Category: Community Outreach and Engagement, and Community Representation and Inclusion – Work in progress

Decentralizing Clinical Trials for a Rural Population

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1. Background
Rural cancer patients (RCPs) account for approximately 15–20 percent of cancer diagnoses in the United States and experience reduced access to oncology specialists, increased travel burden, limited clinical trial availability, and socioeconomic barriers that negatively influence outcomes. Following the COVID-19 pandemic and the rapid adoption of innovations that enabled trial continuity, the clinical research industry has increasingly prioritized broader community engagement and trial populations that better reflect real-world demographics. Decentralized clinical trials (DCTs) have emerged as a key strategy to support this shift. In September 2024, the U.S. Food and Drug Administration released guidance on conducting DCTs to facilitate implementation across research sites. Sanford Health has incorporated telemedicine into select clinical trials for the last 12 years, particularly within gynecologic oncology, and is now expanding infrastructure to support broader integration of decentralized elements across its clinical research portfolio.

2. Goals
To expand representative access to clinical trials for rural patients facing geographic, travel, or socioeconomic barriers and to extend innovative oncology research opportunities to a broader rural catchment area while allowing patients to remain closer to home.

3. Solutions and Methods
In December 2024, Sanford Health launched the Sanford Virtual Care Center (VCC) to advance virtual healthcare delivery across rural communities. The VCC supports initiatives in education, innovation, and clinical care. Through collaboration with the VCC, Sanford Clinical Research established a Decentralized Clinical Trial (DCT) Navigator role in September 2025. The DCT Navigator serves as a liaison among patients, clinical sites, and sponsors, facilitating participation in decentralized and hybrid trials through patient education, logistical coordination, and ongoing engagement to optimize participant experience, adherence, and protocol compliance.

4. Outcomes
Sanford Clinical Research is actively redefining trial conduct through development of infrastructure, policies, and procedures that enable incorporation of decentralized elements across studies. Since September 2025, decentralized support has allowed eligible patients to complete select trial-related activities closer to home, including laboratory testing, clinic visits, growth-factor support, and oncology treatment administration. Early implementation demonstrates feasibility of integrating decentralized components of clinical trials within Sanford's community-based healthcare system and highlights the potential to reduce travel burden while maintaining study integrity.

Patients incorporating at least one decentralized element into their clinical trial experience lived an average of 96.9 miles from the primary trial site. Utilization of local facilities reduced travel to a mean of 18.9 miles per visit, corresponding to an estimated 156 miles saved per visit when accounting for round-trip distance. Sanford Health has also partnered with external organizations to support continued trial

participation closer to patients' homes. In one case, a Sanford oncologist provided local clinical oversight for a patient enrolled in a Phase I trial based in Arizona. In another, a patient enrolled in a California-based trial was unable to travel due to health complications; required laboratory testing, imaging, and office visits were coordinated locally, and securing permission for the shipment of study medication for uninterrupted continuation of treatment (the patient did not continue treatment after this visit).

5. Lessons Learned and Future Directions

Implementation of decentralized trial components requires rapid coordination and complex logistical planning to maintain patient safety, comply with protocol-specified timelines and ensure regulatory compliance. Early engagement with sponsors during study start-up rather than post-activation may improve feasibility and execution. Strengthening partnerships while reducing real barriers (billing, insurance coverage) with rural healthcare providers and organizations experienced in decentralized research will be essential for continued growth. As the DCT Navigator role matures, future evaluation will focus on patient satisfaction and retention, rural enrollment expansion, and protocol compliance to demonstrate the effectiveness of decentralized approaches. Long-term goals include expanding access to more complex oncology trial procedures closer to home and pursuing fully decentralized trial models when appropriate.

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