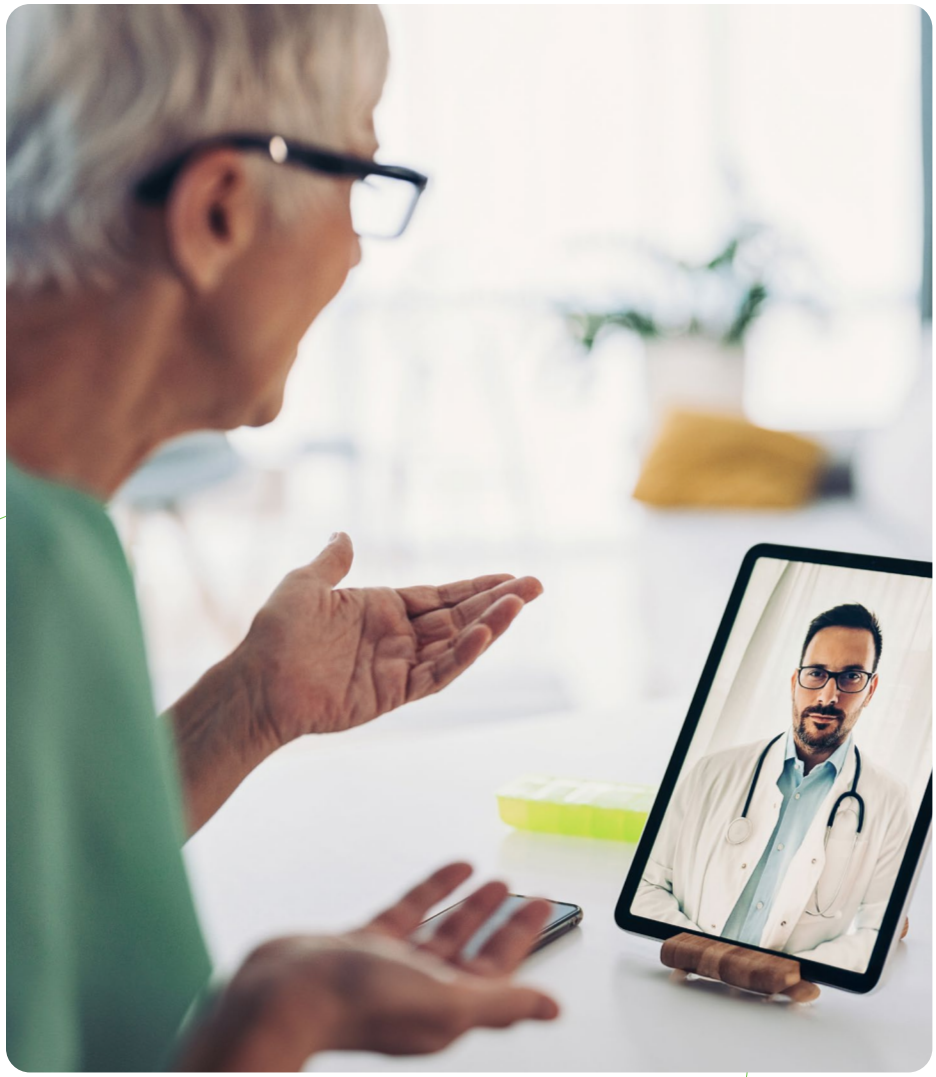
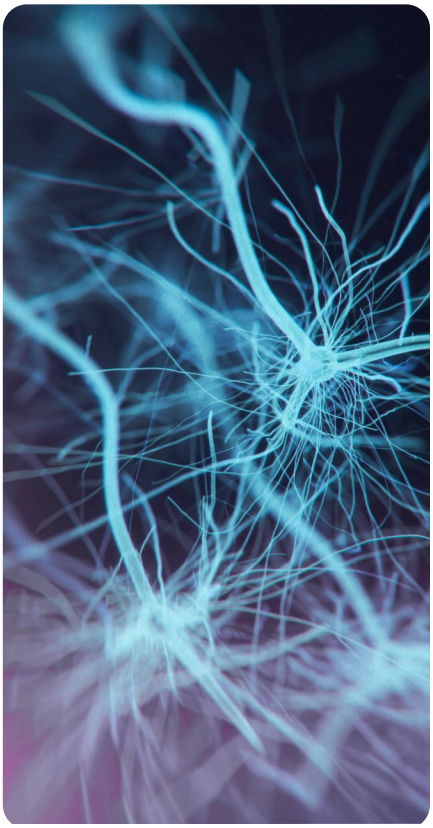
Science 37

