interferon-mediated signaling,” Gajewski observes. “Overall, though, it’s important to consider combination immunotherapy early in the disease course. Eliminating the majority of tumor cells quickly, before extensive genetic variants emerge, may prevent secondary resistance from ever happening.”

NIH Prepares to Launch Precision Medicine Study

The NIH recently awarded $55 million to several institutions to launch its Precision Medicine Initiative Cohort Program (PMI-CP), which aims to enroll at least 1 million Americans by 2020 in a long-term study starting this fall. The PMI-CP will collect genetic information on participants along with their answers to a variety of questions about their lifestyle, behavior, and environment. They will also be asked about their health history, to contribute blood and urine samples for analysis, and to grant access to clinical data stored in their electronic health records.

The project has far-reaching implications for studying cancer and other diseases, says Joni Rutter, PhD, director of the Division of Programs and Strategic Implementation for the PMI-CP. “The comprehensiveness of the program and variety of information to be collected are unmatched,” she says. “It will allow scientists to identify new ways that these factors may be associated with one another and how they might impact diseases like cancer.”

With the PMI-CP, “we aim to achieve quadruple diversity—of people, health conditions, geographic areas, and data types—to build a rich resource for future studies,” adds Eric Dishman, PhD, PMI-CP director.

A unique feature of the project is allowing researchers and the public to access and view deidentified data via a secure website, as opposed to downloading files, says Rutter. Once approved for access, users will be able to identify and analyze the data pertaining to their research questions.

The project will facilitate cooperation among cancer researchers, says Roy Herbst, MD, PhD, chief of medical oncology at Yale Comprehensive Cancer Center in New Haven, CT. “We’re not finding many new genes through individual sequencing studies,” he says.

“Some new centers will make it easier to collaborate and combine data with other research centers, which is especially important for rare cancers.”

In May, the NIH awarded Rochester, MN–based Mayo Clinic $142 million over 5 years to create a biobank to collect, store, analyze, and distribute biospecimens. The latest funds will support development of three additional centers and/or partnerships:

- The Data and Research Support Center will organize and store data-sets. It will also provide research support and analytic tools to researchers and the public. (Awarded to Vanderbilt University Medical Center in Nashville, TN, in collaboration with the Broad Institute in Cambridge, MA, and Verily Life Sciences in Mountain View, CA.)

- The Participant Technologies Center will support direct enrollment of participants and develop mobile applications to collect data from and communicate with them. (Awarded to Scripps Research Institute in San Diego, CA, and Vibrent Health in Fairfax, VA.)

- An initial set of healthcare provider organizations will assist with enrollment. It includes four regional medical centers and their collaborators (Columbia University Medical Center in New York, NY; Northwestern University in Chicago, IL; the University of Arizona in Tucson; and the University of Pittsburgh, PA), six community health centers, and Veterans Administration medical centers. —Janet Colwell

Greenebaum, Stanford Earn Comprehensive Status

The NCI has granted Comprehensive Cancer Center status to the University of Maryland’s Greenebaum Cancer Center in Baltimore and to the Stanford Cancer Institute (SCI) in Palo Alto, CA. They join 45 other centers that have earned the agency’s highest distinction—recognition of their leadership in research, education, and clinical care.

Currently, 69 institutions with strong basic and clinical research programs have been named NCI-Designated Cancer Centers. Comprehensive status requires additional breadth and depth: Institutions should not only bridge their basic and clinical research, but also demonstrate the ability to connect these programs to their local populations. Greenebaum became an NCI-designated center in 2008 and subsequently expanded its activities—particularly in population science and clinical trial recruitment—to qualify for the higher ranking, says Director Kevin Cullen, MD.

“We have focused heavily on improving health disparities in cancer research and access to treatment, especially among African-Americans,” Cullen says. “Our population-science program is a big part of that and was a key component in moving us toward this designation.”

Nearly 33% of participants in Greenebaum’s clinical trials are African-American, compared with about 2% nationally—a testament to strong community ties, Cullen says. The Baltimore City Cancer Program offers breast, cervical, and colon cancer screening to uninsured and underinsured area residents. Those diagnosed with cancer receive information about clinical trials and enrollment assistance.

In addition, Greenebaum has built a network of partnerships with health centers and physicians across the state aimed at increasing access to trials in nonurban areas, which also helps facilitate population-based research, says Edward Sausville, MD, PhD, associate director for clinical research.

