Science 37®

Poster Presentation

Pioneering a first-of-it's-kind **decentralized clinical trial** in depression.

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Pioneering a first-of-its-kind decentralized clinical trial in depression

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Objective

There is a significant unmet medical need for patients with Major Depressive Disorder (MDD) who either do not respond to, or do not tolerate, current augmentation approaches for treatment.

For this Phase II study of an oral investigative compound, Science 37® embarked on a journey to design the first ever decentralized clinical trial (DCT) in depression. The aim was to remove geographical barriers, enable universal access to patients and providers, increase diversity, reduce the burden of participation and, consequently, keep more patients in the study.

Design and deployment

DCT is a complex and bespoke undertaking. It demands an agile and sophisticated Operating System™, consisting of a unified technology platform that can orchestrate workflow, generate evidence and harmonize data seamlessly between specialized networks of patients, investigators, nurses, coordinators and connected devices.

Study design

This study was designed as a phase II, 6-week, randomized, double-blinded, placebo-controlled, parallel group decentralized clinical trial to evaluate efficacy and safety of an oral investigational compound in patients with MDD with inadequate response to antidepressants.

Patient enrollment

Science 37 developed a patient recruitment campaign that included both digital direct-to-patient and physician referral strategies, utilizing online content and behavioral targeting, chart review, and digital look-alike audiences, to identify eligible MDD patients interested in trial participation.

Investigator recruitment

To further boost enrollment, we took an innovative approach to onboarding and training additional investigators — called Bring Your Own Investigators (BYOI) — who could identify and enroll potential participants.

Remote coordinators

Science 37's remote coordinators are highly trained on the study protocol and workflows, and provide eConsenting and conduct remote visits via videoconferencing and phone calls, performing direct data entry into the Science 37 Platform. The MDD study incorporated weekly visits, with a mix of videoconferencing and phone calls. Coordinators work around patients' schedules and are available 7 days a week. They can also track medication compliance & daily mood diaries in real-time via the AiCure app.

Prescription delivery

Investigators were responsible for writing ePrescription orders for the investigational compound, which coordinators sent to our vendor, Catalent, which stores investigational medicinal products (IMP) per sponsor requirements, managing accountability from dispensation to returns. Catalent manages delivery based on subject availability, offeing next-day delivery when needed, and provides temperature tracking from storage to delivery.

Mobile nurses

The Science 37 Nursing Solutions Group is a team of highly qualified and experienced Registered Nurses, skilled in phlebotomy and delivering compassionate, patient- centered care. Nurse Managers provided high-level oversight on all nursing activities for the trial, including management of MRNs, operationalization of the study protocol, developing and delivering all clinical education and training, and prioritizing participant and nurse safety.

Clinician-reported outcomes

The Science 37 rater team is a group of highly experienced masters/doctoral-level clinicians, skilled in administering diagnostic and primary efficacy clinician-reported outcomes (ClinROs) across a broad range of therapeutic indications. They have unique experience administering ClinROs in DCT and prioritize patient-centricity and flexibility. The ability of Science 37's Operating System to support direct administration of ClinROs while also offering the option of video/audio uploads of the administrations has proven to be highly effective in providing accurate and reliable data endpoints.

Results

The study is ongoing so there are no results to share at this point. However, we can report that it took just two days to recruit the first patient, and the study's complex elements are working together with agility and fluidity. Almost all participants report high satisfaction.

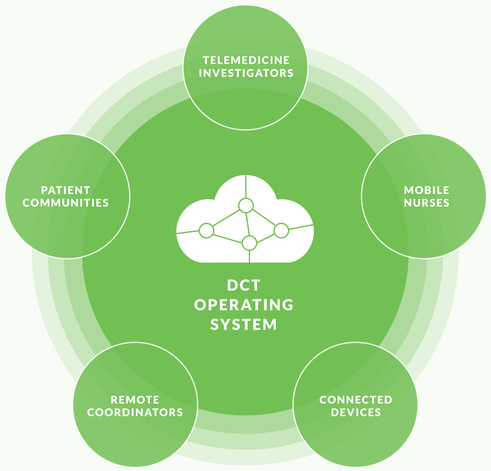
Conclusion

Each DCT execution brings a unique set of challenges and, therefore, demands a unique set of solutions. A successful, agile execution relies on an Operating System that combines sophisticated technology and specialized networks. This is the first such study in depression and, so far, DCT would appear to be a great fit.

Disclosures

Boehringer Ingelheim is the study sponsor. Dr. Reist is the study's principal investigator, and also a Medical Director at Science 37, whose DCT Operating System provides the technology and specialized networks underpinning the study.

Delivering Clinical Trials, the Science 37 Way



Comprehensive Study Team