THE NEUROLOGY CLINICAL RESEARCH PLAYBOOK

How to Operationalize Neurology Clinical Trials with the Science 37 Metasite™





With millions of people worldwide suffering from neurological conditions, research into potential therapies has never been as critical — or as active — as it is right now. Second only to oncology, R&D investment in neurological therapies now represents almost a third of the industry's pipeline and is forecasted to reach US $8 billion by 2030, a CAGR of 5.6% over the next eight years.[1]

For patients with conditions such as epilepsy, Alzheimer's, migraine, movement disorders, rare neurological diseases, and many other conditions, increased R&D activity into potential therapies is encouraging. There is a large unmet need for many disorders within this wide-ranging therapeutic area, and the increased research is helping to create a better understanding of these conditions' complex biology.

For biopharmaceutical sponsors and research organizations, **effective development of neurologic therapies hinges upon two critical components: recruiting and retaining the right patients, and delivering high-quality data** to support the trial's objectives. In fact, a 2022 Science 37 survey of CNS-focused biopharma executives showed that patient recruitment is the single greatest perceived obstacle to running an effective CNS study.

The Science 37 Metasite leverages our broadly-licensed and research- experienced telemedicine neurologist investigators, in-house mobile healthcare providers, and research coordinators — enabled with our unified technology platform — to help plan and conduct clinical trials in neurology. Our virtual approach presents many advantages, including:

- Recruiting participants who accurately reflect the real world patient population,
- The potential to easily centralize eligibility evaluation, with utmost focus on enrolling only the right patients for your study
- Collecting quality endpoint assessment data reliably, and
- Improving the overall clinical trial experience for patients and investigators.

» Read on to learn more about reasons to trust the Science 37 Metasite for your next neurology study.

How the Science 37 Metasite Delivers Quality Data for Neurology Studies

Recruit representative participants

By enabling expansive access, not limited by geography, trial sponsors can reduce start-up time, accelerate enrollment, and obtain a patient cohort more representative of each conditions' real-world populations.

- Find and enroll patients where they are, with the recruitment power of 20 sites in 1
- Leverage omnichannel recruitment inclusive of patient advocacy groups, digital media, testing centers, and retail pharmacy partners
- Engage with patients directly for faster start-up, including consent and release of electronic health records
- Provide patients with the opportunity to participate in studies from the comfort of their home, with patient-reported outcomes (PROs) on familiar digital devices

INDICATIONS

- Alzheimer's Disease
- Epilepsy/ Seizure Disorders
- Huntington's Disease
- Migraine and Cluster Headaches
- Multiple Sclerosis
- Parkinson's Disease
- Rare Metabolic- Neurological Diseases
- Sleep Disorders (including Narcolepsy)

Collect quality endpoints

Science 37's board-certified neurologist investigators assure quality from planning through study conduct and completion. During the planning stages of your study, our investigators, seasoned in both traditional site-based and decentralized clinical research, will help guide you to select the best virtual solution and modalities for your study. During conduct, patient safety and study oversight are of utmost importance to Science 37 investigators, who provide unparalleled attention and availability to both study staff and patients. Endpoints may be collected via ePROs and study diaries, telemedicine interactions with investigators, raters, and/or research coordinators, and in-person interactions with research-trained mobile healthcare providers — all of which are orchestrated seamlessly through Science 37's unified technology platform.

Improve patient experience

We recognize that most patients with a neurologic disorder are productive. They work, they go to school, and they care for their families — yet they may live far away from a study site and not have the time to devote to frequent study visits in-clinic. Direct-to-patient clinical trial models and methods remove this geographic barrier and enable trial participation from anywhere. Considering that many study treatments can easily be taken or completed by patients at home, incorporating virtual technologies into a neurology study provides patients with a convenient way to participate in clinical research.

Science 37's network of mobile nurses and virtual investigators ease participation burden and eliminate the need for clinic visits outside of standard of care. Science 37 manages all safety measures virtually, including labs, vitals, ECG, PK, anti-drug antibodies, and physical and neurological examinations. For studies where drugs require nurse administration, a virtual site enables greater convenience, as the patient does not have to travel to a clinic for IMP administration. The result is a more engaged patient population equipped to provide the high-quality study data you need.

