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Building a robust oncology clinical research program in the community-based setting

Although 85% of cancer patients in the United States are treated within the community-based setting, opportunities for advanced treatment options via clinical trials are lacking. The National Comprehensive Cancer Network (NCCN) Guidelines state “NCCN believes that the best management for any patient with cancer is a clinical trial. Participation in clinical trials is especially encouraged” (NCCN 2018). To address the need for clinical trials in the rural communities served by Sanford Health, efforts described here were employed over the last five years to develop and maintain a robust portfolio of clinical trials for physicians to utilize as innovative treatment options. Successful approaches to cultivating an oncology clinical research program include (but are not limited to): developing a relationship with clinical operations, administration, physicians, support staff, research staff, and external partners. Formal trial selection through a protocol review and monitoring committee ensures physician engagement in the process of building a trial portfolio, and assists the study team in identifying feasibility concerns at the outset of considering the trial at the site. Furthermore, leveraging efficiencies of an integrated health care system are critical for study-start up, data collection, and subject coordination – all of which contribute to a site’s ongoing ability to remain attractive for future site selection. In addition, utilizing existing infrastructure for patient care management to screen eligible patients for trial significantly increases institutional enrollment percentages. The complexities of a clinical trial program focused in oncology are wide and varied. However, building a program is not impossible as long as the appropriate commitment, strategy, and dedication of resources are applied.

Recent Publications

1. Powell S, Dib E, Bleeker J, Keppen M, Mazurczak M, Hack K, Gitau M, Steen P, Terstriep S, Reynolds J, Landsverk M, Chan C H, Nelson M, Thompson P, Ellison C, Black L, Ford J, Chung J, Anhorn R and Gaba A (2018) Delivering precision oncology in a community cancer program: results from a prospective observational study. *Journal of Clinical Oncology, Precision Oncology*. DOI: 10.1200/PO.17.00220.
2. Ersek J, Black L, Thompson M and Kim E (2018) Implementing precision medicine programs and clinical trials in the community-based oncology practice: barriers and best practices. *ASCO (American Society of Clinical Oncology) Educational Book* DOI: 10.1200/EDBK_200633.
3. Powell S, Gitau M, Spanos W, Jensen A, Nowak R, Lohr M, Puumala S, Ellison C, Black L, Cheng J, Sacco A, Cohen E and Lee J (2016) Phase IB study of pembrolizumab in combination with chemoradiotherapy (CRT) for locally-advanced squamous cell carcinoma of the head and neck (LA-SCCHN). *Journal of Clinical Oncology* 34(15).

Biography

Lora Black has professional experience practicing as an Oncology Nurse for over fifteen years, twelve of which focused around oncology clinical research. She has held various positions within the clinical research department at Sanford during her tenure, and currently serves as Senior Director. As Senior Director, she has oversight and responsibility for clinical research performed across the Sanford footprint, which covers six states in the rural Midwest and far-reaching collaborations with national and international health care entities. She provides leadership and strategic vision for clinical research team as well as day-to-day guidance of operations. She holds certifications as an Oncology Certified Nurse and Certified Clinical Research Professional. She completed an MPH from Creighton University with a concentration in Health Policy and Ethics. She is also a Faculty Member for the biomedical ethics program at the South Dakota Sanford School of Medicine.

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