permanently changed by the pandemic. Clinical-trial sponsors need to reassess recruitment strategies, relationships with trial centers and patients, and the overall ways in which study protocols are designed—particularly in-person engagement. This is a time to plan strategies for successful trials in a post-COVID-19 world, not only to succeed in the short term, but also in the “new normal” that will follow.

Improvise, Adapt and Overcome

ADAPT PROTOCOLS TO LEVERAGE EXISTING TECHNOLOGIES

The new guidance documents from FDA and EMA (and from the National Institutes of Health for NIH-funded studies) focus on current trials and allow for some protocol variation in order to protect those involved and provide flexibility due to the global impact on healthcare overall. Regulatory and industry leaders agree that understanding and complying with this guidance is vital to protect patients and keep trials moving forward.

While forward-thinking companies have been moving in this direction for some time, the COVID-19 pandemic is a sea change that will require all R&D organizations to determine how remote digital measures can keep their pipeline development continuing through these difficult times, delivering novel treatments to those who are in need.

- ELENA IZMAILOVA, PH.D, CHIEF SCIENTIFIC OFFICER, KONEKSA HEALTH
Under-enrollment can be an addressable barrier, overcome with better targeting, tailored messaging, and an ongoing, active appreciation of the changing consumer mindset.

Data-driven insights will ensure that recruitment communications keep pace with the fast-moving environment and connect with recipients on an authentic and emotional level.

**Corporate Support of Clinical Trial Innovation**

As the world looks to the life-sciences industry to find treatments, tests, and vaccines to address COVID-19, the industry is showing that it’s up for the challenge. Its nimble response has been in the headlines as many companies add to research work by also pledging funds to help healthcare workers, patients, and communities. The industry’s involvement in the COVID-19 response, from testing to treatments to vaccines, opens an opportunity to showcase drugmakers’ dedication to research and innovation, and support and education of patients and healthcare professionals alike.

Even before the pandemic, clinical-trial recruitment represented a significant challenge for sponsors. From 2006-2010, $2 billion was wasted on starting clinical trials that were not concluded, due to lack of participants. Traditional trial recruitment processes will need to evolve, because in a post-COVID-19 world, rapid trial start-up will be vital.

Not all trials are affected equally. During the pandemic, patients at higher risk seem to include men, the elderly, and those with heart or lung diseases or compromised immune systems. Simultaneously, a higher rate of unemployment and a fear of losing access to healthcare are likely to become a concern or barrier for patients. It’s important to take these realities into account when considering how perceptions about clinical-trial participation are evolving.

It is also important to continue to recruit patients where appropriate. Building a database of potential research participants and creating a support program to keep enrollees up to date on news, reassuring them that their safety is paramount, and providing updates on the study status and its protocols can make patients feel cared for. Patients with ailments that are slower to progress will meet the screener criteria now, and their conditions will be less likely to change while they’re waiting for the trial to begin. Having subjects ready will be helpful when confirming sites.

Similarly, hospitals and commercial sites have varying needs and concerns during the current slowdown of trials. Hospitals will be shifting their focus to handle the pandemic, while commercial sites will see a lack of activity. Again, communication is key to remove uncertainty and help participants – particularly, in this case, commercial sites – feel reassured.

In addition to the individual contributions companies are already making, collective action is critical to ensure any promising studies into vaccines, drugs, and diagnostics are quickly scaled to people around the world who are affected by this pandemic.

– VAS NARASIMHAN, CEO, NOVARTIS
A recent survey of U.S. consumers showed personal values are already shifting as a result of the pandemic. They reported being more concerned about their community and society. The majority of consumers believe brands have a responsibility to help during the pandemic. Life-science companies are on the front lines. The industry is showing conviction, commitment, and action. This can also be a time to improve health literacy about clinical trials, shining a light on what it takes to bring a new treatment to market.

A clinical-trial communication plan and content strategy as part of a full corporate communication plan can ensure transparency and continue to build trust with consumers and trial partners. A clinical-trial education campaign can tap into the current interest in the treatment-discovery process.