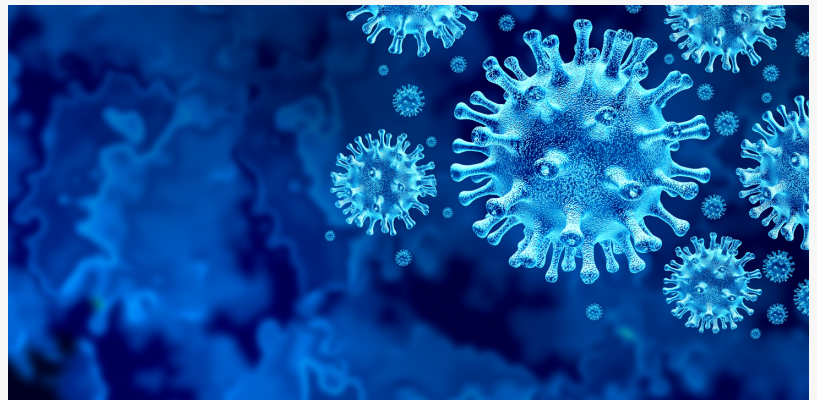


OpenClinica and Quantum Leap Healthcare Collaborative Awarded Support to Power Expansion of the I-SPY COVID Trial

OpenClinica is powering a large adaptive platform trial in partnership with Quantum Leap Healthcare Collaborative for patients hardest hit by COVID-19

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[/Einpresswire.com/](https://www.einpresswire.com/) -- As researchers race to find safe and effective treatments for COVID-19, clinical research software company [OpenClinica](#) is powering a large adaptive platform trial in partnership with [Quantum Leap Healthcare Collaborative](#) for patients hardest hit by COVID-19. In December 2020, the trial's significant life-saving potential drove a major contract to Quantum Leap Healthcare to expand and accelerate their efforts. The investment is being used to scale the phase 2 clinical trial, boost patient recruitment, and accelerate data collection by extending the trial into non-academic hospitals and non-research centers.



SARS-CoV-2



OpenClinica

Electronic Data Capture (EDC)



**Quantum Leap
Healthcare Collaborative**

Quantum Leap Healthcare Collaborative

“We initially built a relationship with Quantum Leap Healthcare when our clinical trial software supported their signature breast cancer adaptive trial,” explains OpenClinica CEO Cal Collins. “When the COVID-19 crisis hit, their leadership team identified that a similar adaptive platform trial design could quickly and efficiently find effective COVID-19 treatments.”

Although adaptive platform trials are not a new paradigm, their advantages are on full display in this particular trial application due to the COVID-19 public health crisis. This study design approach allows multiple therapies to be trialed at once, with new treatments continually added as they become available. Once sufficient data is gathered on a treatment or it is deemed ineffective, it is retired from the trial. Amending the trial to incorporate new treatments—rather



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Cal Collins, OpenClinica CEO

than setting up a parallel trial—radically decreases time to get new treatments incorporated by streamlining IRB approvals, study protocols, staff training, and site approvals. “It is a really efficient way to trial multiple indications and medications in one study,” says Collins.

The initial trial began in the summer of 2020. All trial

participants are seriously ill with COVID-19 respiratory symptoms, with most in ICU on supplemental oxygen, intubated, or ventilated. The funding provided through the partnership will allow the trial to continue and collect data on potentially up to 1,500 patients throughout the US.

An innovative aspect of the trial is its targeted integration and interoperability with electronic medical records. Integrated data will soon be possible at the patient’s bedside for this trial via mobile devices that link EMRs and the research system. COVID-19 is proving the impetus and urgency to integrate research and care processes using technology in order to find effective treatments at a faster pace. “It’s crucial that we move past old ways of doing research, and harness technology to move faster and reach more patients,” says Collins.

About OpenClinica

OpenClinica is transforming healthcare through innovative cloud technology that simplifies running clinical trials. Proven in over 10,000 studies worldwide, the OpenClinica platform is trusted by leading biopharmaceutical companies, contract research organizations, academic institutions, and government agencies. OpenClinica is used across a wide spectrum of clinical research, including drug, device, and diagnostic trials, global health studies involving 200,000 patients, adaptive platform trials, and clinical trials for some of the first gene therapies to be approved for market. Hundreds of small, midsize, and large research organizations leverage OpenClinica to capture better clinical data faster, and to do so in a way that meets the highest standards for security and regulatory compliance (21 CFR Part 11, Annex 11, GDPR, HIPAA).

OpenClinica, LLC is headquartered in Waltham, MA. For more information on OpenClinica’s solutions for electronic data capture (EDC), eSource, ePRO, randomization, and analytics and reporting, visit <http://www.openclinica.com>.

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative (QLHC) is a 501(c)(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to seamlessly integrate high-impact research with clinical processes and systems technology □ resulting in improved data management and information systems, increased access for patients and clinician researchers to clinical trial

matching and sponsorship, better patient outcomes, and greater overall benefit to providers, patients, and researchers. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit www.quantumleaphealth.org.

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