

Incorporate Real-World Evidence to Enable Learning from Every Cancer Patient
NCI Topic Category: Enhanced Data Sharing

What is the research problem?

The American Society of Clinical Oncology (www.ASCO.org) is pleased to submit this Cancer Moonshot idea. One of the most frustrating challenges we face as clinicians is that people with cancer have complex medical conditions and other non-healthcare needs, yet almost all we know about cancer diagnosis, treatment, and prevention comes from a tiny subset of patients—the 3 to 5 percent who enroll in clinical trials, who are typically younger, fit patients. Clinical trials enroll relatively homogeneous patient populations, which leaves us with a lack of evidence to guide treatments for a large proportion of the other 95 to 97 percent who do not participate in, or do not qualify for studies.

Clinical outcomes for millions of individuals with cancer are present in medical records and databases that, for the most part, do not communicate and not easily retrieved. By standardizing the real-life information on our patients—and making data from electronic health records truly interoperable— and aggregating it into a common database, we can vastly speed discovery and enable the possibility of personalized care in the future for every cancer patient. Insights that have taken years to discern could happen much more quickly, helping us to understand treatments that work, those that don't, and high impact areas where additional research is critically needed. In addition, discoveries made possible by the Moonshot Initiative, can be returned quickly to patients and clinicians thereby democratizing data and speeding the distribution of advances. This vision is one that has been accomplished outside of medicine and ASCO is excited by the possibility that the cancer care community can accelerate learning and improve quality of care quickly using this approach.

ASCO is using this approach in both CancerLinQ (Cancer Learning Intelligence Network for Quality) and the TAPUR (the Targeted Agent and Profiling Utilization Registry) study. The primary purpose of CancerLinQ is to promote high quality care for every patient by quickly sharing and exchanging large amounts of data. Similar to the information-aggregating power of Google or Amazon, CancerLinQ will identify trends among millions of patients with almost every treatment, tumor type and genomic profile—and bring them to the attention of medical professionals who can translate them to improved patient care. The TAPUR study is prospectively evaluating molecularly targeted cancer drugs and collecting data on clinical outcomes to learn about additional uses of these drugs outside of indications already approved by the FDA. TAPUR is a study grounded in real-world clinical practice – relying on physician judgment, collecting clinical outcomes as monitored in routine practice, and enabling participation of patients who are more reflective of cancer patients overall.

What is the proposed solution?

Maximize federal support for research projects aimed at learning from real-world clinical data and combining data from multiple sources. The expansion of new science, treatments and diagnostic tests make big data initiatives more important than ever so that we can quickly learn how best to apply these breakthrough treatments to the diverse U.S. population. This type of research also provides important supplemental information to clinical trials data and enhances the overall evidence base, particularly where prospective trials are not possible. Federal support for research with big data will help advance the methodology, encourage collaboration, and help ensure that the results inform the entire research community. ASCO is eager to work with NCI and its funded investigators to collaborate and maximize our potential to learn from data collected in CancerLinQ and TAPUR. For example, linking the Medicare-Surveillance, Epidemiology and End Results (SEER) database to CancerLinQ will increase the reach of Medicare-SEER (currently only 28 percent of the nation's cancer cases) and add important clinical information from physicians' offices, where nearly 80 percent of cancer treatment occurs. Research that leverages real-world data can also improve understanding of demographics and practice patterns related to physicians, patients, and payers that drive delivery of care and outcomes, ultimately leading to interventions to improve quality of care and eliminate disparities.

Cancer Big Data Laboratory - We recommend that NCI provide funding to permit organizations to partner and develop a Big Data Laboratory in which organizations (such as CI4CC and ASCO) could deposit de-identified datasets and make them available to informaticists to use for methods development. We need innovative methods for analyses of big data and our cancer center informaticists are well poised to develop and test methods and strategies. The new methods would then become available to CancerLinQ and others for analysis of other data sets. The field of big data analysis is developing at hyper speed because of the computing potential and large amounts of data that are being collected and accessible. Testing methods and strategies for analysis will require large amounts of data, and the laboratory would be a good environment in which to do it.

This problem could also be significantly addressed through changes to NCI's policies governing research:

- NCI should review its list of common data elements for researchers to collect in clinical trials to ensure that NCI-funded trials capture measures from the geriatric assessment domains (e.g., functional status, comorbid medical conditions, psychological state, cognitive function, nutrition status, and social support), socioeconomic status, and geographic demographics and should provide sufficient per-case reimbursement to capture this information.
- NCI should make supplemental funding available to enable all NIH, NCI, and NCI-funded clinical databases to collect geriatric assessment, socioeconomic status, and geographic data and have the functionality to support studies designed to improve the evidence base supporting the treatment of older adults and underserved populations with cancer.

How will the solution make a difference?

An NCI funding opportunity announcement focused on learning from real-world data across multiple data sources will enable NCI and its funded investigators to be leaders and standard-setters in the rapidly evolving field of big data research. It will also send a strong message to health information technology vendors that the value of the data they are collecting is maximized when it can be securely aggregated across multiple platforms. ASCO is pleased about the recent collaboration between CancerLinQ and the Cancer Informatics for Cancer Centers (CI4CC). The collaboration will bring together CancerLinQ (which has practices in a wide variety of settings throughout the U.S.) with informatics scientists and technology leaders at NCI-funded cancer centers and other academic cancer centers throughout the world. The TAPUR study also involves research sites in the community and at academic centers.

Big data research would provide the potential to learn from cancer survivors about the long- and late-term effects of cancer treatment, as well as ongoing surveillance needs.

Reference(s)/Supporting Documentation