Decentralized Clinical Trials Initiative: Redesigning Clinical Trials to Minimize Patient & Site Burden

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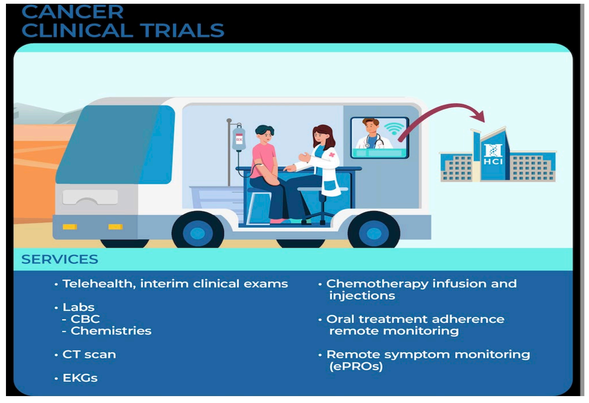
BACKGROUND

- Cancer patients in the Rocky Mountain West often face significant geographic and financial barriers to accessing clinical trials at major cancer centers. Traditional trials require extensive travel, limiting participation among rural populations.
- Decentralized Clinical Trials (DCTs) offer a transformative solution by utilizing telemedicine, mobile health units, and local healthcare providers to reduce logistical burdens while improving inclusivity and diversity in clinical research with the goal of increasing access to clinical trials and new cancer treatments.
- DCTs can reach a broader and more diverse participant pool, including underserved populations who may face logistical barriers to participating in traditional trials. We can reduce participant burden by minimizing the need for frequent site visits, which is advantageous for patients with mobility issues or those living in remote areas. This convenience can lead to higher participant retention and adherence to the study protocol.
- DCTs also enhance operational efficiency. By leveraging digital tools such as e-consent, telemedicine, and remote monitoring, DCTs can streamline trial processes, reduce costs and accelerate timelines.
- DCTs represent a promising evolution in clinical research, offering numerous benefits while necessitating careful consideration of their unique challenges

GOALS

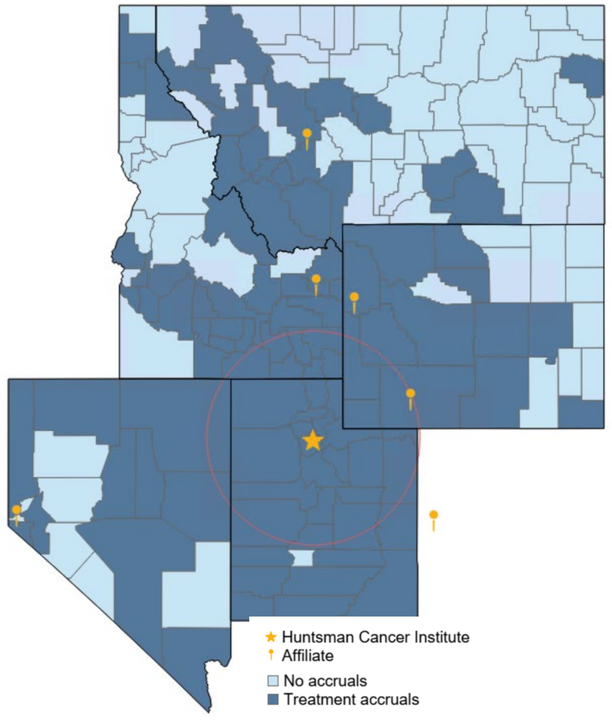
- Expand access to cutting-edge cancer treatments through decentralized trial models.
- Reduce geographic and financial barriers by leveraging technology and local healthcare infrastructure.
- Improve rural patient enrollment and engagement in clinical trials.



SOLUTIONS AND METHODS

- We first established a DCT Working Group with research operations leaders, physician leaders, community outreach director, and pharmacy to get all stakeholders together, review aims and develop a strategic implementation plan for this initiative. We defined the difference between fully decentralized trials versus hybrid trials. We established our focus would be on decentralized interventional treatment trials and will start with trials with oral IP as this is logistically easier than infusions.
- We also require partnerships with community clinics facilitate trial implementation (HCI has affiliate hospital relationships with several facilities in the Mountain West already).
- Key evaluation metrics include patient enrollment rates, retention, and trial completion compared to traditional models. We also want to assess patient and clinician satisfaction in the process. We also want to track our ability to operationalize these processes.

30% of our trial patients travel from >150 miles away



OUTCOMES

Several processes were implemented and are being utilized already:

- Telehealth visits to discuss trial and determine eligibility and interest
- Remote or electronic consenting (e-consenting)
- Local lab collaboration (partner with University of Utah Rural Connections to Research Initiative); rural research phlebotomy collection sites provide in-person protocol-specific services and study accessibility
- Local scans (imaging) with images electronically sent to our institution for research reads
- Class A Pharmacy Licensure and ability to ship IP (investigational product) directly to patients' homes (including across state lines)
- Pilot clinical trials have been identified
- Normalization and revision of patient education materials about clinical trials with our Office of Community Outreach and Engagement, including rack cards, videos, chatbot, and central repository for all materials

LESSONS LEARNED

- Decentralization has demonstrated significant potential to enhance trial accessibility and diversity. Preliminary data suggests increased participation from rural patients, enhanced patient-reported satisfaction, and improved data collection efficiency through remote monitoring. Analysis of enrollment trends suggests a measurable reduction in travel-related barriers.
- However, several challenges remain, including the need to address digital literacy gaps, ensure compliance with evolving regulatory frameworks, and foster seamless coordination between local providers and centralized research teams. Additionally, establishing clear operational workflows and funding models for DCT implementation will be critical for long-term sustainability.
- Continued collaboration with community partners and ongoing assessment of patient and clinician experiences will be essential to refining and expanding this model.

FUTURE DIRECTIONS

- Secure physician and APC interstate licenses for the five states (to support telehealth visits)
- Demonstrate efficiencies of mobile health technologies
- Strengthen partnerships with community clinics to support trial requirements
- Develop operational financial models for decentralized clinical trial billing
- Pilot Decentralized Trial Patient and Data Coordination Teams, including remote teams to conduct safety exams, administer IP, and assess adverse events
- Engage in the ARPA-H PARADIGM Grant with clinical trials use case

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