

Community Oncology Can Close the Gap in Cancer Research



The research program at Lahey Health Cancer Institute

Resources, information, and tools developed as part of the Association of Community Cancer Center’s 2020-2021 President’s Theme, “Community Oncology Can Close the Gap in Cancer Research,” have highlighted practical steps for increasing community engagement (both provider and patient) in cancer clinical trials.

One of the ways in which community oncology is helping to close gaps in cancer research is through participation in the National Cancer Institute Community Oncology Research Program (NCORP) clinical trials. These National Cancer Institute (NCI)-supported multi-site clinical trials—most often phase III studies—are available in the areas of cancer control, prevention, and care delivery.

The NCORP network makes clinical trials available through a hub-and-spoke structure. Seven NCORP research bases serve as hubs for clinical trial development and research coordination for NCORP studies. Radiating out from these hubs are the nearly 50 NCORP community sites (32 community sites and 14 minority/underserved community sites), around which cluster “mini-networks” of local community cancer programs and oncology practices that affiliate to participate in NCORP trials. The mini-networks branching from NCORP community sites range from small (15 affiliated cancer programs and/or practices) to large (100 or more affiliates and sub-affiliates at one site).

Of the seven NCORP research bases, five are associated with the oncology cooperative groups (Alliance for Clinical Trials in

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Oncology, COG, ECOG-ACRIN, NRG Oncology, SWOG) and two are located at cancer centers (Wake Forest Baptist Comprehensive Cancer Center and University of Rochester Wilmot Cancer Center). The latter two research bases focus exclusively on NCORP studies related to improving symptom management, survivorship, and quality of life and do not lead cancer treatment trials.

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The Lahey Health Cancer Institute Experience

Lahey Hospital & Medical Center has a long history of participation in clinical research. The Lahey Health Cancer Institute, a part of the Beth Israel Lahey Health System, continues to expand access to clinical trials and, in particular, the NCI National Clinical Trials Network into the community by partnering with affiliated community hospitals. In 2018 and 2019 Lahey Hospital & Medical Center received the National Cancer Institute's National Clinical Trials Network (NCTN) High Performing Site Initiative award, which recognized trial sites that enrolled large numbers of patients onto NCTN trials while maintaining excellence in trial data quality.

For insight on what it takes for an academic center and an affiliated community cancer program to partner successfully to increase clinical trial access in the community, *Oncology Issues* reached out to Lahey Health Cancer Institute. Sharing perspectives are Paul J. Hesketh, MD, FASCO; Corrine Zarwan, MD; and Julia Roache. Dr. Hesketh is director of the Lahey Health Cancer Institute, director of the Sophia Gordon Cancer Center, and director of Thoracic Oncology at Lahey Hospital & Medical Center and a professor of medicine at Tufts University School of Medicine. He serves as a member of the Executive Leadership Group of the SWOG Lung Committee and chairs a subcommittee focused on community provider engagement. Corrine Zarwan, MD, is interim chair, Division of Hematology Oncology, and associate director and clinical research director of Lahey Health Cancer Institute. Julia Roache has 17 years of experience with Lahey. She is senior research associate and team lead, Hematology and Oncology, Lahey Hospital & Medical Center.

"If we are really going to increase the proportion of patients with cancer that get onto clinical trials, we need to figure out a way to successfully reach out to the sites of care where they are receiving treatment, which for the majority is in the community," said Dr. Hesketh. "This is something that we feel very passionate about at Lahey. It is something that SWOG has been very committed to as well." Dr. Hesketh recommends that community sites answer these four questions in advance of considering opening a clinical research program:

1. **What are our community's cancer research needs?** Does your program see a sufficient volume of patients in disease sites for which NCTN or NCORP trials are available?
2. **Do we have a physician champion(s) and physician buy-in?** Do the providers in your community view the capacity to offer clinical trials locally as an important initiative? Are they interested in participating in research? "It's not going to work in any setting if you don't have provider buy-in," Dr. Hesketh said.
3. **Do we have administration support?** How will your site manage trial activation, patient recruitment, and trial execution? At a minimum, the remote site needs to have administration support to staff a local, on-site clinical research associate position—either full- or part-time. There must be some infrastructure commitment from the community site, which is then supported by the central infrastructure at the main site. Dr. Hesketh attributes Lahey Health Cancer Institute's success in

helping affiliates launch or expand their research programs to this two-way commitment. "At Lahey we have the resources in terms of nurses and senior clinical research coordinators to provide support to our affiliated community research sites," he said.

