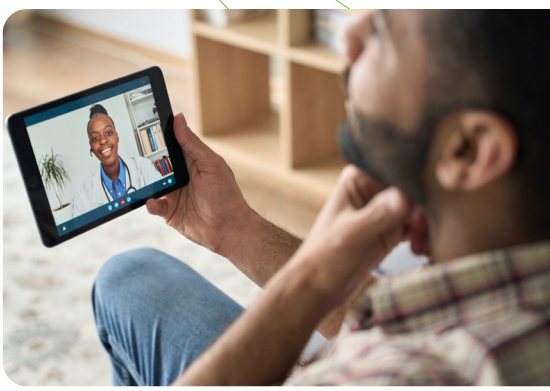
Science 37

THE RESPIRATORY CLINICAL RESEARCH PLAYBOOK

How to Operationalize Respiratory Clinical Trials with the Metasite™



Expanding Clinical Trial Access For Patients With Respiratory Disorders

With more than 450 million cases of chronic respiratory diseases worldwide—making it the third leading cause of death globally—there is a significant unmet need for biomedical research into potential new therapies for respiratory disorders.[1] To fill this unmet need, biopharmaceutical companies conduct thousands of clinical trials, with thousands of patients from different ethnic groups, different geographies, and different socioeconomic situations.

In addition to this, in May of 2023, the FDA released a new Draft Guidance on decentralized clinical trials (DCTs). This important Draft Guidance offers recommendations for trial sponsors as they navigate the incorporation of virtual trial elements, ushering in a new era of innovation.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."

Best Fit Respiratory Indications for the Metasite

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)
- Cystic Fibrosis
- Pulmonary Fibrosis
- Pulmonary Hypertension

Finding, enrolling and retaining these patients into clinical trials is not easy, but a virtual site standalone or in combination with traditional sites that prioritizes patient convenience will be the differentiating factor for the future of respiratory disease research.

As pioneers in decentralized clinical trials, Science 37's people (telemedicine investigators, mobile nurses, clinical research coordinators), processes, and technologies were built to improve the patient experience in clinical research. With almost a decade of experience, Science 37 has mastered the orchestration required for virtual trials, all while keeping quality top of mind. The outcomes are accelerated enrollment, reduced participant burden, better representation, and high-quality evidence to support your trial objectives and regulatory submissions.

Science 37's Approach to Operationalizing Respiratory Trials

Focus on Quality

Clinical trials in respiratory indications frequently require pulmonary function tests, including those measured through spirometry. It is critical that collection of these and other measurements adhere to ATS/ERS guidelines, including equipment calibration and operator procedures to elicit maximal performance from the patient. Science 37 understands the importance of these pulmonary function measurements and brings an experienced team to oversee all aspects of data collection. Read more about how Science 37 has collected pulmonary function tests using spirometry below in The Metasite in Action Case Study.

Improved Technology and In-Home Spirometry

The last five to ten years has seen a tremendous uptick in the volume (and quality) of in-home monitoring and diagnostic equipment for respiratory medicine; technological advances that have greatly improved our ability to perform lung-function testing outside of the traditional clinic space.

- Spirometry technology has expanded even further to cover **additional components of lung function measurement** that up until now could only be performed in a hospital—including lung volume and diffusion capacity that may be applicable for indications like pulmonary fibrosis.
- **Artificial intelligence and machine learning applications further expand our capabilities** by streamlining the process of gathering, transmitting, and processing data acquired through various in-home technologies.

Protecting High-Risk Patients

The COVID pandemic clearly accelerated the use of telemedicine and other technologies to connect patients with their treating physicians remotely instead of coming physically into a clinic. For patients with respiratory diseases—who are at high risk for hospital-acquired infections—there is a renewed (or perhaps permanent) concern about going into a hospital or clinic when it is not necessary.

The Science 37 Metasite **enables patients to participate in clinical research from the comfort of their own homes**—minimizing the risk of potential infections for both patients and traditional site staff.

Increasing Diversity of Trial Participants

As lung diseases can disproportionately affects certain racial groups, it is incumbent on clinical researchers to design trials that enable easy participation for patients who accurately reflect the real-world population of people with the disorder.[2] The vast majority of advanced lung centers, however, are typically located in academic medical centers that may be beyond reach for most people. This has unintentionally introduced a tremendous amount of bias into clinical trials, because recruiting patients only from academic medical centers leaves out tens of millions of people who could potentially benefit from participating in a clinical trial.

- The Science 37 Metasite doesn't just help to expand the volume of clinical trial participants. By opening up access beyond the borders of traditional sites, it also helps **to increase the heterogeneity** of trial participants to further support regulatory and reimbursement submissions.
- **Omnichannel recruitment** from patient advocacy groups, digital media, testing centers, and retail pharmacy partners **accelerates study enrollment.**
- More than eight in 10 sponsors believe **decentralized tools enable better representation** than traditional models.[3]

CASE STUDY

The Science 37 Metasite in Action: How Science 37 is Conducting a First Decentralized Clinical Trial with In-Home Spirometry

A large biopharma company was conducting a Phase IV trial of an approved biologic to understand its potential impact on sleep disturbance associated with asthma. This randomized, double-blind, placebo-controlled study required patients to complete questionnaires about their sleep, wear a device on their wrists to track their activity during sleep, as well as travel monthly to their research sites to complete visit activities including pulmonary function testing using spirometry, blood collection, and study drug dispensation.

Toward the end of the three-year trial, the Science 37 Metasite was deployed for a proof-of-concept study to validate a decentralized clinical trial model and to assess whether in-home spirometry could be as reliable as those performed in the traditional sites in their clinics.

Before screening and enrolling patients, Science 37 partnered with the spirometry hardware vendor **to train and certify our mobile nurses in proper in-home spirometry assessments.** As an added layer of quality assurance, a Science 37 respiratory therapist partners with the mobile nursing team to review collected spirometry data and provide ongoing coaching and training to mobile nurses as needed, to ensure optimal endpoint collection.

The Science 37 Metasite **confirmed that clinical trial-related pulmonary function tests can be conducted in patients' homes,** expanding clinical research access for patients with respiratory disorders.

Home-based patient participation

Improved clinical trial access

Spirometry-experienced investigators and training personnel

The Metasite is Perfect for Respiratory Research

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

The Science 37 Metasite activates 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

Contact us today to activate the Science 37 Metasite for your Respiratory studies.

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[1] The Institute for Health Metrics and Evaluation (IHME). Global burden of chronic respiratory diseases and risk factors, 1990–2019: an update from the Global Burden of Disease Study 2019. April 25, 2023. https://www.healthdata.org/research-article/global-burden-chronic-respiratory-diseases-and-risk-factors-1990%E2%80%932019-update-global

[2] Assari S, Chalian H, Bazargan M. Race, Ethnicity, Socioeconomic Status, and Chronic Lung Disease in the U.S. Res Health Sci. 2020;5(1):48-63. doi: 10.22158/rhs.v5n1p48. Epub 2020 Feb 10. PMID: 32226910; PMCID: PMC7100893.

[3] Science 37. How Decentralized and Hybrid Trials are Impacting Clinical Research. November 2022. https://www.science37.com/decentralized-clinical-trials-trends-report-2022

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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.

