Conducting Clinical Trials and Human Factor Studies During COVID-19 Pandemic for Novel, Non-Contact Mobile-Digital App, InteloMed® TeleHealth Technology (ITT!), that Detects Respiratory and Pulse Rates through Android® or iPhone® Camera

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THE CHALLENGE

The challenge was to develop a variety of study-related documents and conduct four studies for InteloMed®. The studies were conducted to collect clinical data to support the company's 510k application for their non-contact mobile-digital telehealth app. To conduct the testing of the mobile-digital app, CRS developed protocols with unique study procedures, which allowed for in-person testing while maintaining participant and research team safety during COVID-19. A unique challenge to overcome was that, in order to test the mobile-digital app, participants had to have their face fully exposed, requiring participants to remove their masks. Participant recruitment was an interesting challenge as skin tones ranging from extremely fair to dark had to be recruited to ensure that the mobile app was able to collect validated data from a diverse population.

Executive Summary

A Pittsburgh-area digital health app company spun out of the University of Pittsburgh Medical Center (UPMC) developed a novel digital app based upon existing cardiovascular monitoring which was further augmented with image processing technology from Carnegie Mellon University (CMU) in 2019-2020 when COVID-19 hit. The company enlisted the services of Clinical Research Strategies (CRS) to conduct its clinical trials and usability/human factors testing to support a 510k application. COVID-19 presented extremely challenging conditions to conduct in-person testing, but with personal protective equipment (PPE) and special measures that protected the safety and welfare of research staff and participants, multiple clinical trials and human factors testing were successfully conducted during the extreme conditions of the global pandemic.

The Ask

Develop a trials and human factors program with a low-cost solution for the Sponsor. CRS was asked to assist with regulatory set-up, development of clinical protocols, case report forms, informed consent forms, clinical study reports, and tools to assist with data entry and analysis. In addition to the development of study-related documents, CRS was tasked to run the studies from start to finish. Conducting the studies included site selection, participant recruitment and screening, collection of informed consent, adherence to study procedures, data entry, and providing participants with reimbursement. This program lasted 18 months, including the unexpected stoppage of 6 months during COVID-19 to eliminate contact with subjects and the potential spread of the virus.

The Solution

Several CRS members working at different capacities on each study successfully conducted the trials in accordance with GCP requirements. Study documents were developed, reviewed, revised, and approved within requested timelines. Studies were approved by IRBs, subjects were recruited, and participant and research

team safety and protection from COVID-19 remained front and center. Subsequent Human Factors studies were developed and completed with follow-up reports for FDA submission.

The Result

CRS successfully conducted four studies in a short time frame thanks to their team's diverse knowledge, expertise, and skillsets. CRS was creative in their efforts to conduct the studies in ways which allowed participants to remove their PPE while maintaining protection for all involved.

CRS took the mobile app created by InteloMed and verified crucial components of its software to determine whether the app was a feasible and accurate tool for use in telehealth. The data collected during verification of the apps software supported InteloMed's submission of their 510k application. CRS conducted a pilot study to verify the algorithm of the mobile app to ensure accurate collection of pulse and respiratory rate in a small group of subjects. Once the algorithm was verified, CRS then assessed the accuracy of pulse and respiratory rate data collected via the mobile app in a larger group. Accuracy was determined by comparing data collected via the mobile app to data collected from the commercially available Masimo pulse oximeter device, a device commonly used in clinical settings to collect patient pulse and respiratory rates. Additional studies were conducted to ensure that the mobile app was accurate in numerous light settings and to assess the usability of the app to both clinical and non-clinical users. The CRS team emphasized the importance of app usability testing based on years of experience.

CRS developed unique case report forms for the usability/human factors study to provide InteloMed with informative feedback from both clinical and non-clinical users. The feedback provided by users aimed to assist with steering the company in ways to improve their mobile app in the future to capture additional health indications — a special touch CRS knew the client would appreciate, especially down the road!

THE OUTCOME

With the clinical data collected by CRS, InteloMed has successfully submitted their 510k application to the FDA in the hopes of FDA clearance. InteloMed intends to have their mobile app both as a standalone app and integrated into existing telemedicine platforms, such as those developed to address the current COVID-19 pandemic. Having a non-contact app has numerous benefits including reduction of patient and caregiver exposure to diseases and infections in a hospital or doctor's office, empowerment of patients to monitor themselves, and the ability for family members to monitor loved ones health status from far away.

Quotes

"CRS did a very nice job for us and we greatly appreciate their expertise and timeliness, especially pushing at the end despite the COVID-19 difficulties in our trials and human factors programs."

— **Bill Malloy**, CEO
InteloMed

"CRS was very supportive and helpful during our clinical studies and FDA submission preparation."

— **Anne Brumfield**, VP Algorithm & Signal Imagineering
InteloMed

ABOUT THE AUTHOR

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Alyssa serves as a project lead at CRS and is responsible for managing multiple trials involving medical devices and drug development research in GI surgery, abdominoplasty, oncology, infectious diseases, respiratory disorders, and digital therapeutics. Ms. Harris also has experience managing federally funded research programs in vulnerable populations, specifically in the neonatal intensive care unit.

Alyssa earned her master's degree from the University of Pittsburgh in Health, Physical Activity and Chronic Disease, focusing on the research track. Her undergraduate degree is in Exercise Physiology, where Ms. Harris gained extensive experience working in chronic disease research, specifically with metabolic disorders, and leading weight loss and physical activity interventions. Ms. Harris brings a unique range of expertise to CRS, and thrives in an environment that uses new methods and tools in research.

Clinical Research STRATEGIES

ABOUT CLINICAL RESEARCH STRATEGIES

CRS is a US-owned and operated contract research organization and executive management consultancy for start-up and mid-size life sciences companies with a mission to improve their performance and provide a successful clinical research development plan and strategy. Our advisors have been everywhere – clinical research organizations, life science start-ups, medical device companies, and large pharma.