4. **What studies should be activated?** Community sites must make a realistic assessment of studies that will be the "right fit" for their cancer program. "You have to decide how complex a study you can do," said Dr. Hesketh. "For some sites, even some of the cooperative group trials may be too complex. And you have to decide whether the trial matches your patient population. There are certain diseases that you may see disproportionately more commonly than others, and those should be the ones you concentrate on in terms of activating the studies."

NCI NCTN group trials are "ideally designed" to be conducted in the community, said Dr. Hesketh. "Lahey is member of two NCTN groups: SWOG and NRG. I think the NCTN studies have been set up, in a way, to maximize community-based participation by, if possible, limiting some of the complex issues that can at times make the pharmaceutical trials so challenging to do."

Lahey Health Cancer Institute Director of Research Dr. Corrine Zarwan agrees that "must-haves" for affiliated programs to succeed are institutional commitment and willingness to provide resource(s) toward the program.

As an example, Dr. Zarwan describes how Lahey and Winchester Hospital, an affiliated community facility in Winchester, Mass., worked collaboratively to launch Winchester's first cancer clinical trials program. Winchester's cancer program had engaged



Dr. Paul J. Hesketh



Dr. Corrine Zarwan



Julia Roache

physicians eager to offer clinical trials to their patients close to home and administration provided support for a clinical research coordinator (CRC) position. What the site did not have was experience in starting a clinical trials program. “Once Winchester Hospital had secured administration support for that resource [the CRC position], they came to us to help build the program.” Beverly Hospital, another affiliated site, had an existing clinical trials program staffed by a part-time research nurse, and Lahey was also able to extend administrative and regulatory support for this site. “I do find that is the key,” Zarwan said. “A model for a smaller community hospital is to pair with a larger academic center. What works and has worked for us at our successful sites is having a dedicated resource on the ground locally, and having that staff trained at the academic center and working very collaboratively with the academic center.”

The community-site CRC position may not require a full-time equivalent; for smaller community cancer programs this staff member may have the bandwidth to manage additional duties. Without this local on-site staff, however, logistical and coordination challenges are likely. For example, the academic site “would have to send someone to [the remote site] repeatedly to handle research specimens,” Dr. Zarwan said. “You really need a person who is physically there, primarily working out of that site, to handle the day-to-day patient management issues, and then we can help with the regulatory piece.”

Measuring Success

In collaborating with community sites to expand clinical trial access, Lahey Health Cancer Institute’s main measure of success is patient accrual. “We want to make sure that all of our sites are actively accruing patients,” said Dr. Zarwan. This shows that the right trials are open, that providers are engaged, and that effective screening processes are in place to identify eligible patients. As director of research, Dr. Zarwan monitors accrual for all open trial disease sites on at least a quarterly basis. “If any of the community sites have not enrolled during that time period, we investigate further as to what the reasons might be. Do we not have enough trials open? What barriers might there be?”

Attention to physician engagement is another factor critical to the success of affiliate-site research programs. Lahey Health Cancer Institute uses two main tools to keep providers connected: a monthly e-newsletter and consistently incorporating relevant studies into the agendas for regularly scheduled meetings. Dr. Zarwan personally maintains the email list for the research e-newsletter. When highlighted studies involve disciplines outside of oncology, she ensures that those specialists receive the pertinent e-newsletter. “If it’s a urology study, for example, I’ll make sure to add additional urologists onto that newsletter,” she said, “but they wouldn’t receive it every month.” The research e-newsletter goes to the Lahey Health Cancer Institute research sites but also to additional Beth Israel Lahey Health sites. Each issue highlights a specific trial, lists up-and-coming studies, and includes links to all Lahey Health Cancer Institute open trials along with the email address of the clinical research associate who is responsible for the study.

