Curavit’s Remote Clinical Site Is a Model for Recruitment Efficiency

Curavit Applies CTTI’s Digital Health and Decentralized Trials Recommendations

SUMMARY

Curavit Clinical Research (“Curavit”), a CRO specializing in decentralized and direct to participant trials, served as the Remote Clinical Site for the APPROVE Trial (NCT06797245) sponsored by MedStar Health Research Institute. Leveraging CTTI’s Digital Health Trials (DHT) and Decentralized Clinical Trials (DCT) recommendations, Curavit conducted fully remote screening, recruitment, consent, and follow-up for 50% of the trial’s total study participants. Curavit demonstrates how CTTI’s recommendations for regulatory alignment, multi-sector collaboration, and participant-centric design can be operationalized through a real-world digital therapeutic trial.

GOAL(S)

APPROVE is a multi-center, randomized controlled trial evaluating the clinical efficacy and user experience of a prescription digital therapeutic for women with overactive bladder (OAB), for which Curavit Clinical Research operated the remote clinical site. The APPROVE trial seeks to compare outcomes in women with OAB randomized to a digital behavioral therapy (RiSolve app) versus standard behavioral education materials (handouts). Through Curavit’s remote clinical site, the study aimed to operationalize a fully decentralized arm that mirrored traditional site processes while improving participant recruitment and reducing participant burden. Curavit was charged with recruitment, screening, consenting and randomizing participants remotely from across the U.S. using digital advertising and virtual visits. Data captured within the remote clinical site’s proprietary system was integrated into the unified electronic data capture (EDC) system, consistent with CTTI’s recommendations. The team aimed to demonstrate the feasibility and robustness of the Remote Clinical Site participation in a regulated digital therapeutic study.

CHALLENGES

In designing and implementing the remote site, Curavit’s study team faced several challenges common to DCTs and DHTs. The screening process was complex and extended over several days and required participants to complete multiple steps including diary entries, electronic patient-reported outcomes (ePROs), and consent to access their medical records. The team also needed to ensure seamless data integrity between Curavit’s Remote Clinical Site Platform and the sponsor’s EDC and ePRO applications. Other challenges included maintaining participant engagement throughout the study and managing crossover for those participants initially assigned to the placebo arm.

SOLUTION(S)

Curavit designed and implemented its STRATUS Remote Clinical Site Platform to align with CTTI’s recommendations for decentralized trials.

1. Harmonizing Regulatory Requirements and Operational Processes: Curavit maintained oversight through licensed investigators and compliant workflows.
2. Participant-Centric Trial Design: Curavit enabled remote—and at times self-service—participation, automated reminders, and engagement tools, reducing patient and study team burdens.
3. Data Integration and Monitoring: Curavit established interoperable data flows and implemented centralized monitoring in accordance with CTTI recommendations, enabling effective remote monitoring visits.
4. Stakeholder Collaboration: Curavit worked closely with the sponsor, academic and CRO partners to design and run a hybrid trial that could function seamlessly as either a fully remote or site-based study.

TAKING ACTION

Curavit implemented an operations model that included a fully remote study team composed of principal investigators, sub-investigators, clinical research coordinators, and participant coordinators. They customized their Remove Clinical Site Platform to support the unique trial requirements, which included automated data synchronization with the sponsor’s ePRO and EDC applications. The sponsor conducts remote monitoring visits to ensure safety, quality, and compliance. Curavit facilitated clear communications and the sharing of best practices through multi-site investigator meetings.

IMPACT

CTTI’s recommendations provided a foundation for this remote trial to operate reliably, efficiently, and at scale. In this case, they helped a fully remote site meet or exceed expectations across every key performance metric.

Over the 14-month study period, Curavit’s remote site enrolled and managed 50% of all participants (298 women). Curavit’s recruitment was completed two months ahead of the originally agreed six-month enrollment target. During the same enrollment period, the nine brick-and-mortar study sites collectively enrolled just 30 participants, compared to 298 enrolled by the remote site—demonstrating a tenfold improvement in recruitment efficiency through Curavit’s remote site model.

Remote participation also expanded access and improved representation. The remote approach successfully reached women in rural and historically underserved communities. For example, 19% of participants enrolled through the remote clinical site were Black or African American, exceeding US Census estimates of Black women in the US and typical enrollment in OAB clinical trials. Participants reported that the remote experience was easy to use and lowered burdens, contributing to strong engagement and high adherence rates.

Finally, centralized monitoring ensured data quality equivalent to traditional site-based standards, delivering regulatory-grade data integrity.

ADVICE

Curavit's experience underscores several lessons reflected in CTTI's DCT and digital health guidance:

- Remote doesn't mean compromise; remote and physical sites can achieve equal rigor.
- Invest early in data interoperability to enable high-quality data and efficient operations.
- Engage regulators and IRBs early.
- Train staff for digital-first engagement and remote empathy.

"CTTI's recommendations can be used as a roadmap for compliant and scalable remote research," Curavit's CEO advised. "In the APPROVE trial, these recommendations helped us translate regulatory alignment, participant-centric design, and cross-sector coordination into a fully operational and successful remote clinical site."

CITATIONS

APPROVE Trial: Evaluating a Prescription Digital Therapeutic for Treatment of OAB in Women (APPROVE)

ORGANIZATION

Curavit

CONTACT

ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2024-2025

TOPIC

Decentralized Clinical Trials, Engaging Patient & Sites

RELATED CTTI PROJECT

DCT Update Engaging Patients and Sites

CTTI RESOURCES

Learning from patient and site perspectives to develop better digital health trials: Recommendations from the Clinical Trials Transformation Initiative

CTTI Recommendations - Updated: Decentralized Clinical Trials

ADDITIONAL RESOURCES

CTTI Recommendations for Selecting and Testing a Digital Health Technology

CTTI Recommendations: Decentralized Clinical Trials