

Genomic Data Commons Expands

The recently launched National Institutes of Health (NIH) Genomic Data Commons (GDC) will expand its resources after the June 29 signing of a data sharing agreement between the National Cancer Institute (NCI) and Foundation Medicine, Inc. (FMI), a molecular information company that performs genetic profiling. NCI's GDC is a unified data system that promotes the sharing of genomic and clinical data among researchers and is a core component of the Cancer Moonshot and President Obama's Precision Medicine Initiative. The expanded number of cancer cases in the GDC will assist researchers in identifying genomic changes responsible for growth of tumors in individual patients and identify which drugs may block the effects of these mutations.

The GDC was launched in early June and initially included genomic data from several large-scale NCI programs, such as The Cancer Genome Atlas (TCGA) and its pediatric equivalent, Therapeutically Applicable Research to Generate Effective Treatments (TARGET). Together, TCGA and TARGET represent some of the world's largest and most comprehensive cancer genomic datasets, with information generated from about 14,500 patients. The new data come from 18,000 adult patients with a diverse range of cancers who underwent genomic profiling using FoundationOne, FMI's proprietary comprehensive genomic profiling assay. FMI developed FoundationOne as a commercially available test that uses advanced sequencing technology for routine analysis of cancer specimens. All information in the databases has been anonymized.

"This major infusion of data in the GDC will greatly enhance our ability to use this tool to explore genetic abnormalities in cancer," said Douglas Lowy, MD, NCI acting director. "Through TCGA and TARGET, we had already

established a strong cancer genomic foundation for the GDC at its launch, but with the addition of the genomic data from FMI, we believe that the GDC will be an even more useful resource for researchers worldwide to help us unravel the complexities of many forms of cancer."

The genomics information contributed by FMI can be used by authorized researchers after approval by an NIH Data Access Committee. Requesters must affirm that their use of the data is solely for biomedical research purposes and for publication or presentation in scientific journals or at research meetings.

National Institutes of Health

NIH Awards Funds for Million-Person PMI

The National Institutes of Health (NIH) on July 6 announced \$55 million in awards in fiscal year 2016 to build the foundational partnerships and infrastructure needed to launch the Cohort Program of President Obama's Precision Medicine Initiative (PMI). The PMI Cohort Program is a longitudinal research effort that aims to engage 1 million or more U.S. participants to improve the ability to prevent and treat disease based on individual differences in lifestyle, environment, and genetics. The immediate 2016 awards, part of a much larger funding effort through the U.S. Congress, will support a Data and Research Support Center, Participant Technologies Center, and a network of health care provider organizations (HPOs). An award to Mayo Clinic (Rochester, MN) to build the supporting biobank was announced earlier this year. All awards are for 5 y, pending progress reviews and availability of funds. NIH intends to start initial enrollment in the PMI Cohort Program in 2016, with target completion by 2020.

PMI volunteers will be asked to contribute a wide range of health, environment, and lifestyle information. They will also be invited to answer questions about their health history and

status, share genomic and other biological information through simple blood and urine tests, and grant access to their clinical data from electronic health records. In addition, mobile health devices and apps will provide lifestyle data and environmental exposures in real time. As partners in the research, participants will have ongoing input into study design and implementation, as well as access to a wide range of their own and aggregated study results.

"This range of information at the scale of 1 million people from all walks of life will be an unprecedented resource for researchers working to understand all of the factors that influence health and disease," said NIH Director Francis S. Collins, MD, PhD. "Over time, data provided by participants will help us answer important health questions, such as why some people with elevated genetic and environmental risk factors for disease still manage to maintain good health, and how people suffering from a chronic illness can maintain the highest possible quality of life. The more we understand about individual differences, the better able we will be to effectively prevent and treat illness."

