CancerLinQ LLC, Concerto HealthAI, and Tempus are Expanding Collaboration with U.S. Food and Drug Administration on Checkpoint Inhibitors

Technology Companies Concerto HealthAI and Tempus Join to Conduct Data Analysis
For immediate release
August 22, 2018
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*Alexandria, Va. —* CancerLinQ LLC, a wholly-owned nonprofit subsidiary of the American Society of Clinical Oncology (ASCO), has brought on technology collaborators Concerto HealthAI and Tempus to accelerate its joint research effort with the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) aimed at understanding the real-world use, tolerability, and effectiveness of immune checkpoint inhibitors. Concerto HealthAI and Tempus have begun to assist in the analysis of a de-identified data set that CancerLinQ has provided to the FDA, representing more than 10,000 patients who have been treated with immune checkpoint inhibitors for both approved and unapproved indications.

In June 2017, CancerLinQ LLC and the FDA announced a long-term partnership to explore the real-world use of emerging and newly approved therapies, including optimal sequencing of treatments, the impact of non-cancer health issues on treatment tolerability and cancer outcomes, and use of immunotherapy combinations versus single agents.

"These types of research efforts need to span across the cancer community because one organization cannot accomplish them alone," said CancerLinQ LLC CEO Cory Wiegert. "We are
excited that Concerto HealthAI and Tempus are bringing their technical capacity and analytic expertise to this important effort in support of the FDA's evaluation of these therapies outside of clinical trials."

Through this research agreement, the collaborators will study a de-identified data set of patients who have received any of the following immune checkpoint inhibitor medications: atezolizumab (Tecentriq), avelumab (Bavencio), durvalumab (Imfinzi), ipilimumab (Yervoy), nivolumab (Opdivo), or pembrolizumab (Keytruda). Concerto HealthAI and Tempus are providing analytic support through their existing agreement with CancerLinQ LLC, announced late last year, in which both companies will curate CancerLinQ® data into high-quality datasets to be used to improve quality of cancer care and for research.

The FDA will then evaluate the incidence of immune-related adverse events in patients receiving these therapies. CancerLinQ® data will also enable the FDA to examine the use of immune checkpoint inhibitors in patients who are poorly represented in clinical trials, including older patients, racially diverse populations, and individuals with autoimmune diseases.

CancerLinQ and the FDA will then 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.

CancerLinQ LLC entered into an agreement with Concerto HealthAI (formerly: Precision HealthAI Solutions) and Tempus, announced in December 2017, to accelerate the development and delivery of high-quality, de-identified clinical databases for use by CancerLinQ®, its oncologist subscribers, partners, and the broader cancer community. Through the agreement, Concerto HealthAI and Tempus are curating information into high-quality, HIPAA-compliant datasets to be used to improve quality of cancer care. These datasets will be made available through the core CancerLinQ® quality improvement platform and CancerLinQ Discovery®, a service that provides access to high-quality, de-identified datasets for non-profit organizations, health care providers, academic researchers, and government agencies.

CancerLinQ® is supported in part through Conquer Cancer, the ASCO 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 nearly 45,000 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 more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube.

About CancerLinQ LLC

CancerLinQ LLC is a subsidiary of the American Society of Clinical Oncology (ASCO) established for the development and operation of the CancerLinQ™ initiative. CancerLinQ® is a health information technology (HIT) platform aimed at enhancing and improving the understanding and treatment of cancer. To learn more, visit www.cancerlinq.org.

About Concerto HealthAI

Concerto HealthAI is a technology leader in Definitive Real World Data and AI solutions for precision health. Our mission is to accelerate drug development, clinical trials, HEOR analytics and patient outcomes through definitive RWD and AI Solutions. Concerto HealthAI's businesses include Precision HealthAI, Vector Oncology and ProMetrics. Concerto HealthAI is a SymphonyAI company. For more information, visit us at www.concertohealthai.com.

About Tempus
Tempus is a technology company that is building the world's largest library of molecular and clinical data and an operating system to make that data accessible and useful. We enable physicians to deliver personalized cancer care for patients through our interactive analytical and machine learning platform. We provide genomic sequencing services and analyze molecular and therapeutic data to empower physicians to make real-time, data-driven decisions. Our goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as we gather more data. For more information, visit tempus.com and visit us on Facebook (Tempus Labs) and Twitter (@TempusLabs).