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Groundbreaking Collaborative Breast Cancer Study Aims to Unlock the Doors of Individualized Patient Care with Big Data

Thirty-two researchers from 14 institutions joined forces to identify personalized treatment options for a patient with metastatic triple-negative breast cancer.

FORT WASHINGTON, PA — An unprecedented approach to clinical research, documented in the January issue of *JNCCN – Journal of the National Comprehensive Cancer Network*, brought together 32 researchers from 14 different institutions, including community and academic cancer centers, universities, and biotechnology and data sciences companies, to identify potential interventions for a patient with metastatic triple-negative breast cancer (TNBC)—an especially aggressive subset of breast cancer that is widely considered to be incurable. The Intensive Trial of OMics in Cancer (ITOMIC) deeply characterizes and tracks the molecular features of a patient's tumor, aggregates experts to generate hypotheses regarding treatments that are predicted to be beneficial, allows these predictions to be tested in the patient, and learns from these experiences to help future patients. This first report from ITOMIC describes a patient with triple-negative breast cancer metastatic to bone, who had markedly elevated circulating tumor cells (CTCs) that were monitored 48 times over nine months.

Full access to the *JNCCN* article, titled, "A Distributed Network for Intensive Longitudinal Monitoring in Metastatic Triple-Negative Breast Cancer," is available until February 23, 2016, on JNCCN.org.

A team of multidisciplinary researchers, led by C. Anthony Blau, MD, Director of the Center for Cancer Innovation and Professor of Medicine, Division of Hematology, University of Washington School of Medicine in Seattle, biopsied multiple regions of the patient's tumor to perform whole-exome sequencing, RNA-sequencing, and deep sequencing of a panel of cancer associated genes. Data from these initial biopsies and from repeated samplings throughout the patient's disease course were shared on the cloud and accessed by researchers at different institutions with the goal of trying to find treatments that might help the patient.

"On a molecular level, every cancer is unique," said Dr. Blau, a UW Medicine researcher. "By breaking down institutional barriers, this collaborative study brings a 'no-holds-barred' effort to trying to help an individual cancer patient using tools that virtually unite experts from around the world."

According to Dr. Blau, the team found a high level of heterogeneity within the patient's tumor both at study entry and over the course of her disease. Researchers across a wide range of scientific disciplines and geographic locations weighed in, generating hypotheses regarding treatments to which the patient's tumor was predicted to respond.

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Over the course of the patient's illness two hypotheses were generated. The first arose after surveying experts in Seattle; Boston; Portland, Oregon; Lawrence, Kansas; Taiwan; and Germany, and predicted that a U.S. Food and Drug Administration (FDA) approved drug used in certain forms of lung cancer might be effective. However, the drug costs nearly $10,000 per month, and since it is not approved for breast cancer, it would not be paid for by the patient's insurance company. With assistance from the research team the patient's doctor was able to obtain crizotinib from the manufacturer without cost; however, the prediction proved wrong, as the tumor did not respond. A second prediction emerged from the ad hoc development of a high throughput screen that tested the patient's circulating tumor cells against a panel of 160 drugs. Two inhibitors of a molecular target known as Bcl-2 were predicted to be effective, but researchers were unable to obtain either drug from the pharmaceutical manufacturers, even though these same drugs were being tested in clinical trials for other cancers. The patient died shortly thereafter.

"This case highlights the complexity involved and the investment required for implementing true precision medicine. It also underscores some of the challenges faced in bringing molecular medicine to the bedside," said Margaret A. Tempero, MD, Editor-in-Chief, *JNCCN*. "As the practice of interrogating patient tumor samples for 'actionable' mutations grows, we have to simultaneously build principles for aligning this with evidence-based medicine in order to understand when to test, how to interpret, and most importantly, whom to treat."

To date, 12 patients have enrolled in the University of Washington Center for Cancer Innovation study, which began in October 2013.

"The ITOMIC studies are about learning. While we pull out all stops to try to help our patients, we receive far more from our patients than we are able to give. The patients who enroll in this study, as exemplified by the patient described in this initial report, are true heroes. They are hugely motivated by the knowledge that their experience with cancer might help future generations of patients," said Dr. Blau.

To access the *JNCCN* article, visit JNCCN.org. Full access to the article is available until February 23, 2016.

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About *JNCCN – Journal of the National Comprehensive Cancer Network*
More than 23,000 oncologists and other cancer care professionals across the United States read *JNCCN–Journal of the National Comprehensive Cancer Network*. This peer-reviewed, indexed medical journal provides the latest information about best clinical practices, health services research, and translational medicine. *JNCCN* features updates on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), review articles elaborating on guidelines recommendations, health services research, and case reports highlighting molecular insights in patient care. *JNCCN* is published by Harborside Press. Visit JNCCN.org.

About the National Comprehensive Cancer Network
The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 26 of the world's leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better

lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers.

The NCCN Member Institutions are: Fred & Pamela Buffett Cancer Center, Omaha, NE; Case Comprehensive Cancer Center/University Hospitals Seidman Cancer Center and Cleveland Clinic Taussig Cancer Institute, Cleveland, OH; City of Hope Comprehensive Cancer Center, Los Angeles, CA; Dana-Farber/Brigham and Women's Cancer Center | Massachusetts General Hospital Cancer Center, Boston, MA; Duke Cancer Institute, Durham, NC; Fox Chase Cancer Center, Philadelphia, PA; Huntsman Cancer Institute at the University of Utah, Salt Lake City, UT; Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance, Seattle, WA; The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL; Mayo Clinic Cancer Center, Phoenix/Scottsdale, AZ, Jacksonville, FL, and Rochester, MN; Memorial Sloan Kettering Cancer Center, New York, NY; Moffitt Cancer Center, Tampa, FL; The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute, Columbus, OH; Roswell Park Cancer Institute, Buffalo, NY; Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, St. Louis, MO; St. Jude Children's Research Hospital/The University of Tennessee Health Science Center, Memphis, TN; Stanford Cancer Institute, Stanford, CA; University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, AL; UC San Diego Moores Cancer Center, La Jolla, CA; UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; University of Colorado Cancer Center, Aurora, CO; University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; The University of Texas MD Anderson Cancer Center, Houston, TX; Vanderbilt-Ingram Cancer Center, Nashville, TN; and Yale Cancer Center/Smilow Cancer Hospital, New Haven, CT.

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