New Resource for Specimens and Data From Cancer Clinical Trials

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NCI announced the launch today of a new resource for cancer researchers interested in conducting studies using specimens and clinical data collected from cancer treatment trials in NCI's National Clinical Trials Network (NCTN) and former NCI Cooperative Group Program.

Known as NCTN Navigator, the resource includes information about specimens, such as tumor and blood samples, donated by patients in NCI-sponsored clinical trials. The clinical trials included in Navigator are published phase 3 studies that evaluated cancer treatments.

Investigators can use the NCTN Navigator website to search the inventory for specimens with specific characteristics. Investigators who develop proposals and get approval can use the specimens, along with the trial participants' clinical information, in their research.

"The optimal research proposals for this resource are those that capitalize on the large clinical trial study design and its associated specimens to develop ways to confirm how drugs work, select patients who benefit from a given treatment, and assess new methods to monitor treatment effectiveness," said Jeffrey S. Abrams, MD, acting director for Clinical Research in NCI's Division of Cancer Treatment and Diagnosis (DCTD).

Hundreds of Thousands of Specimens From Clinical Trials

NCI has supported large cancer treatment trials for decades through what is now the NCTN. For many of the trials, donated specimens were collected and stored in NCI-funded specimen banks. The clinical data from the trials include detailed information about patient responses to treatments and their outcomes.

The NCTN Navigator inventory includes data from more than 80 trials, 50,000 patients, and 600,000 specimens.

"Navigator's strength, and what sets it apart from most other resources, is the combination of specimens and the associated clinical information collected over the course of a trial," said Irina Lubensky, MD, of NCI's Cancer Diagnosis Program, which worked with NCI's Cancer Therapy Evaluation Program (CTEP) and NCTN specimen banks and researchers to develop Navigator.

Although the researchers who conducted these clinical trials have long been using the specimens and clinical data in studies, Navigator will now make the materials available to any investigators who submit research proposals that are approved by a scientific review board.

“Navigator will make NCTN trial specimens more visible and accessible to the broader translational cancer research community,” said Mark Watson, MD, PhD, of the Washington University School of Medicine in St. Louis. Watson directs one of the specimen banks where NCTN specimens are stored and was a member of the original Navigator project development team.

Proposals Undergo Peer Review

“Navigator is an amazing resource,” added Lee Ellis, MD, of the University of Texas MD Anderson Cancer Center.

Ellis also co-chairs a committee of scientific experts and patient advocates that will review proposals from investigators to use Navigator resources. “It will allow the cancer research community to develop new tools, such as predictive biomarkers, that will help us improve the care of our patients,” he said.

To ensure the optimal use of the resources in Navigator, the scientific review committee will consider the importance of a proposed project with the value of the specimens in mind. “The standards are high because the specimens are a nonrenewable resource,” said CTEP’s Grace Mishkin, MPH, who helped develop Navigator.

In general, successful Navigator proposals will use the specimens and data to test a research question that builds on prior knowledge and has potential clinical implications, noted Mishkin. The specimens in Navigator will generally not be appropriate for studies that are more exploratory in nature, she added.

The Enduring Value of Large Clinical Trials

Before developing or submitting a research proposal to the Navigator program, investigators can perform searches on the program’s website to ensure there are specimens and related data to meet their research needs.

If they would then like to move ahead, they can use the website to submit a proposal for how they would like to use the specimens.

“If their ideas are approved, they will receive the clinical data along with the specimens to conduct their analyses,” said Abrams.

There is no charge for the specimens or clinical data in Navigator, but investigators with approved proposals will be responsible for the costs associated with processing and delivering the

specimens and clinical data.

Although Navigator currently includes only specimens and information from adults, specimens and data from patients with pediatric cancers are expected to be added later this year.

Phase 3 clinical trials “remain an invaluable proving ground” for confirming findings from smaller studies, Abrams noted. The competitive process to obtain samples from Navigator will allow researchers to expand the value of these trials even further, he said.

Ellis agreed: “We hope that by making these specimens searchable on a user-friendly database, we can translate findings from these innovative research studies into better care for our patients.”

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