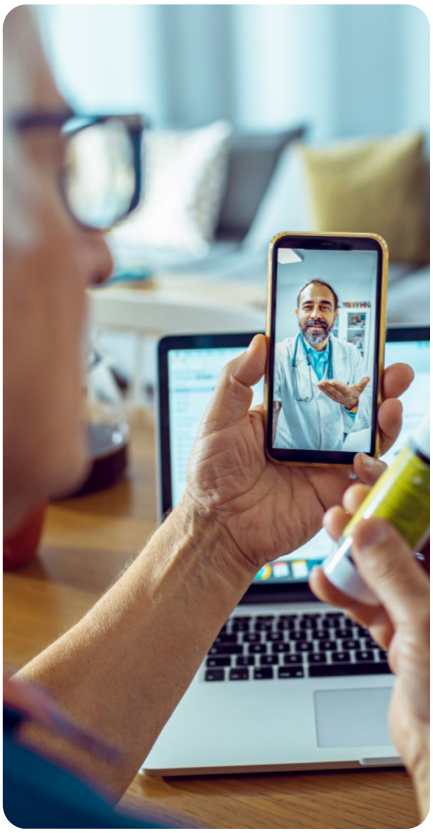
Science 37

THE CARDIOLOGY CLINICAL RESEARCH PLAYBOOK

How to Operationalize Cardiology Clinical Trials with a Metasite™



Why Consider a Virtual Approach For Your Cardiology Study?

In May of 2023, the FDA released a new Draft Guidance on decentralized clinical trials (DCTs). This important Draft Guidance offers recommendations for trial sponsors as they navigate the incorporation of virtual trial elements, ushering in a new era of innovation. The FDA recognizes that DCTs offer significant benefits and recommends the use of virtual conduct to help increase diversity and inclusiveness in trial populations, stating that "remote clinical trial visits and clinical trial-related activities are important strategies to make trials more convenient and more accessible to trial participants."

The Science 37 Metasite™ (a virtual site) offers a number of advantages for clinical trials in cardiology. The benefits of a decentralized model can all be realized with the peace of mind that board-certified investigators with extensive experience conducting both traditional and decentralized cardiology trials meticulously oversee study conduct.

- Improved access means **better enrollment**, delivering the recruiting power of **20 sites in one**. The Metasite is a site without borders—allowing us to find and recruit participants from anywhere.
- Cardiology patients often have chronic conditions that require long-term treatment and/or monitoring. The **convenience** of the Metasite makes **retention** easy—allowing trials to follow participants wherever they might move.
- Science 37 supports remote data collection for trials that require the use of **devices and remote monitoring technologies**. Beyond devices for real-time monitoring, the Science 37 platform allows participants to **contact the study team for real-time support** or to **self-report events**—supporting patient safety. When **in-person support** is required, our trained mobile research nurses are there to help.
- When trial participation can impact routine clinical care, the Science 37 investigator initiates earnest and transparent **bi-directional communication with participants treating physicians/specialists** to ensure awareness of their patient's participation.

» Read on to learn more about how the Science 37 Metasite can reach new cardiology patients and deliver high-quality data to your next study.

The Science 37 Approach to Operationalizing Cardiology Trials

Best Fit Cardiology Indications For The Metasite

- Arrhythmia
- Atrial fibrillation
- Cardiomyopathy
- Cardio-oncology
- Coronary artery disease
- Diabetes
- Heart failure
- Hypertension
- Hyperlipidemia
- Obesity
- Stroke
- Valvular disease
- Vascular disease

Technology Powers the End-to-End Trial

Science 37's unified platform provides workflow orchestration and a schedule of assessments to ensure high-quality data capture and protocol compliance throughout the end-to-end trial. The platform enables virtual visits through a patient app, with integrated eConsent, ePRO, and oversight by telemedicine investigators.

Flexibly Accommodates Remote Monitoring and Wearables

The unified platform allows for the integration of cardiac devices that support remote monitoring, and provide critical data capture when needed. The Metasite can also support validation studies — on their own or as a study within a study.

Cardiology Investigators and Mobile Nurses Ensure Patient Safety

In the skilled hands of the Science 37 team, every step of the clinical trial is built to ensure patient safety. With vast experience in remote clinical trial conduct, board-certified cardiologists deliver oversight across cardiology studies. Highly-trained mobile nurses collect patient data regardless of location with expertise in ECG, specimen collection and processing, endpoint facilitation, IMP administration, and the facilitation of physical exams.

Science 37's Contracted Network of HCPs Expands Access

Science 37 partners with our contracted network of healthcare providers (HCPs) to expand patient access. By identifying patients potentially eligible for a clinical study in the acute setting, HCPs that are part of Science 37's network can easily refer their patients to a Science 37 trial that may be of interest and maintain open, bi-directional communication with Science 37 investigators along their patient's clinical trial journey.

