Science 37

INSIGHT BRIEF

Why Migraine and Other Headache Disorders Are a Good Fit for DCT.

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Characterized by recurring episodes of moderate to severe headache, elevated sensitivity to sound and/or light and other unpleasant symptoms, migraines can often be debilitating for the roughly 35 million people in the U.S. who suffer from this condition. The diagnosis of migraine is based on clinical presentation and treatment decisions are often based on subjective measures such as severity of attacks, associated disability and quality of life. Thus, clinical research in migraine may fail to accurately capture the whole effect this disorder has on persons with migraine. Combined with the overarching movement toward conducting clinical research in a more patient-friendly manner, these factors create a unique opportunity for clinical researchers to apply decentralized clinical trial (DCT) technologies to migraine studies.

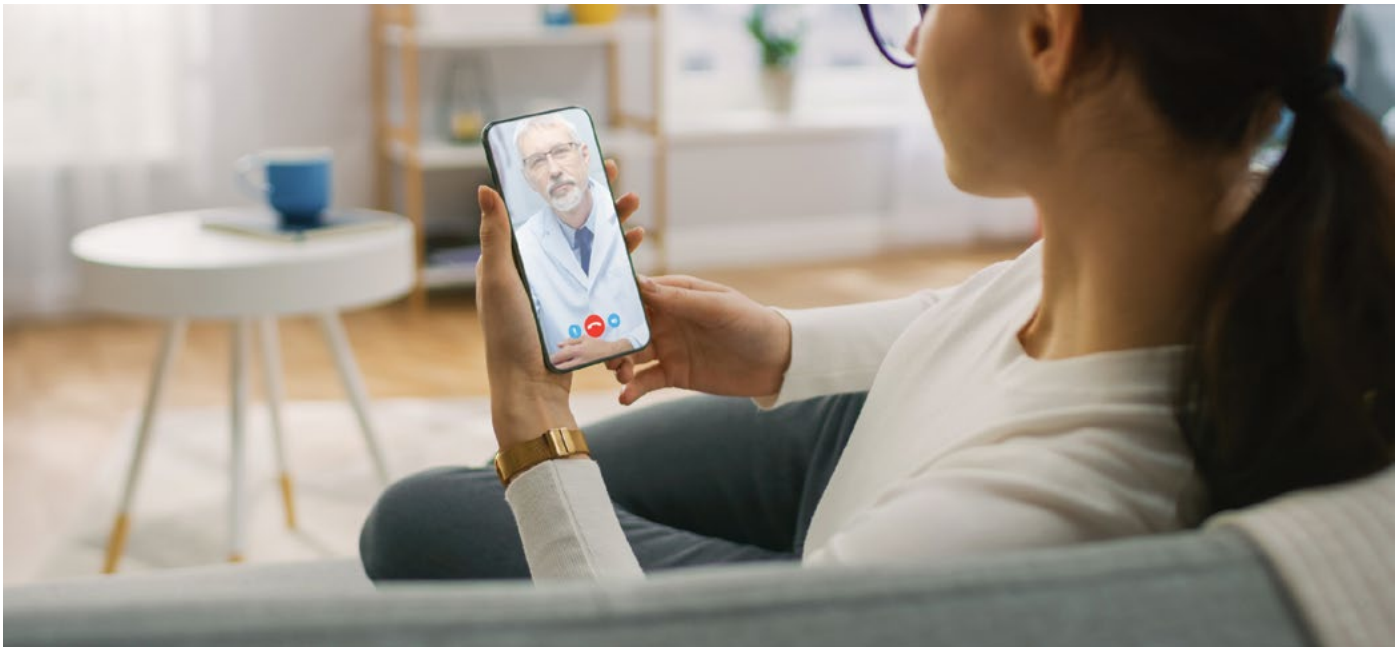
Migraine Treatment and Clinical Research

Most people with migraine experience episodic migraine (EM), with fewer than 14 migraine days per month. About 5% suffer from chronic migraine (CM) which is defined as 15 or more headache days per month, of which at least eight are migraine days. Migraine occurs more commonly in females with a 3:1 female to male ratio. It also occurs in about 8% of children and can manifest in many ways including headache, vomiting, dizziness and recurring abdominal pain.

