

# Increasing Clinical Trial Accrual Through the Implementation of a Clinical Trials Navigator



Virginia Cancer Specialists, PC, is a large, multidisciplinary, community-based oncology practice in Northern Virginia, with expertise in medical, surgical, and radiation oncology. The practice's footprint spans 9 offices throughout the region, anchored by a central cancer center in Fairfax, Virginia, and is strategically positioned to meet the growing needs of the community. Currently, there are more than 35 physicians and advanced practice providers (APPs) on staff, as ongoing recruitment and expansion efforts continue to achieve the practice's goal of delivering cutting-edge, world-class cancer care to patients close to home.

Critical to this effort is the Virginia Cancer Specialists Research Institute—one of the largest research programs on the East Coast. This clinical trials program investigates novel agents across the full spectrum of solid tumors and malignant hematologic diseases, spanning from early phase and first-in-human studies to late-phase protocols. The research institute was founded in 1997 under the supervision of Nicholas Robert, MD, a founding partner of Virginia Cancer Specialists. The first activated clinical trial was AOR 97-001, which looked at using 2 doses of gemcitabine as a second-line treatment for metastatic non-small cell lung cancer. At the time of its inception, the research institute comprised 3 team members—a clinical research coordinator, data coordinator, and regulatory coordinator. Alexander Spira, MD, PhD, then assumed the directorship of the Virginia Cancer Specialists Research Institute in 2007 and was tasked with growing it based on the foundations laid by Robert. Spira's passion for research and continuous desire to provide better care to patients are evident in the program he has nurtured, which now includes 71 full-time research staff members and more than 170 clinical trials (about half are phase 1 studies).

Additionally, the Virginia Cancer Specialists Research Institute is a key member of US Oncology Research, the research arm of The US Oncology Network, allowing our patients to participate in national and international studies and our providers to collaborate with leading cancer research institutes across the country. Parallel to its size, the scope of the research institute has widened, with incredible diversification of studies across different malignancies and increased inclusion of tumor-agnostic, molecularly driven protocols. In 2021, Mitul Gandhi, MD, joined the research institute as a codirector, overseeing its malignant hematology portfolio. Then, in 2022, M. Adham Salkeni,

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MD, FRCPC, was recruited as a phase 1 clinician investigator. Clinical trial accessibility has also grown to include the practice's satellite sites with dedicated and local clinical research coordinators and an increased roster of subinvestigators. Since the inception of the research institute, Virginia Cancer Specialists, has enrolled over 3500 participants in more than 700 clinical trials, and the overarching goal remains: identifying clinical trials with promising novel agents that benefit patients in our community and continuing the mission of improving cancer care nationally.

Even with our robust program, we recognize the ample room for improvement that exists in enrolling more patients into clinical trials via the Virginia Cancer Specialists Research Institute. Although less than 5% of the adult oncology population is enrolled in clinical trials in the United States,<sup>1</sup> the national oncology community aims to address health system-specific and patient-centric barriers in cancer research. Improved understanding of these factors is necessary to catalyze the development of initiatives by the Association of Community Cancer Centers (ACCC) and American Society of Clinical Oncology (ASCO), among other organizations, to help guide cancer programs and practices nationwide in breaking down these barriers to promote clinical trial accrual and increase diversity in participation that better reflects the demographics of the oncology population at large.

In 2021, The US Oncology Network announced its call for a "culture of research" grant opportunity with the goal of developing reproducible cancer research programs that promote increased accruals to clinical trials. Virginia Cancer Specialists was 1 of 4 organizations

to receive the award for its proposal to create a new full-time position—the clinical trials navigator. “The clinical trials navigator has made a huge difference in accrual and patient and physician satisfaction,” Spira said. “It has provided patients with an accessible conduit to trial evaluation and entry, as well as helped providers navigate the complicated world of enrollment criteria and trial selection.”

To measure the effectiveness of the clinical trials navigator position, specific metrics will be developed (eg, overall site accrual, number of referrals to trials, and increases in enrollment by “low enroller” providers), compared to baseline numbers.

