

# Community Oncology Can Close the Gap in Cancer Research



## The Research Program at Highlands Oncology Group

**T**hough the critical role of clinical trials in advancing treatment for cancer is undisputed, increasing nationwide patient participation in cancer clinical trials remains challenging for many reasons. As knowledge of the molecular biology of many cancers grows, so do the number of trials aimed at developing targeted therapies. In the current oncology landscape, we know that trials close due to insufficient enrollment. We know that providers are asked to do more with less, that the oncology workforce is unevenly distributed across the country, and that clinician burnout is a real threat.

Despite these obstacles, we also know that cancer programs in the community are succeeding at establishing and growing access to clinical trials for their patients whether through developing research programs on-site, affiliation with academic medical centers, participation in cooperative group trials, or some combination of these approaches. This is the story of how a large independent practice in northwest Arkansas has nurtured its research program over several decades and is now able to offer patients access to phase I, II, and III trials close to home and their families.

### Highlands Oncology Group At-a-Glance

Situated in the northwest corner of Arkansas, this freestanding cancer center employs multispecialty providers and operates four clinical sites. With a total staff of 450, the practice sees nearly 6000 patients annually. Highlands Oncology Group staff include 11 medical oncologists, three radiation oncologists, two supportive care physicians, five surgeons, 52 registered nurses, four oncology pharmacists, one genetic counselor, four social workers, two physical therapists, and two massage therapists. Since 1999

All new patients, as well as patients who have new scans or new pathology, are screened for clinical trial eligibility at Highlands Oncology Group.

Highlands Oncology Group has operated The Center for Chest Care in its Fayetteville location. With a high incidence of lung cancer in the region, three local physicians established The Center for Chest Care with a goal of improving on the diagnosis and treatment of cancers in the lung and chest employing a multidisciplinary approach to diagnosis and care. Working together, they developed a community-based, multidisciplinary thoracic cancer clinic—unique in the United States at that time. In 2011, Highlands Oncology Group opened a 50,000-square-foot facility in Rogers, equipped with 40 infusion chairs and 24 exam rooms.

As the group continued to grow, in 2015 surgical oncology services (i.e., gynecologic and colorectal surgeons) were added in a new site in Fayetteville.

Most recently, in August 2020, Highlands Oncology Group realized a long-time goal of consolidating many of its services into a new 125,000-square-foot facility in Springdale, which includes 48 infusion chairs and 34 exam rooms. Importantly, the new building brings the Highlands Oncology Group Research Program together under one roof in one location.



Highlands Oncology Group Medical Director of Research J. Thaddeus Beck, MD, FACP.

### Planting the Seeds

Turn back the clock to 1996, when the story of the practice and its research program begins. Highlands Oncology Group was established that year by three medical oncologists, J. Thaddeus Beck, MD; Daniel Bradford, MD; and Malcolm Hayward, MD.

Dr. Beck came to the practice from a staff position at the University of Arkansas Medical Center, having previously completed a fellowship in hematology/oncology at Duke University Medical School. In the process of being recruited to the Highlands Oncology Group, Dr. Beck mentioned his interest in continuing to engage in clinical trials through SWOG, the cooperative group in which the University of Arkansas research program participated. His partners agreed but suggested that research could be something Dr. Beck might pursue in addition to his other clinical responsibilities.

As Dr. Beck recalls, the Highlands Oncology Group Research Program started without any funding for staff. “We actually partnered with the hospital to hire a single staff person, and we managed to open some trials and completed them.” The part-

nership with the hospital only lasted for one year, but the practice’s fledgling research program persevered, first adding some industry trials in conjunction with contract research organizations and, ultimately, working directly with industry on trial participation. After more than 20 years of commitment to offering clinical trials in the community, the research program at Highlands Oncology Group is now able to offer more than 45 phase I, II, and III trials across all cancer types. “We still do SWOG trials and other NCI [National Cancer Institute] trials through the CTSU [Cancer Trials Support Unit], and also a large volume of industry-sponsored trials,” said Dr. Beck.

### Nurturing Research in the Community

For more than two decades, Dr. Beck has championed clinical research at his cancer program driven by the knowledge that “it’s how we change cancer care.” Over the years, patients in his community have benefited from having access to cancer treatment trials close to home.

“If you don’t have those options in your community, then there is nothing for patients to do,” said Dr. Beck. “If you live in northwestern Arkansas where it’s five hours from St. Louis, four hours from Kansas City, three hours from Oklahoma City, five hours from Dallas, and three-and-a-half hours to Little Rock, you have great barriers to participation in clinical trials that are university based. You need community-based research for these patients.”