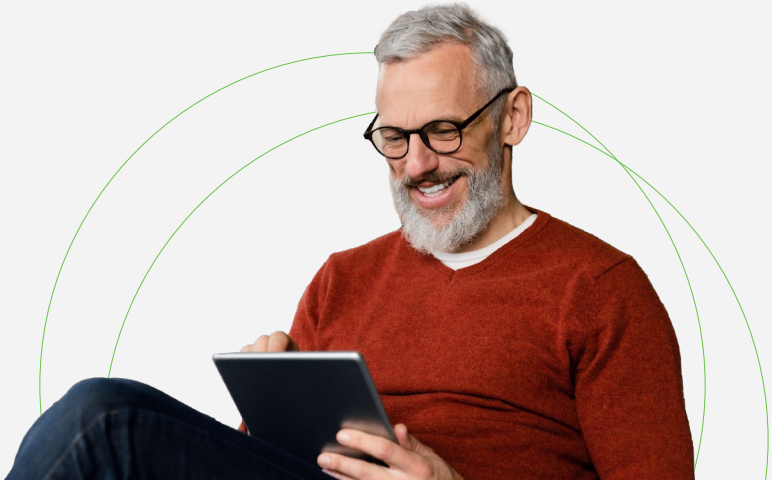
Co-management with Treating Physicians

Science 37 works to establish trust with participants' treating local cardiologists early in the screening period and continues engagement with these providers throughout the study as appropriate. Depending on the protocol, providers may be fully engaged with their patients' care during the trial, or they may simply receive notifications about their patient's progress.

Including providers in the early stages helps ensure that the local team is comfortable with the clinical trial, that their patient is being managed appropriately, and that there is a continual level of feedback throughout the study. This enables the treating physician to monitor and be engaged in their patient's care, helps patients feel safe, and ensures that the study proceeds smoothly.

