CancerLinQ Partners with FDA to Study Real-World Use of Newly Approved Cancer Treatments

Collaboration supports FDA’s future-oriented priority to create empirical frameworks, incorporate real-world evidence into data-driven, decision-making

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CHICAGO, Il. – CancerLinQ LLC today announced a long-term partnership with the U.S. Food and Drug Administration (FDA) that will harness cancer patient information and big data analytics to examine the real-world use of emerging and newly approved cancer therapies. Real-world data from CancerLinQ® will be used to grow the knowledge base about patterns of care across all cancer types and therapies, accelerate development of novel insights that might otherwise be challenging to obtain through standard research initiatives and data collection means, as well as potentially inform FDA regulatory strategy and decision-making processes.

CancerLinQ® is the American Society of Clinical Oncology’s big data initiative to rapidly improve the quality of cancer patient care. Under the new partnership, FDA and CancerLinQ researchers will use CancerLinQ Discovery™, a research and analytics platform that allows users to analyze real-world, aggregated, de-identified patient care data from oncology practices that participate in the CancerLinQ data-sharing program. The rapidly expanding CancerLinQ network currently includes a vastly growing number of patient records from nearly 90 diverse oncology practices and institutions from 40 states and the District of Columbia, making it among the largest and most robust sources of real-world evidence in oncology.

“This collaboration addresses one of oncology’s central challenges – to quickly learn about the real-world impact of cancer therapies once a drug is approved,” said Clifford A. Hudis, MD, FACP, FASCO, CEO of ASCO and Chairman of the CancerLinQ Board of Governors. “Until now, our learning about new treatments was hindered by the limited number of physicians and patients involved in traditional research and slowed significantly when formal clinical trials ended. CancerLinQ Discovery addresses this gap and fulfills the need, picking up where trials leave off
and opening up a new world of insights to guide the use of new therapies and improve the lives of everyday patients with cancer.”

“This is an important collaboration in our regulatory science research portfolio that can contribute to the development of an empirically-derived framework for incorporation of real-world evidence into regulatory decision making,” said Sean Khozin, MD, MPH, acting associate director for oncology regulatory science and informatics in the FDA’s Oncology Center of Excellence and the director of the FDA’s INFORMED initiative. “Studying the real world experience of patients is an opportunity to not only gain new insights beyond conventional clinical trials, but also advance patient-centered drug development by turning our focus to the point-of-care, where the majority of cancer patients are being treated.”

The initial FDA and CancerLinQ project, focusing on treatments for advanced melanoma, aims to characterize the real world experience of these patients, inform the clinical use of currently approved therapies, and potentially inform future FDA regulatory review of targeted drugs and immunotherapies.

The partnership addresses some of the most important and talked-about advances of the last decade. They include the groundbreaking class of immunotherapies known as checkpoint inhibitors, as well as several molecularly targeted therapies. While these treatments have collectively transformed care for advanced melanoma and extended many patients’ lives, there still exist unanswered questions about their use and adoption in the real world setting. For example, relatively little is known about their specific benefits and risks in the elderly or in those with other serious health problems, because such patients are often not able to participate in studies, due to the stringent nature of most clinical trials.

CancerLinQ and FDA investigators will explore a variety of issues related to the use of newly approved therapies, including the optimal sequence of treatments, the impact that other health problems have on treatment tolerability and cancer outcomes, and the experience with immunotherapy combinations versus single agents. CancerLinQ and the FDA will share their findings with the cancer community to help guide the use of these treatments and inform the development of future clinical trials. The FDA may also apply the findings to future drug reviews or labeling refinements.
"We at CancerLinQ are humbled by the opportunity to officially partner with the FDA and, ultimately, share our collective findings with the oncology community," said Kevin Fitzpatrick, Chief Executive Officer of CancerLinQ LLC. "We are thrilled to be growing our coalition of collaborators in such a short span of time and be identified as a key resource for the federal agency to support the FDA’s interest and commitment to leverage real-world evidence in their decision making."

The FDA partnership is one of many that CancerLinQ has established over the past year. Today, CancerLinQ also announced the launch of a collaboration with the National Cancer Institute (NCI) to facilitate the exchange of information between CancerLinQ practices and NCI’s Surveillance, Epidemiology, and End Results (SEER) program.

Previously, CancerLinQ has announced official partnerships with leading organizations, such as the American Academy of Physician Assistants (AAPA), American Society of Radiation Oncology (ASTRO), Cancer Informatics for Cancer Centers (CI4CC), College of American Pathologists (CAP), Hematology/Oncology Pharmacy Association (HOPA), National Comprehensive Cancer Network® (NCCN), Oncology Nursing Society (ONS), and Society of Gynecologic Oncology (SGO) and AstraZeneca, which is the founding enterprise partner of CancerLinQ Discovery™. Through all these efforts, CancerLinQ hopes to learn and share insights that can improve the quality and efficiency of the entire cancer care system.

CancerLinQ is supported in part through the Conquer Cancer Foundation, whose generous donors have helped make the system possible. Major supporters include Amgen; Astellas; AstraZeneca; Bayer HealthCare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Cancer Treatment Centers of America®; Chan Soon-Shiong Family Foundation; Genentech BioOncology™; HELSINN; Janssen Oncology; Lilly; Raj Mantena, RPh; Novartis Oncology; Pfizer Oncology; Thomas G. Roberts, Jr., MD and Susan M. DaSilva; and Susan G. Komen®.

CancerLinQ® and CancerLinQ Discovery™ are projects of CancerLinQ LLC. For more information on how to participate or partner with CancerLinQ, please visit CancerLinQ.org.

**About ASCO:**

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn

**About CancerLinQ LLC**

CancerLinQ LLC is a wholly-owned nonprofit subsidiary of American Society of Clinical Oncology, Inc. established for the development and operation of the CancerLinQ® initiative. CancerLinQ is a health information technology platform aimed at enhancing and improving the understanding and treatment of cancer. To learn more, visit [www.cancerlinq.org](http://www.cancerlinq.org).