Science 37®

One Site. Any Patient. Total Access.

DELIVERING RESULTS:

Science 37's Direct-to-Patient Site for CNS Trials

AUTHORS

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Boehringer Ingelheim

Phase 2 Randomized Placebo-Controlled Trial of BI-1358894 in Treatment-Resistant Major Depression (MDD)

KEY ACHIEVEMENTS

- **First-of-its-kind direct-to-patient trial in treatment-resistant MDD** - Successfully demonstrated feasibility of fully decentralized interventional trial in psychiatric population previously considered unsuitable for remote participation
- **Massive screening reach** - 80,836 patient sign-ups across 35 states; 45 subjects randomized in 18 months using digital recruitment strategies
- **Outstanding retention and completion** - 97.1% study completion rate with only 1 withdrawal, demonstrating exceptional engagement in vulnerable psychiatric population
- **High patient satisfaction and critical access** - 88.5% reported satisfaction with DCT approach; 65% would not have been able to participate if trial required traditional site visits
- **Validated remote assessments** - Successfully administered psychiatric rating scales, including MADRS via telehealth with trained raters, maintaining data quality standards
- **High-quality data capture** - Remote medication management, telehealth visits, at-home assessments, and direct-to-patient IMP shipment maintained protocol compliance and data integrity
- **Study resulted in first peer-reviewed publication** - Scan this QR code to view the article, including study details and lessons learned

View the Scientific Publication →

Jazz Pharmaceuticals

Phase 3 Randomized Controlled Trial Studying a Treatment for Narcolepsy

KEY ACHIEVEMENTS

- **Direct-to-Patient Site dramatically outperformed** traditional brick-and-mortar sites, overcoming geographic barriers and strict eligibility criteria in a rare disease population
- **Enrolled 55% of total participants** - (33 of 60 patients) from a single direct-to-patient site vs. <1 patient average across 45 traditional sites
- **56% of total study screening volume** - (91 patients) vs. average of 3 patients screened per traditional site
- **98% visit completion rate** - Via mobile Research-Grade Nurses conducting in-home visits, eliminating patient travel burden
- **Closed enrollment 5 months ahead of schedule** - Contributed 77% of completers (n=43) for interim analysis
- **Protocol optimization** - Collaboration led to amendments reducing screen failure rates across all sites
- **Sponsor recognition** - Performance led to consultation requests on recruitment strategies and protocol evaluation

View the Case Study →

sanofi

Phase 3 Pivotal Trial Evaluating a Novel GM2 Gangliosidosis Treatment for Tay-Sachs & Sandhoff Disease

KEY ACHIEVEMENTS

- **Hybrid trial support** – Direct-to-Patient Site complemented traditional sites, enabling at-home neurological assessments for geographically dispersed rare disease patients
- **Reduced patient burden** – At-home visits eliminated repeated travel for patients with late-onset neurological disease experiencing mobility challenges. Science 37's ability to conduct visits in the home enabled participation despite limited site availability and travel barriers
- **Expert mobile rater network** – Science 37-credentialed Mobile Raters conducted neurological assessments with Investigator oversight and real-time guidance via telemedicine
- **Seamless clinical coordination** – Clinical Research Coordinator and Medical Affairs Lead ensured continuity from trial start through completion
- **Complex assessments at home** – Successfully performed pharmacokinetic blood draws and detailed neurological evaluations in patients' homes alongside standard labs
- **Unified platform efficiency** – Integrated data capture, telemedicine, workflow Integration and eClinical tools for streamlined execution. Psychiatric rating scales are completed remotely by a centralized rater team

Phase 2b/3 Multicenter, Randomized, Double-blind Study Evaluating NRX-101 (D-Cycloserine/Lurasidone) for Bipolar Depression with Suicidal Ideation

KEY ACHIEVEMENTS

- **Direct-to-Patient Site strategy to rescue site-based study -** Science 37 rapidly implemented (within 2 months) a DCT model to augment struggling enrollment among traditional sites
- **Successful direct-to-patient adaptation for high-risk population** - Science 37 enabled virtual visits for a suicidal ideation study while maintaining robust safety protocols, including emergency contact procedures
- **Significant recruitment impact** - Science 37 screened 159 subjects with 14 ultimately randomized
- **Complex remote assessments** - Administered MINI, MADRS, and C-SSRS via audio-recorded telemedicine; mobile Research-Grade Nurses conducted physical exams and phlebotomy in subjects' homes
- **Safety protocol management** - Established procedures for suicidal ideation escalation, including Investigator judgment options, emergency services, and facility transport when necessary
- **Topline results contribution** - Akathisia seen in 2% of NRX-101 subjects vs. 11% with lurasidone; NRX-101 associated with more rapid, sustained reduction of suicidal ideation

Zynerba PHARMACEUTICALS

Phase 3 Rare Neurology Study for Fragile X Syndrome (FXS)

KEY ACHIEVEMENTS

- **Top enrolling site** - Enrolled 25% of total participants despite being an add-on site (49 of 50 goal), ranking as the highest-performing site
- **94% retention rate** in difficult, rare disease pediatric population through at-home visits
- **Reduced family burden** - Eliminated overstimulating office visits for pediatric patients via in-home participation
- **Enhanced protocol adherence** - Mobile Research-Grade Nurses managed complex lab draws and caregiver dosing requirements
- **Strategic partnerships** - Leveraged advocacy groups and provider networks for effective patient outreach and referrals
- **Family-centered approach** - At-home model better suited for Fragile X and pediatric needs, building trust with overwhelmed caregivers. Science 37 enabled families with multiple Fragile X children to participate through simultaneous at-home visits

View the Case Study →

Listen to the Participant Testimonial →

Sage Therapeutics®

Phase 4 Postpartum Depression Trial Testing At-Home Brexanolone IV Infusion vs. Infusion Center Treatment

KEY ACHIEVEMENTS

- **Proven at-home feasibility** - Successfully demonstrated a safe alternative to infusion center for 60-hour continuous brexanolone treatment
- **Remote vital sign monitoring** - Science 37 Investigators monitored pulse oximetry, respiratory rate, and other vital signs remotely throughout infusion
- **Eliminated family separation** - Mothers remained home with newborns and family instead of having extended infusion center stays
- **Broad geographic access** - Direct-to-patient trial design allowed participation from any location, removing travel and facility access barriers
- **Complex safety management** - Coordinated mobile nurse deployment, drug shipment, continuous monitoring, and investigator oversight via unified platform

biovie

Phase 2 Double-Blind, Randomized, Placebo-Controlled Study Evaluating NE3107 in Subjects with Early Parkinson's Disease (PD)

KEY ACHIEVEMENTS

- **Population:** Treatment-naïve early PD patients not yet on L-dopa or dopamine agonists
- **Direct-to-Patient Site** - Science 37 operating as one of 6 sites with fully remote conduct, targeting 60 enrolled and 50 completers
- **Expanded access for early PD patients** - Fully remote model enables participation of treatment-naïve patients without travel to traditional sites
- **Rigorous diagnosis confirmation** - Medical record review and neurologist interview conducted to establish preliminary eligibility
- **Innovative remote motor assessment** - Mobile Research-Grade Nurses assist the remote Investigator to complete modified MDS-UPDRS examinations with video capture for central rater review
- **Comprehensive remote evaluations** - PD Q39 quality of life assessments, CGI, biomarker collection, and adverse event monitoring via telemedicine and mobile Research-Grade Nurses
- **Video-based quality control** - Captured video assessments uploaded to the platform for central rater review, ensuring standardized outcome measure evaluation across sites

AFFILIATIONS

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DISCLOSURES

The authors are employees of Science 37.