UNMATCHED EXPERIENCE

Telemedicine and mobile nursing broaden participation in rare headache disorder trial

CHALLENGE

Science 37 worked with a global pharmaceutical firm developing an injectable drug to treat the rare condition of cluster headache. This Phase II study faced several hurdles, chief among them were two time-sensitive protocol requirements: The medication (or placebo) had to be prepared and injected subcutaneously by the patients upon headache onset, and all site visits had to be scheduled within one day of onset of symptoms. Further, site-led recruitment was constrained with only three physical locations across three countries.

SOLUTION

Science 37 addressed the study with expertise, providing three broadly-licensed investigators, including a cluster headache key opinion leader, to increase trial access. The investigators performed remote telemedicine neurological and physical exams, assisted by mobile nurses who were present with participants. The mobile nurses also collected vital signs, ECG, blood (including PKs), and urine samples, and instructed the participants on preparing the study drug for self-administration at the time of their next acute cluster headache attack.

RESULTS

The impact is indisputable.

Science 37 enrolled
70% of the trial participants
6.5 times faster
than traditional sites.

The home-based modality shortened the trial by ~7.9 months,
according to timeline projections based on brick-and-mortar enrollment rates.

UNMATCHED EXPERIENCE

Home-based option reduces burden for rare disease patients with limited mobility

CHALLENGE

Science 37 partnered with a global pharmaceutical company on an open label study investigating a new treatment in neurometabolic rare disease. The patient population is debilitated by severe ataxia that limits mobility, and the sponsor looked to Science 37 for a solution to drive recruitment and to reduce the burden of having patients physically travel to sites for study visits.

SOLUTION

Science 37 collaborated with academic centers and specialist sites to add a home visit option to this Phase III, placebo-controlled trial. A broadly-licensed Science 37 neurologist served as a sub-investigator overseeing home visits and ensuring multi-state coverage. Mobile nurses and mobile physician assistants (trained as Neurology raters) visited patients' homes to perform assessments including vitals/weight, physical and neurological exam, urinalysis, PK/PD sampling/processing, Friedreich's Ataxia Rating Scale, 25-foot walk test, assessment of intelligibility of dysarthric speech, neuromuscular testing, and clinical global impression.

The Science 37 platform was used extensively in this study including for eSource, Telemedicine, and eCOA. The sponsor successfully reduced patient and site burden by supporting participants who would otherwise have been unable to participate due to geographic location and/or limited mobility.

RESULTS

Science 37 was able to **accelerate enrollment and reduce patient burden** by enabling patients to participate in clinical research from home.

This trial further **showed the breadth of neurologic assessments that can be conducted safely and effectively at home**, including Friedreich's Ataxia Rating Scale, 25-foot walk test, assessment of intelligibility of dysarthric speech, neuromuscular testing and more.

The Metasite Leads the Way in Neurology 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 Neurology studies.

sales@science37.com / science37.com

[1]Grand View Research. Neurology Clinical Trials Market Size, Share & Trends Analysis Report By Phase (Phase I, Phase II), By Study Design (Interventional), By Indication, By Region, And Segment Forecasts, 2022 – 2030. February 2023. https://www.researchandmarkets.com/reports/5457652/neurology-clinical-trials-market-size-share-and

Authors:

Dr. David Kudrow
Medical Director of Neurology, Medical Affairs
Science 37

Dr. David Kudrow is the Medical Director of neurology in the division of medical affairs at Science 37. He is a board certified neurologist and practices general neurology with an emphasis on headache disorders in Los Angeles.

In addition to his clinical work Dr Kudrow has been a principal investigator on more than 120 phase II, III and IV clinical trials in migraine, Alzheimer's disease, epilepsy, neuropathic pain and other neurological indications. He has numerous publications in peer reviewed journals and speaks widely on the topic of migraine and headache disorders.

Dr Kudrow received a BSc degree in biology from the University of Southern California and completed medical school at the Keck School of Medicine at the University of Southern California.

He did his neurology residency at Harbor-UCLA in Torrance, California and a fellowship in clinical neurophysiology also at Harbor-UCLA. He is the director-emeritus of the Harbor-UCLA headache clinic where he served for over 20 years.

Dr. Jonathan Cotliar
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.

Science 37®

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.