### Realizing This Necessary Role

The concept of a clinical trials navigator was partly borne by reviewing the accrual patterns of the research institute. Of the approximately 35 oncologists at Virginia Cancer Specialists, historically, about one-third (11 oncologists) were participating in clinical trials. Of this subset, approximately one-third (3 oncologists) were enrolling patients into clinical trials consistently. Many of our providers and APPs, while quite interested in providing clinical trial options to patients, perceived the whole process as mystifying and complicated, despite the presence of dedicated, site-specific clinical research coordinators. The desire and willingness to refer patients to clinical trials, while evident, was clearly hindered by a lack of time and familiarity with the research institute’s protocols, as well as the logistical requirements of enrolling patients into a study. Given the demanding nature of oncology and the clinical responsibilities providers often feel, patients’ participation in clinical trials was not always at the forefront of treatment decision-making. Even with electronic aids, identifying appropriate clinical trials is a laborious endeavor for providers, who already have busy clinic schedules. Although our clinical trial coordinators are quite skilled, identification of trials and appraisal of relevant inclusion and exclusion criteria fell out of their purview and normal workflow. Moreover, these clinical trial coordinators are tasked with the day-to-day care of patients enrolled in clinical trials and lack the bandwidth to take on more responsibilities.

Spira and Gandhi say they believe that the most critical element to having a pervasive culture of cancer research at Virginia Cancer Specialists rests on the personal level. Although efforts, including provider-to-provider engagement, were conducted, these exchanges were too infrequent to catalyze substantive change in our culture. A clinical trials navigator would serve as an effective bridge to fill the knowledge gap of the research institute’s trial portfolio and coordination of patient-related logistics. More importantly, a clinical

trial navigator can broaden the reach of the research institute’s leadership needs to directly engage with providers on a frequent basis to facilitate a desired change. In creating a clinical trials navigator role, we are confident that we can change the culture of research at Virginia Cancer Specialists.

### Making the Business Case

It is expected that provider participation in clinical trials at Virginia Cancer Specialists will improve with this individualized support. Increased revenue from the rise in accrual will more than offset the cost of the clinical trials navigator’s salary. The navigator will also provide introductory education on clinical trials to patients and is anticipated to increase both provider and patient satisfaction scores. Although this role started as a pilot at the research institute, early validation suggests that it is a replicable model for all other sites in The US Oncology Network.

The goal is that the clinical trials navigator will act as the primary source of research information across the practice, including all satellite sites, and educate and act as a liaison to promote the research institute. This responsibility will require repetitive engagement with our providers.

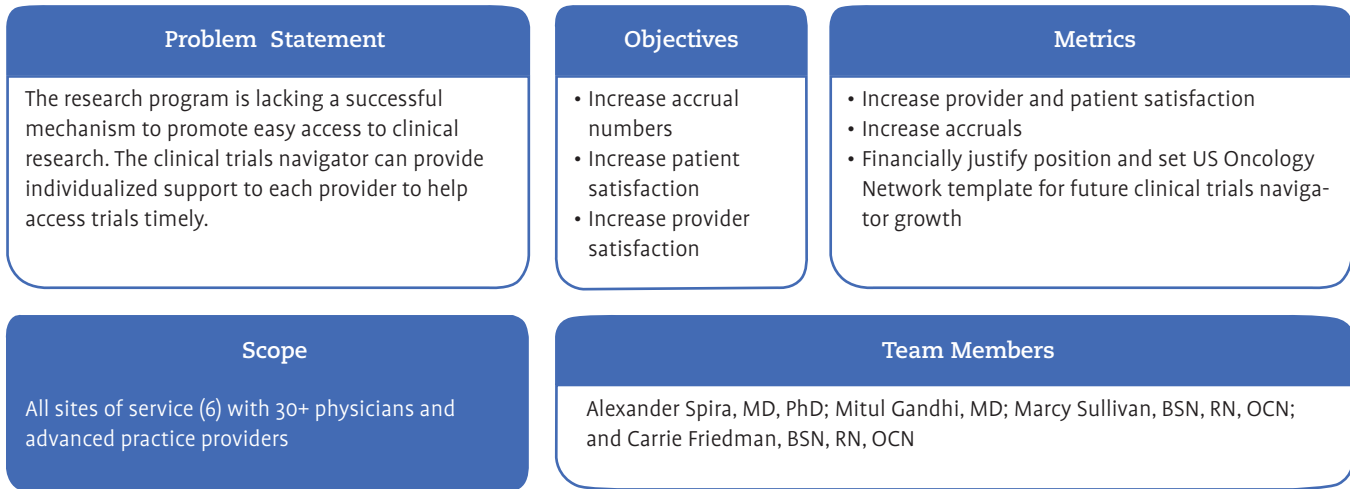
The expectation is that the clinical trials navigator will enable us to increase accrual rates by approximately 10% to 20% over the next year. Additionally, we expect to decrease the number of providers who are considered to be “low enrollers” in cancer clinical trials.

