

An Alternative Approach to Continued COVID-19 Research

COVID-19 has dominated our lives for two years now. Although we are returning to a new normal, with the help of rapidly developed vaccines, do we truly understand the virus? Why does it affect one patient more than another? Why do some patients deteriorate rapidly, while other slowly recover? COSMIC-19 is aiming to answer these questions using AI (Artificial Intelligence) and wearable technologies.

COSMIC-19 is an innovative study which has combined a range of expertise to deliver a new approach to clinical trial delivery. COSMIC-19 stands for COntinuous Signs Monitoring in Covid-19 patients. The study has been delivered by Aptus Clinical in partnership with Zenziium (AI technology), The Christie NHS Foundation Trust and in collaboration with Manchester University Foundation NHS Trust.

COSMIC-19 is unusual in that it is utilising advanced AI capabilities, to search for patterns in the patient's data. AI allows vast amounts of data to be assessed from each individual patient and patterns proposed and reviewed.

In August 2020 we were able to announce recruitment had started. Whilst the focus was on finding a vaccine, COSMIC-19 became one of a few investigatory studies to try and learn more about the virus. The study recruited 60 patients who were suspected or confirmed COVID-19 cases.

These patients went on to have their vital signs and observations monitored using advanced wireless wearable sensors, with AI technology used to retrospectively look for and predict patterns in the patients' vital signs. The sensor used were the Isansys LifeTouch and LifeTemp skin sensors which measure heart rate, heart rate interval, respiratory rate and body temperature. In addition, patients' blood pressure and oxygen saturation were measured via separate devices. Alongside this sensor data, patients' medical history, ongoing care and clinical outcome were captured and validated using an Electronic Data Capture (EDC) system. This provided additional data to enhance the AI model development.

The concept tested the potential that the medical team could be proactively alerted if the patient is predicted to deteriorate in the coming hours or even days. If the prediction indicates that the patient needs critical care, the medical team could then intervene earlier giving patients the best chance of recovery.

The COSMIC-19 Principal Investigator, Professor Fiona Thistlethwaite, medical oncologist at The Christie, said, "Unfortunately some patients who are suffering from COVID-19 on our hospital wards can become seriously unwell. By using this system, we hope to be able to identify these patients early and this may mean

we can optimise their management without the need for them to go to intensive care."

Dr. Anthony Wilson, the Intensive Care Consultant coordinating the trial at MFT, said, "This technology is a glimpse of how we will monitor hospital patients in the future and it's fantastic that MFT and The Christie are frontrunners in such innovation."

Our involvement and collaborations have led us to being entrusted with a new type of clinical trial data that includes the vast amounts of wearable data collected alongside the usual clinical data. This utilised our EDC (Electronic Data Collection) and file sharing systems in the best way, truly showcasing how they can be used to deliver a collaborative and state of the art study design. This study also included co-development of an eTMF (electronic Trial Master File) for several key pieces of data that the wearable sensors presented.

The new elements of the EDC and eTMF will benefit future studies in the collation and processing of data from a range of sources, specifically when the study involves AI modelling. These studies are at the forefront of digital advancements and to have been able to facilitate the data management demonstrates a passion for developing with technology whilst maintaining clinical integrity.

Steve McConchie, CEO of Aptus Clinical said: "We are delighted to have provided clinical operations and Data Management support for this important and transformative clinical trial. Working with the NHS and AI partners, we have developed a novel data sharing system that compliantly integrates biosensor data from patients with their clinical data and transfers it seamlessly to Zenziium for analysis. We are confident that the infrastructure we have built in Manchester can be easily applied to ensure future clinical trials benefit from these AI driven insights, and ultimately lead to better therapies for patients."

Anthony D. Bashall, Managing Director & Founder of Zenziium stated, "We are extremely excited to apply our AI technology based on time-series Deep Learning including DeepHRV® to this challenge, with the potential to make a substantial impact on patient outcomes."

Paul Blaney

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