Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

How to Successfully Open a New Medical Center to Clinical Research

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1. Background
Establishing a clinical research program in a new facility requires extensive planning and preparation. Eastpark Medical Center (EMC), a 479,000 square foot ambulatory health care facility, was designed to provide advanced treatments and multi-specialty care – including oncology services – for patients in Wisconsin and beyond. EMC serves as an extension of our main University of Wisconsin Health University Hospital (UH) location. Construction was completed in 2024, and upon opening, we were prepared to implement our plans to launch clinical trials safely, efficiently, and in a manner that met the expectations of both patients and staff.

2. Goals
Our team at the University of Wisconsin Carbone Cancer Center was tasked with extending our expertise in clinical research trial execution to the new facility while maintaining the highest quality of patient care. Key objectives included ensuring the seamless transfer of study materials (e.g., kits, study drugs, and documents) between EMC and UH, determining which patient visits could be conducted at EMC, and developing an orientation plan to familiarize staff with the new building and workflows.

3. Solutions and Methods
Multiple standard operations procedures, policies, and workflows were developed to facilitate the secure and efficient transfer of study kits, equipment, drug, and patient records. Locking bankers' bags were implemented for the secure transport of PHI, accompanied by a paper transport manifest for audit trail purposes. Study drugs are transferred via a courier system equipped with AirTags for real-time location tracking. Additionally, we established clear criteria to determine whether a patient visit can be conducted at EMC. To support staff onboarding and information dissemination, we created a comprehensive knowledge base (KB) page, an orientation binder, and designated a site manager to assist new employees.

4. Outcomes
The opening of Eastpark Medical Center was a success, with patient visits beginning on October 28, 2024 (go-live). As of December 31, seven weeks after the full EMC Oncology clinic launch:

- 151 subjects have been consented at EMC. Of these, 70 were for interventional trials, including 53 treatment trials and 10 NCTN trials.
- Additionally, 353 treatment trial research visits have been completed for 184 unique patients across 90 unique protocols at EMC.
- Currently, only four (of 436) studies lack IRB approval to conduct research at EMC, excluding those still in the activation process.

A retrospective for staff was held on January 30, 2025, and little to no concerns were voiced.

5. Lessons Learned and Future Directions
It’s impossible to anticipate every challenge when opening a new facility. However, having a dedicated project manager, a dedicated operations team, and collaborating with all area leaders at EMC was essential to the success of this project. Looking ahead, our goals and potential enhancements include:

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- Improving Item Transport Efficiency: While item tracking has been effective, delays in pickup have led to inefficiencies and frozen drugs are not able to be safely transported at this time. Implementing better monitoring and accountability measures will help streamline this process as well as allow additional types of study drugs to be transported to this location.
- Measuring Staff and Patient Satisfaction: Introducing surveys and feedback mechanisms will provide valuable insights to guide future improvements.
- Expanding Clinical Research Beyond Oncology: Rolling out established clinical research processes to non-oncology departments will enhance research capabilities across EMC.
- Streamlining Visit Eligibility Determination: the current process remains time-consuming – need to explore ways to streamline this process.