The responsibilities of the clinical trials navigator include as follows:

- Crafting specific and dynamic recruitment plans and identifying gaps in processes or training
- Making routine visits to all clinic locations for personalized assistance
- Assisting providers when they have questions about patient eligibility prior to consent
- Performing phone triage for referring providers and patients who are interested in a clinical trial
- Identifying, developing, and maintaining relationships with key contacts at each of the practice’s locations to facilitate timely fulfillment of accrual targets
- Attending research meetings
- Working with patients to answer their questions about clinical trial participation.

It is our expectation that the clinical trials navigator will have a significant and positive impact on clinical trial enrollment by bringing cancer research to the forefront of care for all our providers. Patient education provided by the navigator will help increase awareness of the research opportunities that exist and explain the research process and related timelines to participating patients. Regular provider engagement will not only benefit clinical trial accrual rates but also improve provider and patient satisfaction because we can offer additional treatment options. Facilitating assistance with clinical trial recruitment can also foster a more collaborative environment by giving providers greater support in navigating our research portfolio. Additionally, clinical trials will increase patient retention and network visibility.

**Figure 1. Establishing a Clinical Trials Navigator Position to Help Increase Accrual Numbers**



To measure the effectiveness of the clinical trials navigator position, specific metrics will be developed (eg, overall site accrual, number of referrals to trials, and increases in enrollment by “low enroller” providers), compared to baseline numbers. Based on estimates per patient revenue, our plan is to measure the benefits of including this navigator on the team against the cost of staffing the position. Provider satisfaction will be assessed by a survey at baseline and later compared to results 1 year after full implementation. See Figure 1, above, for a detailed infographic on the implementation of the clinical trials navigator role.

**Onboarding and Making the Role Her Own**

As a result of receiving a US Oncology Network grant for improving the “culture of research,” Carrie Friedman, BSN, RN, OCN, was hired in March 2021 to help implement the project activities and meet predefined goals. With more than 20 years of oncology nursing experience, Friedman was new to the cancer research space but joined the team with excitement and passion to make a positive impact on increasing clinical trial accruals at Virginia Cancer Specialists. Friedman’s first task was to meet with each provider to assess their needs, challenges, and desires as they related to clinical trial accruals. Virginia Cancer Specialists providers have since embraced the clinical trials navigator role and offered consistent feedback that they do not have the time to identify available clinical trials for patients. That is where Friedman has stepped in to support providers; she identifies available clinical trials with help from Spira, Gandhi, and Salkeni, as needed, and communicates these options to all providers. Our providers are now routinely reaching out to Friedman with their referrals, and our referral numbers have steadily increased over the past year as a result (Table 1, page 8). Several of the previously identified “low enroller” providers are now consistently referring patients to clinical trials.

Friedman has also developed innovative mechanisms for providers, so they now have heightened awareness of the Virginia Cancer Spe-

