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The Impact of COVID-19 on Clinical Research in the Life Sciences Industry: Is there a Silver Lining?

Related Professionals

Matthew B. Roberts
803.253.8286
mroberts@maynardnexsen.com

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Clinical research is one of the foundations of the Life Sciences industry as it involves the scientific investigation and treatment of diseases and other medical conditions in order to improve medical knowledge related to the diagnosis, treatment, and prevention of such diseases and medical conditions. Clinical research is the underlying process that results in the development of ground breaking new drugs and treatments that cure or treat diseases that improve all of our lives. One of the best and most recent examples of the importance of clinical research is the development of vaccines for the COVID-19 virus which to date has taken the lives of over 5 million people across the globe since early 2020.

The impact of the COVID-19 pandemic on the clinical research industry has been profound and in some respects may prove to be an inflection point for the Life Sciences industry.

The COVID-19 pandemic created massive disruption within the world of clinical research. In 2020, over 79% of ongoing clinical trials were disrupted in one way or another by COVID-19[1]. The disruptions ranged from stopping ongoing trials, pausing recruitment of ongoing trials and pausing the development of new clinical study sites[2]. Enrollment in clinical trials dropped dramatically during the early stages of the pandemic as potential participants were reluctant to make trips to hospitals or other research sites. In addition, many investigators, sub-investigators, and research staff had to shift focus to COVID related support instead of working on clinical research efforts.

Beyond the disruption to existing clinical research studies, however, COVID-19 has had other impacts on the clinical research industry that could have a potentially positive impact on how clinical research is conducted in the future.

COVID-19 Resulted in an Acceleration of the Clinical Research Process

When faced with the rapidly spreading COVID-19 virus, pharmaceutical companies and governments collaborated to accelerate the clinical research process in order to develop a vaccine that would work against COVID-19. Previously, the fastest a vaccine had been developed in the U.S. was four years when the vaccine for the mumps virus was developed in the 1960s[3]. In light of the global health emergency created by the COVID-19 pandemic, researchers were able to reduce the normal time to arrive at a vaccine by years. How was this done? One of the reasons for the rapid development of the COVID-19 vaccine was the years of prior research on vaccine development for other viruses, like HIV[4]. Researchers were also able to quickly determine the specific genetic makeup of the SARS-COV-2 virus by early 2020 and they used technology from RNA-based templates to develop a potential vaccine[5]. Another important factor in streamlining the development for the COVID-19 vaccine was the hundreds of thousands of people who volunteered to participate in the clinical studies for the vaccine development. In addition, the U.S. Government implemented Operation Warp Speed which provided very large government contracts and research grants to pharmaceutical companies to research and produce vaccines. The U.S. Government also had the FDA advance all COVID-19 vaccine clinical research studies to the front of the regulatory approval line through the use of emergency use authorizations (EUAs). This lead to the development of multiple COVID-19 vaccines that were ready for mass distribution within 1 year of the identification of the COVID-19 virus, which is a remarkable accomplishment. The FDA also used EUA to expedite other responses to COVID-19 by approving new testing and additional sources and types of personal protective equipment ("PPE"). The development and distribution of the vaccine was a groundbreaking accomplishment that reflected the resilience and innovation of the clinical research industry. According to some clinical researchers, the rapid creation of COVID-19 vaccines is "a sea change in how to develop vaccines in the future[6]."

As we continue to work through the COVID-19 pandemic, it remains to be seen how much faster future clinical research studies will be accelerated in the future based on our COVID-19 clinical research experience. The FDA is under both political and media pressure to accelerate its approval process because of the COVID-19 experience and the clinical research industry is looking at its normal processes to determine if things can and should be done in a different way in order to streamline and accelerate the overall process while at the same time maintaining safety and scientific integrity.

A New Focus on the Clinical Research Participant

Another potential change in clinical research that was caused in part by COVID-19 is an effort by clinical trial sponsors to focus more on the clinical trial participant and their experience during the clinical trial. This includes trying to reduce the administrative burden on clinical trial participants and making the process simpler and easier for participants to navigate. Clinical trial sponsors are also evaluating trials with more of a focus on quality of life for the participants and increasing the use of patient support groups or patient advocates so it is easier for clinical trials to recruit new participants and to keep the participants engaged throughout the life of the clinical trial[7].

Use of More Decentralized Clinical Research

A decentralized clinical trial (DCT) is defined as a clinical study executed through telemedicine and mobile /local healthcare provider processes and technologies that brings the trial's activities to the patient at home rather than using the traditional model of bringing patients to a trial site[8]. Because much of the world was in lockdown mode to deal with the implications of COVID-19, clinical researchers increased the use of DCTs during 2020. This included the use of more virtual encounters and technology to connect clinical trial participants with the investigators. It is anticipated that this will occur more in the future as researchers can gather better data when it is easier for patients to report the data. With DCTs, patients can report data via their smart phone or tablets from home instead of having to be physically present at a clinical research site[9]. Use of DCTs is also seen as a successful tool in recruiting the appropriate patient populations by increasing both access to clinical trials and the overall diversity of trial participants[10]. Having a diverse group of clinical trial participants can help ensure that the drug or device being tested is safe and effective[11].

Increased use of Digital Technology

The use of digital technology by patients and participants in clinical trials has steadily increased over the last several years. During COVID-19 and with the increase in DCTs, the use of mobile devices such as smart phones or tablets, digital wearables or other types of biosensors have steadily increased[12]. The use of this digital technology provides clinical researchers with access to continuous data for longer periods of time and it is easier for clinical trial participants to use this technology on a daily basis without disruption to their daily lives. The use of digital technology has also increased the opportunity for clinical trial sponsors to obtain real-world data (RWD) and real-world evidence (RWE) from clinical study participants. This result stemmed in part from the FDA's launch of a program focused on the increased use of RWD and RWE[13]. This kind of information has been used to support clinical trial designs and studies to generate innovative approaches to clinical studies[14].

Is there a silver lining from COVID-19 when it comes to clinical trials?

The long term impacts of COVID-19 across the health care spectrum still remain to be determined, but one of the short term impacts of this global pandemic could prove to be potentially significant and positive changes in the way that the clinical research industry operates. These changes could lead to a faster clinical research process that embraces the use of new technology such as digital therapeutics and development of a broader and more diverse base of clinical participants.

For a look at the regulatory framework for clinical trials in the life science industry and the risks faced by companies within the industry – including a discussion of potential future changes caused by the pandemic – watch Nexsen Pruet's on-demand webinar, "Understanding Clinical Research Framework and Challenges in the Life Sciences Industry," presented by Matthew Roberts of Nexsen Pruet and Rakel Meir of Biogen.

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