Providers in the community often benefit from having strong, established relationships. One reason for the success of the research program at Highlands, Dr. Beck believes, is the practice’s ties to the community it serves. “Our patients all live here in our community. I can open a trial in the morning, go through our list of patients whom we’ve previously identified, call them up, and they’ll come in the afternoon and register for the trial, which is hard to do at a tertiary center where patients have to fly in and travel to be seen and evaluated. For all these reasons, we’ve worked hard to keep clinical trials available in our community.”

Most patients with cancer receive their care in the community, close to family and friends. “If you want to double or triple national enrollments, you have to have community participation, especially in phase I trials where the visits might be daily for a week and weekly for a month,” said Dr. Beck. “If you want to break down barriers within eligibility criteria, at some point you have to have phase I trials, which probably have the least barriers due to eligibility criteria,” asserts Dr. Beck.

Despite the COVID-19 pandemic, the Highlands Oncology Group Research Program managed to stay close to its schedule for transitioning to new offices in Springdale, Ark., in late August 2020. The move culminated more than five years of planning. Previously, the research staff were spread out in three locations. Clinical trial patients were seen in two facilities and regulatory and data management staff were in a third building. With this move, the research program is now in one location (Figure 1, page 29).

Figure 1. Staffing a Community-Based Research Program

**As of August 2020, the following staff comprise the Highlands Oncology Group Research Program:**

**Medical Director of Research**

J. Thaddeus Beck, MD, FACP

**Director of Research**

Helen Holtzen, RN, MS

**1 Research Manager**

Meagan Higginbotham, BS

**1 Research Secretary**

**Principal Investigators**

Thaddeus Beck, MD, FACP

Eric Schaefer, MD

Patrick Travis, MD

(All practice medical oncologists serve as sub-investigators)

**1 Clinical Research Supervisor**

Adam Torres, RN, BSN, BSBA

**8 Full-Time Clinical Research Coordinators**

**1 Part-Time Clinical Research Coordinator**

**2 Research Medical Assistants**

**3 Research Regulatory Coordinators**

**1 Data Manager Supervisor**

Curtis Randolph, EdD, LTL, CCRP

**3 Research Data Managers**

**Screening and Enrolling Patients**

All new patients, as well as patients who have new scans or new pathology, are screened for clinical trial eligibility at Highlands Oncology Group. Patients are screened the day before their clinic visit. The practice has integrated OncoTrials with its OncoEMR platform to assist with the screening process; however, the clinical research coordinators also manually screen patients, and physicians may identify patients they believe to be candidates for a clinical study and contact the research program staff directly. Highlands continues to be proactive in exploring technological solutions to streamline trial screening processes. For example, previously, Highlands Oncology Group conducted a study comparing the Watson for Clinical Trial Matching system with manual screening for trial eligibility.<sup>1</sup>

Under the current screening process, patients' charts are flagged in the electronic medical record if they may be appropriate for a specific clinical study. Providers see the flag and know that their patient has been screened. If time permits, physicians may speak with the study's clinical research coordinator about a specific trial before the patient visit. The Research Department also maintains an open protocol list for physicians to reference that includes bullet points with key information on eligibility inclusion or exclusion criteria. This list is updated weekly. During the patient visit, the flag alert prompts the provider to respond on whether to continue with the trial enrollment process or not.

The enrollment process has six basic steps:

1. The patient expresses to their physician an interest in a specific clinical trial.
2. The study coordinator provides an informed consent form and visits with the patient to discuss and encourages the patient to take the form home and review it.



Highlands Oncology Group Research Department Staff.



Top: Light-filled Infusion Center at Highlands Oncology Group. Bottom: Parkway Cancer Center skyline.

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In August 2020, Highlands Oncology Groups Medical Research program moved to one central location in the Parkway Cancer Center.

3. If the patient consents to the study, the screening process is scheduled.
4. The screening data are reviewed by the principal investigator to determine eligibility.
5. If eligible, the patient is enrolled in the clinical trial and treatment is scheduled.
6. The protocol's schedule of events is initiated.

Research Program Director Helen Holtzen, MS, RN, says that the practice accrues about 4 percent of its patients to clinical trials annually, and it is rare for a patient to have no interest in clinical trials.