Community physicians are kept informed about clinical trials at various Lahey and system-wide meetings. At Lahey Health Cancer Institute, system-wide disease site-specific multidisciplinary model of care meetings are held each quarter. “As part of the meeting agenda, we try to include a focus on research, highlight specific trials, and provide a list of available trials,” said Dr. Zarwan. “For example, in the breast team quarterly meeting, I will usually present on breast cancer trials, often with a focus on the studies that are more pertinent for the broader group in terms of the community centers ... the studies that I think will be easier for them [community sites] to accrue to or interesting studies that I encourage them [community sites] to refer to us if it is a particularly exciting trial.”

Supporting Research Staff

Lahey Health Cancer Institute’s model—a local clinical research coordinator on the ground at the community site with ongoing support from the larger research program—is one that has proven effective and replicable. The level of support provided to the remote clinical research coordinators is an important component. “Every other week, I meet with our research team and this includes the research associates from the other hospitals,” said Dr. Zarwan. “They attend our local research meeting, and we get updates on their program. They learn a lot from continuing to meet with their colleagues locally and are able to bring issues forward, and I get to hear if there are any provider-related issues so that I can follow up and support them.”

For instance, research associates may sometimes struggle to get an email response from busy providers and are hesitant to “nag.” “We have a policy that if they haven’t gotten a response after two attempts, they can include me on the correspondence,” said Dr. Zarwan. “That usually gets it done. I don’t have a problem tapping the person on the shoulder virtually or in person and saying can you please take care of this now. It’s a way for research staff to have somebody to hear their concerns on a regular basis.”

Two-Way Communication

Affiliate sites that have worked with Lahey Health Cancer Institute to initiate or expand clinical trials in their communities also benefit from ongoing education and resources through Lahey’s oncology cooperative groups, SWOG and NRG. Providers at the affiliate sites are encouraged to attend cooperative group meetings, where newly opening trials are discussed. “We do have engaged physicians at these sites that have requested that we consider opening trials and we’ve done that,” said Dr. Zarwan.

Achieving Excellence in Data Collection

Julia Roache is senior clinical research associate and team lead in the clinical trials research program at Lahey Health Cancer Institute. She heads a team of five clinical research coordinators who manage patients through the clinical trial cycle—from the point at which the patient consents through the end of the trial (or to the point at which the patient comes off treatment). “We make sure the consent forms are correct, that they’ve [patients] gotten all the tests that are required per the protocol, and that we have the information to ensure everything is done correctly



Lahey Hospital and Medical Center



Beverly Hospital



Winchester Hospital

for the trial,” said Roache. “We ensure that every test is ordered and that the patient is booked for the appropriate appointments, and we coordinate with our research nurses as well.”

In addition to Roache and five CRCs, the Lahey Health Cancer Institute’s dedicated research staff includes two regulatory coordinators, one of whom also serves as an administrative assistant. Two research nurses are assigned to see on-trial patients but are not dedicated full-time to cancer clinical trials.

The CRCs are typically assigned to specific disease sites. So, for example, one CRC will manage only on-study patients with breast and gynecological cancers. This approach enables the CRC to become knowledgeable about the active trials for their assigned disease sites and to become acquainted with the specialist clinicians who care for these patient populations. This policy also streamlines communication between physicians and the research coordinators.

The CRCs coordinate the patient screening for and enrollment into the clinical trial. At Lahey Health Cancer Institute, identifying patients who may be eligible for trial participation is a cooperative effort. As time permits, each week the CRCs scan the physicians’ schedules for any new patients or any incoming patients who fit trial eligibility criteria but, still, “a lot of the time, it’s the physicians finding these patients for us,” said Roache.

Research is further embedded into routine practice at Lahey Health Cancer Institute during regularly scheduled tumor boards. In advance of the disease site conference, the CRCs provide lists of currently available disease-specific protocols so that the conference participants have information at hand. The CRCs also attend the tumor board conferences for their assigned disease sites.

High-Quality Data Collection

As mentioned previously, in 2018 and 2019 Lahey Hospital & Medical Center received NCI’s NCTN High Performing Site Initiative award, which recognized trial sites that enrolled large numbers of patients into NCTN trials while maintaining excellence in trial data quality. Close collaboration and communication between the research nurses and the CRCs are the key to this achievement.