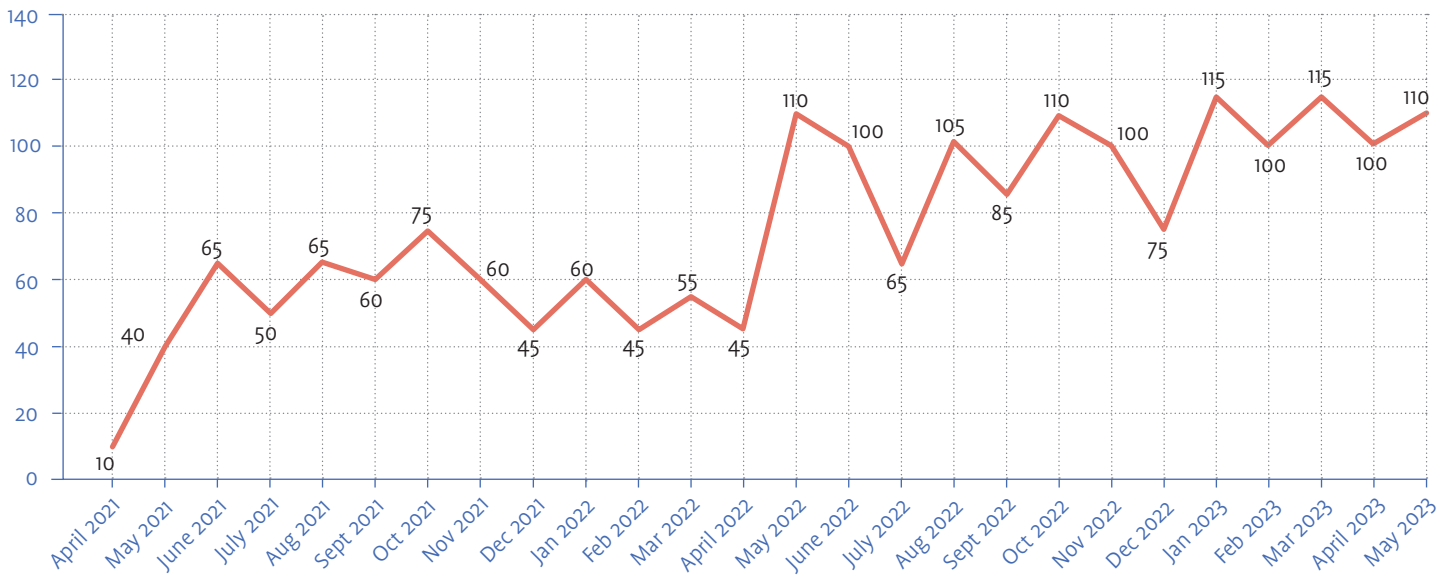
cialists Research Institute portfolio. She develops and maintains active lists of available clinical trials, grouped by disease site, making it an easy to access reference for providers. Further, Friedman creates bimonthly newsletters for the practice to raise awareness of newly available clinical trials, the research institute’s successes, and general oncology research-related education, which has been well received by our care teams. Friedman meets with Spira on a weekly basis to ensure all recent patient referrals are discussed, which is crucial to providing updated information to patients as needed. Finally, Friedman attends meetings with both the phase 1 and phase 2/3 clinical trials teams to ensure they are aware of any new information relating to their roles. Figure 2, page 8, details the role Friedman has played in ensuring successful implementation of the clinical trials navigator role.

**Demonstrating Return on Investment**

One of the most important aspects of creating the clinical trials navigator role is being able to financially justify the position. Prior to hiring Friedman, the team estimated that 6 accruals to 10 accruals per year to Phase I clinical trials would be necessary to justify the new position. Friedman met this goal very early on and continues to meet this goal monthly and, sometimes, weekly. This financial justification excludes the benefit the clinical trials navigator has brought to both our provider and patient satisfaction scores, which is equally important to the practice. Another common issue that came up early in 1-on-1 provider meetings is the timing of when patients hear from our research team after a provider discusses clinical trial opportunities with them. Often, some time passes before the clinical research coordinators, who complete prescreening and schedule appointments, reach out to patients. In turn, patients are anxious to hear from the research team and feel that they may have been forgotten about when they do not hear from the team for some

