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COVID-RED consortium launches Decentralized Clinical Trial built on Castor's DCT platform

When the pandemic hit, **Julius Clinical** was passionate to help in the global fight against COVID-19 and excited to expand on its experience with Decentralized Clinical Trials (DCT) in a real-world setting. However, the extraordinary circumstances and trial design brought new challenges to overcome.

> *"When COVID 19 hit, we knew we could help. Teaming up with Castor helped to increase the probability of success."* – *Julius Clinical*

Forging a new path

COVID-RED (Remote Early Detection) is a fully remote clinical trial aimed at the early detection of COVID-19 infection. Implementing this study put new Decentralized Clinical Trial (DCT) methods to the test. The study leveraged wearable sensor technology and machine learning to detect changes in breathing rate, pulse, heart rate variability, perfusion, and skin temperature. Participants received the Ava bracelet, a wearable medical device, and downloaded the complementary Ava COVID-RED smartphone app each morning and received real-time alerts about a possible COVID-19 infection. This personalized digital feedback could result in the advice to get tested, even before symptoms appeared.

The COVID-RED study was not just any clinical trial. The enrollment targets were 13,000 people from the general population and an additional 7,000 from high-risk groups. Under ordinary circumstances, recruiting 20,000 participants would require multiple sites, complicated administrative processes, and in-person participant visits. Under COVID-19 restrictions, travel was discouraged if not outright prohibited. Further, high-risk participants often preferred to stay at home as much as possible, meaning a study coordinator might have needed to visit each participant to gather informed consent and instruct a (partially elderly) population in the use of a wearable device. Running the trial entirely remote was, therefore, the best option.

Julius Clinical

Combining forces

To achieve the challenging targets, participants needed to be engaged and retained remotely, while data was automatically collected from thousands of devices. At the same time, researchers had to be provided with a clear oversight dashboard of the study's progress. Because of its positive experience with Castor's software and support in the past, Julius Clinical decided to combine forces with Castor to make the COVID-RED study a success. They adopted Castor's eClinical suite and designed a new trial workflow:



1. Participants were screened via a Castor-powered registration and participant portal, where they entered their email addresses and completed a pre-screening survey to determine eligibility.

2. Through Castor eConsent, eligible participants read the informed consent form and signed it electronically; in case of any questions, participants could contact the COVID-RED helpdesk through email or by phone.

3. The participants' consent was securely recorded and updated in Castor EDC, along with necessary personal information like address and phone number for shipping the participant study-related materials.

4. Once the Ava bracelet had been received, the data collection process could start.

5. Survey data was captured and distributed through Castor ePRO, including data on the participant's vaccination status, exposure to infected individuals, and other medically sensitive information.

"Castor's infrastructure ensured we were able to effectively carry out this study while keeping administrative burden, costs, and losses in participant engagement to a minimum. More importantly, we achieved our objectives while maximizing participant safety and well-being via DCT during a global pandemic. We felt supported by the Castor team, with the Support and Success Team standing by in case we encountered issues. The simplicity of their user interface made it easy to get new study staff trained quickly."

– Julius Clinical

Castor made it easy to scale this vital research as required while minimizing overhead. Julius Clinical succeeded in recruiting over 17,824 participants in 15 weeks during a global pandemic; this achievement would have been very challenging to accomplish without tools purpose-built for decentralized trials.

Experience the power of Castor today

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