Category: Network Operations, Decentralized Trials, and Multi-site Research – Work in progress

Cancer Treatment Trials Using Decentralized Capabilities to Change Cancer Treatment

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1. Background
In 2023, a multi-site comprehensive cancer center developed three investigator-initiated trials written with focus on community engagement and inclusion. The interventional treatment trials were written by the physician investigators who utilized various decentralized tools: including real world data from the EHR to correlate treatments, virtual consent, virtual data capture, and using imaging to de-escalate cancer treatment for the purpose of minimizing patient burden. These inclusive designs and decentralized tools permitted greater participation of underrepresented patient populations and allowed for additional development of processes and technology to support clinical trials.

2. Goals
These clinical trials aim to answer critical questions for cancer treatment in clinical practice and promote inclusivity in cancer research. These trials are typically not sponsored by industry but answer important practice questions on how to treat patients in practice to improve patient outcomes. These practice changing answers will inform survival, improve toxicity, identify best current treatment for disease, and inform the best way to deliver therapy. The trials selected span liquid and solid cancer, including treatment, radiation, and imaging Theranostics.

Trial 1: NCT05979883 seeks to answer if machine learning assisted radiation treatment planning improves treatment planning versus standard radiation treatment planning.

Trial 2: NCT06037863 seeks to answer if there is an impact on radiation treatment for prostate cancer when a bladder is full versus empty.

Trial 3: NCT06200103 seeks to answer whether post-therapy imaging can be used to personalize and optimize the use of radionuclide therapy for prostate cancer.

3. Solutions and Methods
Using decentralized tools, one clinical trial is open nationally – any cancer center and community site can refer patients to a central location using a flyer and QR code. Another trial is open at a cancer center hub and available to rural community sites through decentralized tools including remote consenting and electronic data capture.

4. Outcomes
The trials were written, activated, and opened to accrual in less than a calendar year. Accrual is currently open throughout the multi-site center that spans 4 states.

Trial 1: Accrual N=83; 45 (54 percent) URP
Trial 2: Accrual N=64; 31 (48 percent) URP
Trial 3: Accrual pending

5. Lessons Learned and Future Directions

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Why These Trials Matter:
Each trial seeks to answer questions that will directly influence cancer care. The inclusive design of each protocol seeks to assure broad representation that will allow better understanding of how treatments affect individuals. Through inclusive designs and broad eligibility criteria, the trials are expected to accrue faster and inform standard of care.