*(Continued on page 9)*

**Table 1. Total Referrals to Clinical Trials, 2021 to 2023 (YTD)**



**Figure 2. The Role of the Clinical Trials Navigator**

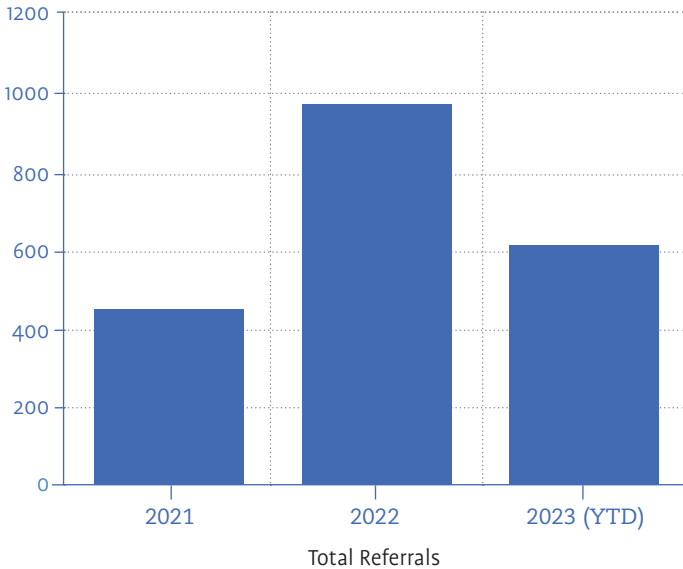


**WHAT WE DID...**

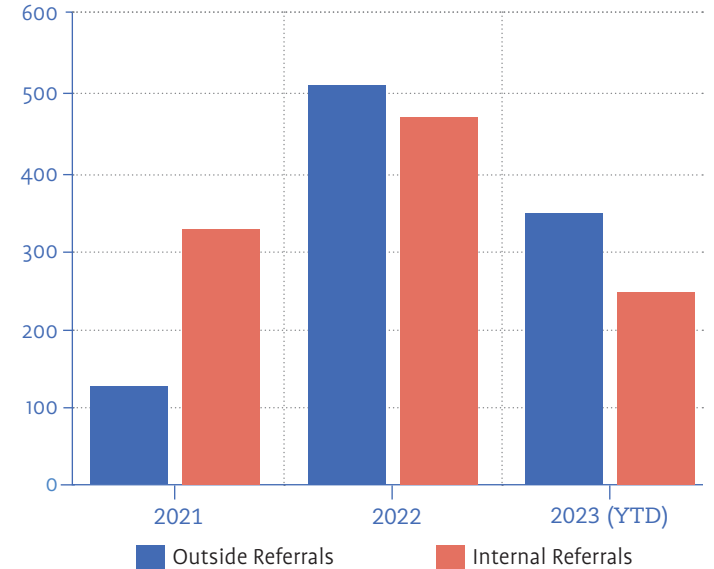
The Virginia Cancer Specialists Research Institute is, and will continue to be, a cornerstone of the organization. The research institute houses a robust early- and late-phase program.

1. Hired the clinical trials navigator, who started at the end of March 2021.
2. Met with all physicians to discuss the role of the clinical trials navigator and determine opportunities.
3. Created disease-specific summaries of all open clinical trials.
4. Developed monthly research newsletter for all Virginia Cancer Specialists staff.
5. Created easy access to Virginia Cancer Specialists clinical trial information for internal and external patients.
6. Created a clinical trials 101 class on the Virginia Cancer Specialists website.

**Table 2. Total Referrals to Clinical Trials in 2021, 2022, and 2023**



**Table 3. Total Referrals for Internal vs External Patients in 2021, 2022, and 2023**



*(Continued from page 7)*

time. To meet this need, Friedman now calls patients during this time to educate them on the enrollment process and timing of their appointments. Often, patients are grateful to hear from Friedman and learn about the process and timing of enrolling in a clinical trial. Due to the large volume of clinical trials at Virginia Cancer Specialists Research Institute, Friedman has also taken on screening all external referrals and coordinating the care of these patients to get them a consultation. And because of the increased number of external referrals to the research institute, Virginia Cancer Specialists has hired a second position to support the clinical trials navigator, just shy of 2 years into the full implementation of the role. Table 2, above, shows the total number of combined internal and external referrals from 2021, 2022, and 2023, and Table 3, above, illustrates the differences we have seen in internal versus external referrals for 2021, 2022, and 2023.

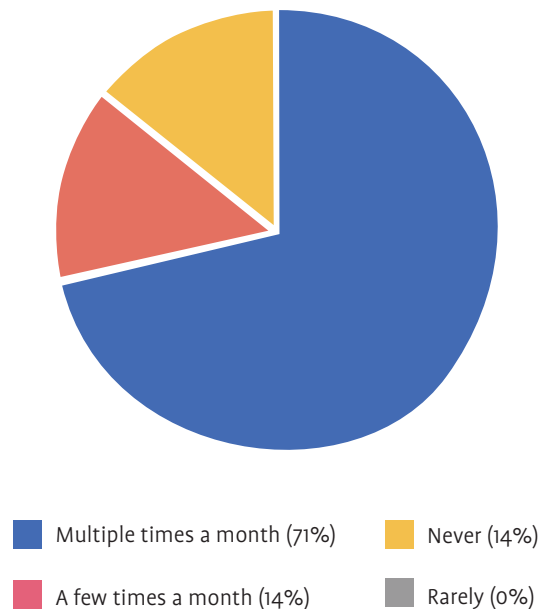
As mentioned earlier, Friedman sent out a survey to our providers early in her role and again several months ago. Although participation hit close to 50% on the second survey, the data gleaned shows that the clinical trials navigator has made a difference in referring and enrolling patients in clinical trials. It also shows that our providers are referring patients more often today than they did in previous years (Figure 3, right, and figure 4, page 10).