“Eighty percent of our referrals come from the city of Baltimore and 10 adjacent Maryland counties,” Sausville says. “Comprehensive designation will certainly be a basis for continuing to build alliances in those areas in order to ensure that all citizens of Maryland have the opportunity to consider clinical trial participation.”

Always strong in basic science, SCI was named an NCI-Designated Cancer Center in 2007. Garnering comprehensive status “was a matter of building our clinical research enterprise, recruiting physicians who are also superb researchers, and building our population-science program,” says Director Beverly Mitchell, MD.

The Stanford Cancer Initiative, launched in 2013, boosted the institute’s recent NCI review. The initiative “applies rigorous research analysis to every aspect of patient care in order to identify which modalities improve the care experience,” Mitchell explains. For
instance, patients at SCI are assigned a professionally trained multidisciplinary care coordinator to help them navigate the many decisions related to cancer treatment, which are otherwise complex and often overwhelming.

Patients at SCI can also “detail their concerns right into their electronic medical records prior to their appointments, so physicians can review them in advance and be prepared to address them,” Mitchell says. “It's another tangible way to involve people in their own care.”

Comprehensive status, and the increased funding it can attract, will enable SCI to continue developing its programs in early-phase clinical research, immunotherapy, and genomics and precision medicine. In addition, “Stanford has a history of innovation in data management and analysis,” Mitchell adds, so it is well positioned to help achieve an important goal of the National Cancer Moonshot—finding ways to merge myriad types of medical data. –Janet Colwell and Alissa Poh

ADCs Show Promise in Leukemias

Two investigational antibody–drug conjugates (ADC) have shown positive results against acute lymphocytic leukemia (ALL) and acute myeloid leuke- mias (AML), according to study results presented during the 21st Congress of the European Hematology Association in Copenhagen, Denmark, in June.

Patients with relapsed or refractory ALL typically have to achieve a complete remission before receiving an allogeneic stem-cell transplant, the only potential cure. Intensive chemotherapy usually doesn’t produce complete remissions, however, and phase II investigations have suggested that inotuzumab ozogamicin (Pfizer), which targets CD22 on B cells, might perform better. Hagop Kantarjian, MD, of The University of Texas MD Anderson Cancer Center in Houston, presented data—simultaneously published in The New England Journal of Medicine—from a randomized phase III study of this ADC (N Engl J Med 2016 June 12 [Epub ahead of print]).

Kantarjian and colleagues assigned 326 patients with relapsed or refractory ALL to receive either inotuzumab ozogamicin or a standard chemotherapy regimen. In an analysis of the first 218 patients, 80.7% of individuals in the ADC arm had a complete remission (CR) with full or incomplete hematologic recovery, the latter meaning their blood counts didn’t return to normal. In contrast, 29.4% of patients who received chemotherapy achieved these milestones. As a result, 41% of patients who received inotuzumab ozogamicin were able to have a stem cell transplant, versus 11% of those who received chemotherapy.

For the entire group of 326 patients, the median progression-free survival was 5 months for the inotuzumab ozogamicin arm and 1.8 months for the standard chemotherapy arm.

Side effects of the ADC included blockage of small veins in the liver, a potentially fatal complication.

Because many patients with AML are older, they can’t tolerate aggressive chemother-apy and instead receive hypomethylating agents, which are less likely to produce remissions. Amir Fathi, MD, of Harvard Medical School in Boston, MA, reported data from a phase I study of vadastuximab talirine (Seattle Genetics) in 53 patients who received the CD33-targeting ADC in combination with the hypomethylating agents azacitidine or decitabine as first-line therapy.

Among 49 evaluable patients, 41% had CRs and 30% had CRs with incomplete hematologic recovery. The median relapse-free survival was 7.7 months. Adverse events were mainly hematologic, with 45% of patients developing febrile neutropenia, for instance, and 53% developing thrombocytopenia.

Overall, vadastuximab talirine plus a hypomethylating agent “is a highly promising combination that requires further study,” Fathi says.

For Mark Litowitz, MD, of the Mayo Clinic in Rochester, MN, who wasn’t involved with either study, “it’s very exciting to see the complete remission rate is 80%” in the ALL trial. Vadastuximab talirine plus hypomethylating agents also has potential against AML, he says. “I think this is impressive early data.” –Mitch Leslie

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CANCER DISCOVERY

Greenebaum, Stanford Earn Comprehensive Status


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