Migraine treatment strategies include both acute or abortive therapies, and preventive therapies. Acute/abortive treatments are meant to stop or reduce the duration of a migraine attack, or to alleviate symptoms such as pain and nausea. Preventive treatment aims to prevent the occurrence or reduce the frequency of migraine attacks by using a daily or regular medication regimen.

Clinical trials in migraine therapeutics have studied both acute treatments and preventive treatments. Acute therapies can be oral (pills, capsules, tablets), nasal spray, subcutaneous injection, intravenous treatment, and more recently, a skin patch. There are also non-pharmacologic treatments such as non-invasive electrical stimulation devices.

For preventive treatment of migraine, standard of care consists traditionally of oral medications such as anti-epilepsy drugs, anti-depressants, blood pressure medications, and others. More recently, there is a new class of preventive medications called CGRP antagonists, which include both traditional pill formulations or injectable medications that are self-administered every month or every quarter. This treatment is often very effective with few side effects in comparison to the older standard of care medications.



Applying DCT to Migraine Research

At their core, decentralized clinical trial technologies and methods aim to improve the patient experience in clinical research by enabling trial participation from any location. When used for clinical studies in indications with subjective endpoints or patient reported outcomes such as migraine, DCT methods help to improve the patient experience from enrollment through trial completion — with numerous benefits to sponsors and research organizations as well.

These benefits could broadly be categorized into four areas: recruiting subjects accurately reflective of the real-world patient population; collecting endpoint assessment data reliably; improving the overall clinical trial experience for both patients and investigators; and including patients who, due to geographic barriers, might not have the opportunity to participate.

Targeted Recruitment

With millions and millions of migraine sufferers — most of whom have not been diagnosed and/or treated properly — recruiting appropriate candidates into clinical trials should not be difficult. Enrollees in clinical trials for migraine are traditionally around 85 to 90% female, and 80 to 85% white. This does not reflect the true diversity of migraine sufferers, and a trial with a homogenous patient population might run the risk of increased regulatory or payor scrutiny down the line.

Reliable Outcome Assessments

The primary outcome measure for migraine studies is typically the change from baseline in mean monthly migraine days measured with an electronic diary. In addition, secondary endpoints are usually derivatives of the migraine diary and may also include % responder rates (50, 75 and 100% RR).

Outcomes measures in QoL questionnaires are very amenable to electronic recording and may include assessments such as Migraine Disability Assessment Score (MIDAS), Migraine specific quality of life (MSQ), work productivity (WPAI), Headache impact Test (HIT-6), and patient and clinical global impression of severity and change, among others.

Improved Patient Experience

We recognize that migraine patients 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 monthly study visits in-clinic. DCT tools and methods remove this geographic barrier and enable trial participation from anywhere. Furthermore, considering that most migraine study treatments can easily be done by patients at home (either under the supervision of a coordinator or by themselves), implementing DCT technologies into a migraine study provides patients with a convenient way to participate in clinical research.

THE SCIENCE 37 SOLUTION

Science 37's Operating System™ underpinned by an end-to-end technology platform and centralized networks enables us to target and recruit migraine patients outside the usual clinical trial catchment areas, providing you with an accurate population of real-world patients.

Our experienced migraine investigators and in-house experts assure quality, by helping to guide and select the appropriate DCT or Agile solution for your study.

Our centralized networks of mobile nurses and virtual investigators manage all of your study's safety measures virtually, including labs, vitals, ECG, PK, anti-drug antibodies, physical, and neurological examinations.

Within our centralized network of patient communities, we effectively identify appropriate patients for your trial — even for pediatric studies — and deliver quality study data efficiently and securely.

We can conduct the trials using a Bring Your Own Device (BYOD) approach with all ePROs, eConsent, study migraine diaries, and telemedicine interactions with investigators and clinical research coordinators.

The result is a better engaged patient population more equipped to provide the high-quality study data you need.

About Science 37

Science 37, Inc.'s (Nasdaq: SNCE) mission is to enable universal access to clinical research, making it easier for patients and providers to participate from anywhere. Since 2014, we've pioneered decentralized and agile clinical trial approaches and having conducted more than 125 agile clinical trials, we're helping forge the future of research. The Science 37 Operating System (OS) supports today's more agile clinical research design, enabling up to 15x faster enrollment, 28% better retention, and 3x more diverse patient population. To learn more about our solutions, and how we can help you implement Agile and Decentralized Trials, visit www.science37.com, or email science37@science37.com.

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