Roache explained: “We have a ‘start-up’ phase when we’re opening a new trial. During that phase, our research nurses will work with the clinical research coordinators to go through all the data that needs to be collected for the entire length of the study. Our research nurses will then go through in advance and create a template for each visit of the study. For each visit, the nurses have a set of forms to capture the required data and collect the data points that the study needs. When the nurses see the patient at the study visit, they will capture all the information that the study is asking. I think that’s a huge part of being able to enter the data correctly and get all the information that the study requires—the research nurses asking the appropriate study required questions.” With the requisite data collected in the progress notes, the CRCs can easily capture it. “The research nurses make our job easy.”

Pre-COVID-19, the CRCs and regulatory staff were co-located at Lahey Hospital & Medical Center. This proximity helped

facilitate team communication, Roache said. However, the COVID-19 public health emergency required some work site changes as staff switched to remote work on specific weekdays.

On-Boarding and Training CRCs

When new clinical research coordinators join the team, they go through a well-developed on-boarding program. Experienced CRCs at Lahey Health Cancer Institute manage, on average, between 15 and 20 studies. During the on-boarding process, a new CRC may be assigned just a few trials to start. “Or we’ll have the new staff shadow an experienced coordinator who may have taken on an extra trial while we were waiting for the new employee,” explained Roache. “When the new staff arrives, we’ll have them shadow that CRC for a few days or a few weeks. It just depends on how complicated the study is. We all really work as a team and if anybody has questions, it’s a great, very open team environment.”

This on-boarding process is extended to community sites partnering with Lahey Health Cancer Institute for clinical research, Roache said. For example, the team at Lahey supported the recruitment and training for the newly created CRC position at Winchester Hospital. “Because we knew what they were looking for, we were able to help them hire the coordinator,” said Roache. Once this new staff was hired, “she actually spent some time working at our site to see the research patients and see how the data gets entered. She spent several weeks with us. It was a great training experience, and she actually helped us with some of the data collection.” Going forward, the team at Lahey would handle the clinical trial administrative and regulatory tasks for the Winchester Hospital cancer clinical trials program. A further significant benefit for Winchester’s fledgling research program was the ability to use Lahey’s institutional review board.

“This is a huge advantage for smaller hospitals,” said Roache. Winchester Hospital’s cancer program now had the opportunity to open any of the trials that Lahey opens through the NCTN oncology cooperative groups SWOG and NRG, and providers at the affiliate hospital can also become members of these cooperative groups.

Each of the cooperative groups offers training programs for clinical research coordinators and clinical trial nurses. Additional training opportunities are available for physicians and allied research staff. “When new coordinators on-board, I have them complete those trainings as well. Our research administration department also provides training on the conduct of clinical trials that everyone involved in research is required to complete, including the study investigators.” CRCs at Lahey are also required to complete a Collaborative Institutional Training Initiative (CITI) human protections course. Education is an ongoing process, Roache said.

Cancer programs looking to grow or strengthen their research programs often want to know the attributes needed for a successful CRC. “It takes a very type-A person to do this job,” said Roache. “There are many little details and things you need to keep track of. You really have to be organized. It means finding that right




Infusion center at the Sophia Gordon Cancer Center

person that’s going to read every line of that protocol to make sure they didn’t miss something.”

In addition to skilled CRCs, the team at Lahey Health Cancer Institute offers these takeaways for success in partnering to offer clinical trials in the community setting. Clinicians at the community sites need to:

- Have a clear understanding of the clinical trial process. Be responsive to the study staff when they have queries.
- Be willing to follow the schedule of assessments and dose modifications within the protocols.
- Make an effort to be very familiar with the studies open at their sites.
- Have access to updates when there are amendments to the protocols.

Finally, a physician leader should oversee this process and be available to step in when procedures are not followed or staff do not respond to the research team. 

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Beth Israel Lahey Health At-a-Glance

In 2012 Lahey Clinic Medical Center in Burlington, Mass., merged with Northeast Health System to form Lahey Health. Seven years later, in 2019, Beth Israel Deaconess Medical Center, its affiliated community hospitals, three additional previously independent hospitals, and Lahey Health merged to form Beth Israel Lahey Health, the state’s second largest health system. Within the Beth Israel Lahey Health network are three academic teaching hospitals that have affiliations with Harvard Medical School and Tufts University School of Medicine, eight community hospitals, specialty hospitals for orthopedics and behavioral health, and ambulatory and urgent care centers. The health system serves 1.3 million patients in eastern Massachusetts.