

Expansion of Oncology Clinical Trials in the Indianapolis Suburban region

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1. Background

The availability of cooperative group and investigator-initiated clinical trials is a major differentiator in the local oncology market. The goal is to expand oncology statewide research within the Indianapolis Suburban region hospitals. Patients will have not only standard-of-care treatment options but will have access to the latest clinical trials. Providing research options locally will prevent the leakage of patients to external systems and out of state providers.

In collaboration with Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) it will provide more treatment options than are available at competing facilities in the region. The IUH Schwarz Cancer Center includes a 20-bay infusion center, compounding pharmacy, phlebotomy/lab processing and dedicated research space. Oncology specialties include Breast, Gynecological, Thoracic, Head & Neck, Gastrointestinal, Radiation Oncology, Surgery, and Hematology Malignancy, all staffed by IUSCCC physicians.

2. Goals

- Providing patients access to IU Simon Comprehensive Cancer Center trials without having to drive to the downtown locations
- Support a clinical trial portfolio that offers options to patients with a variety of cancer diagnoses
- Build a comprehensive research team that manages all aspects of clinical trial research (screening, consenting, eligibility, treatment, correlative sample processing, data management, and follow-up)

3. Solutions and Methods

- In collaboration with the IU Health system, we developed a milestone-dependent accrual mechanism; the clinical research infrastructure continues to grow as accruals are met
- Developed a mechanism to identify clinical trials feasible for the surrounding sites
- Dedicated research office space and a research laboratory for correlative sample processing
- Established a courier system for transporting samples and Investigational products
- Dedicated site-specific research staff (CRN, CRPS, CRS, DC) to support clinical research and allow for real-time data entry
- Ensured physicians have access to the clinical trials portfolio and can access trials through the website
- Developed strong and supportive relationships with IU Health leadership and the site's physicians and staff
- Integrated research staff into the daily workflow of the Schwarz Cancer Center
- Screened physician schedules to identify potential study patients

4. Outcomes

The IU Health Schwarz Cancer Center opened in January 2020 and is supported by 2.4 FTE (1 Clinical Research Coordinator and part-time CRN, regulatory, finance, and manager support). A milestone-dependent achievable plan to increase support is approved with 6.4 FTE as of January 2023. Thus far, all

milestones have been met. The Schwarz Cancer Center has enrolled 85 patients in its first year, 99 in its second year, and 146 patients in the third year.

5. Lessons Learned and Future Directions

- We are in our third year of a five-year plan and will need to prepare to renegotiate our budget with the IU Health System
- It is critical to have the research infrastructure in place to support clinical research
- The Schwarz Cancer Center is our model of success and plan to expand research operations to the West region of Indianapolis
- We have hired an Oncology Statewide Research Administrator to provide operational oversight for the expansion of the Indianapolis suburban regional sites
- Health System Leadership and site physician buy-in are essential for success

Figure

Yearly Accrual growth from CY2020-22