**Moving Forward**

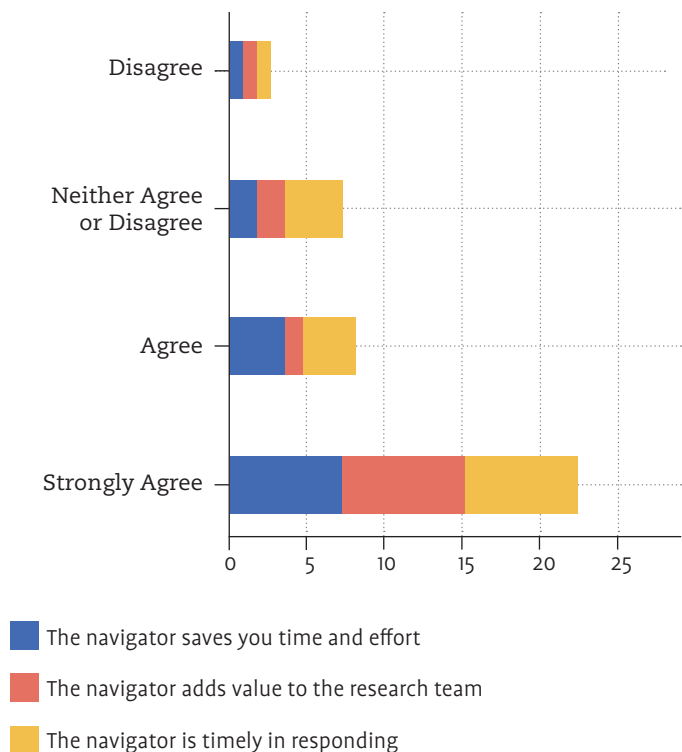
Friedman has now been in the clinical trials navigator role for almost 2 years and has defined her role successfully. She receives referrals from providers practice-wide and identifies clinical trial opportunities that are appropriate for patients. Virginia Cancer Specialists Research

**Figure 3. Frequency of Patients Contacting the Clinical Trials Navigator**


How often do you contact the clinical trials navigator?



**Figure 4. Provider Survey About the Clinical Trials Navigator**



Institute’s portfolio of varied clinical trials continues to grow, attracting external patients from across the region and the country. One important responsibility that Friedman has taken the lead on is navigating these external referrals. Because all referrals go through Friedman, she has valuable understanding of all the patients being evaluated for clinical trials at the research institute. This task is critical as staff at Virginia Cancer Specialists rely on Friedman to provide patient status updates.

While there have been some challenges to overcome with the implementation of the clinical trials navigator role, processes have fallen into place over time. It is difficult for Friedman to spend dedicated time at all practice locations as often as she would like because of the volume of referrals coming in; however, by having a second set of hands to help, Friedman will now be able to make those essential visits. It has also been challenging to stay current on available clinical trials, with many openings and closings occurring monthly. This is when Friedman relies on Spira and Gandhi for support. Despite settling into the role, there will continue to be challenges to overcome, and one aspect of the role Friedman appreciates the most is the genuine willingness of Virginia Cancer Specialists providers and staff to support one another to benefit patients. 

*Alexander Spira, MD, PhD; and Mitul Gandhi, MD, are medical oncologists; Marcy Sullivan, BSN, RN, OCN, is director of research operations; and Carrie Friedman, BSN, RN, OCN, is a clinical trials navigator at Virginia Cancer Specialists, PC, in Fairfax, Virginia. For questions email: [carrie.friedman@usoncology.com](mailto:carrie.friedman@usoncology.com).*

**Reference**

1. Unger JM, Cook E, Tai E, et al. Role of clinical trials participation in cancer research: barriers, evidence, and strategies. *Am Soc Clin Oncol Educ Book*. 2016;35:185-198. doi: 10.14694/EDBK\_156686