

“Decentralized Clinical Trials Initiatives: Redesigning Clinical Trials to Minimize Patient and Site Burden”

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1. Background

Decentralized Clinical Trials (DCT) became a common theme in oncology during the COVID global pandemic as a way to rethink clinical trials but has mostly fallen out of common conversation as sites and sponsors realized the challenges in designing and conducting trials with decentralized components. Both the Huntsman Cancer Institute Clinical Trials Office and the Memorial Sloan Kettering (MSK) Clinical Research Innovation teams continue to pursue initiatives around DCT Models for the delivery of cancer treatment. Huntsman Cancer Institute and MSK serve different geographic catchment areas yet have common goals in bringing together experts in trial operations and informatics and technology to support the advancement of DCT models within their centers. At Huntsman Cancer Institute, the DCT Initiative was launched to address the needs of rural and frontier populations in the Mountain West by overcoming geographic and logistical barriers to cancer trial participation. At MSK, the DCT initiative is primarily focused on increasing access to a wide range of trials, including rare cancer trials that require a larger population base. Both initiatives aim to ensure equitable access to trials by making it easier for patients and sites to participate.

2. Goals

The DCT initiatives are multidisciplinary and involve collaboration across the clinical trials operations continuum from investigators to pharmacists and data science experts. Both cancer centers involved leaders in the initiative and mapped initial successes, opportunities and future work.

3. Solutions and Methods

We have developed key visualizations to model the clinical trial lifecycle from Activation to Study Close-out and identified components of the “Traditional Trial Model” and countered them with “Decentralized Trial Model” for each operational area of the clinical trial lifespan. These models identify how the Cancer Center can be a coordinating site to reduce the burden of traditional trial conduct for both an external site and reduce participant burden. Goals of these initiatives include identifying operational challenges and proposing solutions to improve trial accessibility; direct-to-patient drug delivery to minimize travel; telehealth consultations for remote care; mobile phlebotomy and digital health technologies for clinical and research activities; and simplified trial designs to reduce complexity while maintaining rigor.

4. Outcomes

The DCT initiatives aim to successfully demonstrate improved access to clinical trials for patients while measuring protocol and regulatory compliance as well as user experiences with digital health technologies, remote access, streamlined and centralized trial operations, drug delivery, and patient care.

5. Lessons Learned and Future Directions

The Decentralized Clinical Trials Initiative reflects both Huntsman Cancer Institute and MSK’s commitment to improving cancer outcomes for all populations within the Areas We Serve. By utilizing digital health technologies, simplifying trial designs, and reducing the need for travel, this initiative helps overcome geographic disparities and enhances the inclusivity of clinical trial participants. The success of

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these programs is expected to demonstrate the potential for decentralized clinical trials to transform oncology research and make it more accessible to populations.