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CASE STUDY

REMOTE ENROLLMENT IN A NON-SIGNIFICANT RISK DEVICE STUDY

DURING THE COVID-19 PANDEMIC

The COVID-19 pandemic arrived in the United States as IMARC was working with a client to initiate a new non-significant risk (NSR) study. Since the study involved a simple device for a common, debilitating condition (migraine headaches), and the chosen study sites were standalone clinics, we worked with the study sponsor and study site teams to implement a process to enroll subjects remotely. After reviewing the protocol and data collection that would typically be completed in person, the IMARC study team determined that all required and pertinent study information could be collected remotely from the subject via phone or virtual visits without adding additional risks to the subjects.

We referenced the FDA Guidance on the Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic[1] and WIRB recommendations for continuing research due to the COVID-19 pandemic[2]. Once the IMARC study team had agreed on the feasibility of a remote trial, we reached out to each study site to discuss the possibility of converting the study to a remote approach.

A few study sites had already been put under stay-in-place orders to help control the pandemic, meaning that they had minimal workforce, in-person study enrollment was halted, and research staff were working completely from home. This imposed some unique challenges, but study sites were motivated to propose solutions to remotely screen, enroll and conduct the study, while ensuring their staff could remain safely working in such uncertain times. Much collaboration and many phone calls ensued, resulting in workable solutions for each site.

The proposed updates to the study plans were detailed in a study COVID-19 clarification memo which was submitted to, and approved by the IRB prior to implementation. Since the timeline of the pandemic's impact is unknown, the IMARC study team ensured that the study could be completed according to the original study plan, in case the difficulties resulting from the pandemic resolved prior to implementation.

Several new processes, including remote informed consent, and investigational device and study diary provision were needed.

The following processes were developed:

CONSENT

In order to obtain over-the-phone consent, subjects underwent the phone screening process that was planned prior to an in-person baseline visit. If the subject met the screening criteria and was agreeable to participating in the study, a copy of the most current IRB-approved informed consent form was provided to the subject electronically or via mail based on the subject's capabilities.

Members of the research team then spoke with the subject, provided an in-depth discussion on the study and the study specifics, answered any questions the subject may have had, and verified subject understanding of the study. If the subject was agreeable to take part in the study, they were asked to provide verbal consent, which was to be documented by the site staff. Once the subject had verbalized consent, the site followed two possible options:

1. If the subject was able and had the resources and knowledge, they were asked to sign, scan and return via email the completed informed consent form. The completed informed consent form was printed and maintained in the study's subject binder.

2. If the subject was unable or did not have the resources or knowledge to complete the informed consent form electronically, the most current IRB-approved informed consent form was mailed to the subject. The subject was asked to sign and return the form in the provided return-postage envelope. The original consent form was then filed in the subject's binder.

In order to ensure subject identity, we recommended that a copy of the subject's driver's license or identification card be included with the signed consent form the subject sent back to the site.

INVESTIGATIONAL PRODUCT

Once the signed consent was received by the site, the members of the research team would contact the subject and complete the baseline visit. These remote visits occurred over the phone or through channels such as FaceTime, Skype, Microsoft Teams, WebEx or other remote portals.

Once the subject was determined to have met all enrollment criteria, they were randomized and a copy of the fully signed consent, the investigational device, subject diaries and written completion instructions were sent to the subject via courier or mail service. This also included self-addressed, prepaid mailers for subjects to return the device and diaries upon completion of the study. Some sites decided to use a courier versus mail service to show complete product accountability and limit possible damage to the product.

Due to the unknown impact COVID-19 may have on subjects and subsequent study data, the IMARC study team needed to decide whether diagnosed subjects could be enrolled, and what should happen if an enrolled subject became diagnosed during study participation. It was decided that individuals who were known to have been diagnosed with COVID-19 would not be included or enrolled in the study (adding an additional exclusion criterion to the study).

It was also decided that if subjects were enrolled in the trial and later diagnosed with COVID-19 or hospitalized with suspected COVID-19 during the duration of study enrollment, that they would be withdrawn from the study due to the unknown certainty the diagnosis may have on the study results. For these cases, the site would notify the subject of study discontinuation and instructions for the return of study diaries and devices and maintain all relevant documentation of such within the subject's binder.

Monitoring of the study was completed remotely using a 21 CFR Part 11 compliant document-sharing platform. This platform would also be used to ensure Principal Investigator (PI) oversight in the event that the PI was unable to review the documents on site.

Understandably, this approach may not work for all studies and sites, but in our case, COVID-19 caused us to rethink our mindset and either postpone due to across-the-board enrollment holds and in-person visits, or find collaborative solutions to turn this once in-person study to a successful remote study, while not compromising subject safety or study data. **To us, this pandemic showed that critical thinking, flexibility, and adaptability are critical to conducting successful studies in uncertain times.**

AUTHORS

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SOURCES

1. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic; Guidance for Industry, Investigators, and Institutional Review Boards. March 2020, Updated on April 2, 2020.
2. Resource Center: COVID-19 and Clinical Trial Operations; https://www.wcgclinical.com/covid-19/