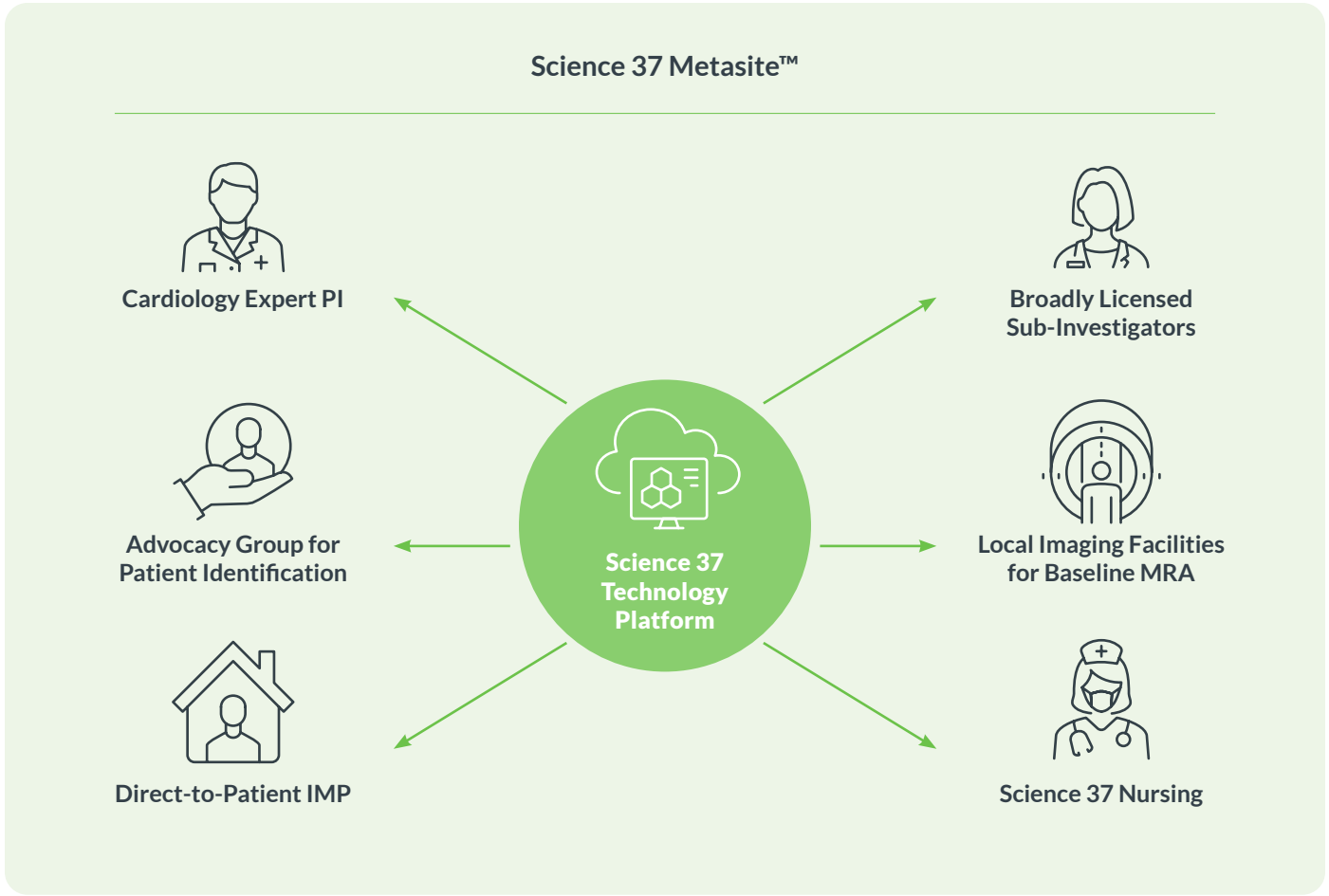
THE METASITE IN ACTION

Fully Decentralized Trial for a Rare Vascular Disorder



Science 37 worked with a biopharma company to plan and conduct a prospective, **Phase III, efficacy trial of a drug to treat a rare and serious vascular disorder**. For a traditional site, the three-and-a-half-year follow-up period would have created a significant burden that might have hampered retention. **Science 37 implemented the Metasite to orchestrate trial workflows, coordinate communication** among health care providers (HCPs) and specialists, and **reduce patient burden** by enabling virtual visits and electronic clinical outcomes assessments (eCOA).

For this **fully virtual trial study**, medications were shipped directly to patients' homes and administered by a mobile nurse, under the supervision of a Science 37 telemedicine investigator. In coordination with their providers and cardiology sub-specialists, patients recorded their progress and/or any predefined events in an electronic patient diary—data the sponsor could access real-time throughout the study. The Metasite made it easier for patients with a rare vascular disease to participate in a clinical trial from home and delivered high-quality, compliant data to support the sponsor's regulatory submissions.



The Metasite Leads the Way in Cardiology Trials

A virtual site like the Science 37 Metasite offers a **patient-centered approach** that brings the clinical trial to the patient, allowing patients to be recruited from anywhere and seen in the comfort of their own homes or at a nearby clinic. To reduce patient burden, clinical trial protocols are designed to leverage telemedicine, mobile nursing, direct-to-patient shipping, and direct-from-patient endpoint and biospecimen collection.

The Science 37 Metasite leverages a unified set of people, processes, and technology, to deliver greater consistency and high-quality data. As the pioneer of the virtual site, Science 37 delivers the power of ~20 sites in one, with 3-4 months faster startup times, and in-house medical and operational expertise that enable the end-to-end clinical trial.

The Science 37 Metasite expands access beyond research site confines.

100%
of patients can participate

2x
faster start-up

3x
more diversity

Accessing patients you could never reach before and accelerating start-up times *works for everyone.*

Delivering the Recruiting Power of 20 Sites in One.

LET'S TALK

To learn how the Science 37 Metasite can be activated for cardiology studies, please get in touch:

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Science 37®

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Chief Medical Officer
Science 37

Jonathan Cotliar is the chief medical officer for Science 37. He previously served as vice president of medical affairs, where he contributed as an investigator on a number of virtual clinical trials in addition to his work in support of business development and regulatory strategy.

Jonathan is board-certified in both internal medicine and dermatology. He serves as director of inpatient dermatology at Harbor-UCLA Medical Center, with previous full-time faculty appointments at the David Geffen School of Medicine at UCLA, Northwestern University Feinberg School of Me dicine, and City of Hope National Medical Center, where he was chief of the Division of Dermatology. Jonathan specializes in complex medical dermatology with a focus on oncodermatology, including graft-versus-host disease, adverse drug reactions, and the management of cutaneous toxicities related to chemotherapy and targeted anticancer therapies.

Jonathan received his B.A. from Trinity College, MD from the University of Kentucky College of Medicine, and completed his training in dermatology and internal medicine at the David Geffen School of Medicine at UCLA. While at UCLA, he completed an NIH-sponsored K30 Fellowship in translational investigation.

About Science 37

Science 37 Holdings, Inc.'s (Nasdaq: SNCE) mission is to accelerate clinical research by enabling universal trial access for patients. Through our Metasite™ we reach an expanded population beyond the traditional site, delivering on our goal of clinical research that works for everyone—with greater patient diversity. Patients gain the flexibility to participate from the comfort of their own homes, at their local community provider, or at a traditional site when needed. Our Metasite is powered by a proprietary technology platform with in-house medical and operational experts that drive uniform study orchestration, enabling greater compliance and high-quality data. To learn more, visit www.science37.com, or email science37@science37.com.