Cancer clinical studies are requiring increasing involvement across disciplines, notes Clinical Research Supervisor Adam Torres, RN, BSN, BSBA. In this regard, the Highlands Oncology Group Research Program benefits from the practice's relationships in the community, he said. Although, as a multispecialty group, the practice is able to perform many of the tests needed for clinical trial participation in-house—for example, radiology and labs—“more and more studies these days are requiring ophthalmology exams, dermatology exams ... we even had a study that required an audiologist,” he said. “We are very active in our community and have great partners.”

### Building a Culture of Research

One step that Highlands Oncology Group has taken that supports a culture of research is agreement among practice providers to subspecialize, said Dr. Beck. As mentioned previously, for more than 20 years, Highlands Oncology Group has held a multidisciplinary thoracic clinic through The Chest Center. Pulmonologists, surgeons, radiation oncologists, and medical oncologists meet to evaluate new cases, “get them properly staged and determine the best treatment,” said Dr. Beck. “In that setting it's very easy to have clinical trials based around thoracic oncology and everyone is excited to have cutting-edge care available.”

The practice instituted the same multidisciplinary approach for breast cancer. “For 25 years we've had a multidisciplinary breast conference (a clinic without walls) every Thursday morning at 6:30 a.m.,” Dr. Beck said. The conference brings together all of the stakeholders in breast care to review cases, and the venue is the ideal for keeping everyone updated on available new clinical trials. “We can enroll patients on neoadjuvant clinical trials through that education process within that conference. It can move very quickly when [all of the stakeholders] know that there is a clinical trial for BRCA-mutated triple negative breast cancer.”

In this way, Highlands Oncology Group's Research Program complements the collaboration among these providers and extends access to clinical trials.

"I know that for whatever reason our area is unique," Dr. Beck said. "You seldom find physicians from different specialties collaborating on patient care, but when you see it happen and be successful then it begets the process again for another subspecialty conference. It may start out as a conference and turn into a clinic. And there's advantages for all the providers in that it's just more efficient. Highlands has created the collaboration by providing the infrastructure to make it work. We've been so driven to make it happen that we've broken down the barriers [with the infrastructure and staff] to make it happen ourselves."

### All Together Now

With the research staff together in one location, the Highlands Oncology Group continues to strengthen its commitment to a community-based research program. "We've set up our desk areas so that all the data managers are together, all the study coordinators are together, all the regulatory [staff] are together," said Helen Holtzen, MS, RN. "Everyone worked so hard to make this move successful, and it was important to champion that with the staff." The physical proximity enhances communication and "now we're training a new clinical research coordinator. She's been able to go around to each individual and spend time—from the research business manager on up—to see everyone's piece in how we get this clinical trial from signing the [confidential disclosure agreement] to the close-out visits. It's so much easier [for new staff] to get a picture of how a clinical trial works."

In addition to the new facility, the research program staff now includes a dedicated research advanced practice registered nurse (APRN) who will work closely with the physician team. In this role, she will see study patients for visits that do not require an MD. The APRN will oversee lab results for all clinical trial patients, and the APRN will be highly involved in monitoring and managing patient adverse events and seeing patients who may need an acute visit for an adverse event, further improving continuity of care.

For other community cancer programs looking to build a similar research program, Dr. Beck encourages the commitment. "I hope that more practices will try to have a robust clinical trials program. It's work, but it's professionally satisfying and it's good for patients." 

*Amanda Patton, MA, is a freelance healthcare writer. She worked as a senior writer and editor for the Association of Community Cancer Centers for more than 15 years.*

### References

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### Arkansas by the Numbers

Fayetteville, population 87,590 (per 2019 census estimate<sup>2</sup>), is the third largest city in Arkansas. Located in the northwest corner of the state in the Ozark Mountains, Fayetteville is home to the flagship campus of the University of Arkansas.

Cancer is the second leading cause of death in Arkansas. In 2020 the American Cancer Society estimates that 17,200 Arkansans will be diagnosed with cancer and 6730 individuals will die from the disease. Cancer of the lung and bronchus is expected to remain the leading newly diagnosed cancer in 2020, followed by breast, prostate, colorectal, and kidney/renal cancers.<sup>3</sup>

According to the most recent statistics, Arkansas is among the five states with the highest age-adjusted lung cancer death rates per 100,000. These states are Kentucky (53.5), West Virginia (50.8), Mississippi (49.6), Arkansas (47.4), and Oklahoma (46.8). In 2018 the age-adjusted lung cancer death rate in the United States was 34.8 per 100,000.<sup>4</sup>