The new awards are designed to continue to build the large infrastructure of public and private partnerships necessary to power research on this unprecedented scale. "This is an incredibly complex study requiring new kinds of strategic and operational partnerships—this can't be business as usual," said Kathy L. Hudson, PhD, NIH Deputy Director for Science, Outreach, and Policy who helped coordinate the PMI Cohort Program. "We are excited to break new ground in engaging people in research and building a study of this scale and scope." Among the key components and organizations of the cohort will be the: (1) Data and Research Support Center, awarded to Vanderbilt University Medical Center (Nashville, TN), in partnership with the Broad Institute (Cambridge, MA) and Verily Life Sciences (Mountain View, CA). This center will

acquire, organize, and provide secure access to the project's datasets, as well as offer research support for data and analysis tools; (2) Participant Technologies Center, awarded to the Scripps Research Institute (San Diego, CA) and Vibrent Health (Fairfax, VA), which will support direct enrollment in the cohort (other participants will be enrolled through HPOs), as well as develop, test, maintain, and upgrade PMI Cohort Program mobile applications; and (3) HPOs, which will form a network of regional, national, and community health centers, as well as medical centers operated by the U.S. Department of Veterans Affairs. Four regional medical centers identified in this round of funding are Columbia University Medical Center (New York, NY), Northwestern University (Chicago, IL), University of Arizona (Tucson), and University of Pittsburgh (PA). Others are expected to be announced in the coming months, along with subawards to other organizations that will extend the geographic reach of the HPO network; and (4) Biobank, awarded to Mayo Clinic, which will support collection, analysis, storage, and distribution for research use of biospecimens.

Detailed information about the NIH PMI Cohort Program is available at <https://www.nih.gov/precision-medicine-initiative-cohort-program>.

National Institutes of Health

Mapping the Human Cerebral Cortex

In a study e-published on July 20 ahead of print in *Nature*, Glasser and colleagues from Washington University Medical School (St. Louis, MO) and from the John Radcliffe Hospital at the University of Oxford (UK), the University of Minnesota (Minneapolis), and Radboud University (Nijmegen, The Netherlands) unveiled new brain analysis software and resulting mapping of 180 distinct areas in the cortex, more than twice the previously identified number. The authors used multimodal MR images from the National Institutes of Health (NIH) Human Connectome Project (HCP) and a semiautomated neuroanatomic approach to identify these

areas on the basis of boundaries formed by sharp changes in cortical architecture, function, connectivity, and/or topography. The HCP data came from 210 healthy young adults. This "parcellation" process characterized 97 new areas and 83 areas that had been previously reported using post-mortem microscopy or other highly specialized and study-specific approaches. A machine-learning classifier was used to recognize what the authors called the multimodal "fingerprint" of each cortical area. This process was not only validated in new subjects but was able to correctly identify areas of atypical parcellation. The automated "areal classifier" and related tools are being shared with the research community through <http://www.humanconnectome.org/>, and the extensively analyzed data underlying each of the project's published figures can be accessed via an NIH-funded database at <https://balsa.wustl.edu/>. The authors concluded that this technique and data will "enable substantially improved neuroanatomical precision for studies of the structural and functional organization of human cerebral cortex and its variation across individuals and in development, aging, and disease." Lead author Glasser added "The ability to discriminate individual differences in the location, size, and topology of cortical areas from differences in their activity or connectivity should facilitate understanding of how each property is related to behavior and genetic underpinnings."

Nature

2015–2025 U.S. Health Expenditure Data

In a study released on July 13, the Centers for Medicare & Medicaid Services (CMS) projected that total health care spending in the United States will grow at an average rate of 5.8% annually over the 2015–2025 period. At this rate, projected national health spending growth will remain lower than the average from 1988 to 2008 (almost 8%). National health expenditures are estimated to have reached \$3.2 trillion in 2015. Health spending is projected to grow 1.3%

faster per year than the Gross Domestic Product (GDP) over the next decade. As a result, the health share of GDP is expected to rise from 17.5% in 2014 to 20.1% by 2025.

Other findings from the report:

- In 2015, medical price inflation slowed to 0.8%, down from 1.4% in 2014. Hospital prices increased by 0.9%, whereas price growth in physician services fell by 1.1%.
- The share of health expenses that Americans pay out of pocket is projected to decline from 10.9% in 2014 to 9.9% in 2025.
- The insured share of the population is expected to continue to rise from 89% in 2014 to 92% by 2025.
- Private health insurance expenditures are estimated to have increased by 5.1% from 2014 to 2015, reaching \$1.0 trillion. Average annual growth through 2025 is expected to be similar (5.4%).
- Medicaid spending growth is slowing significantly in 2016, to 5.3%, which the report attributes to slower enrollment growth and stronger utilization management.
- In 2015, Medicare expenditures are expected to have been \$647.3 billion, a 4.6% increase from 2014, driven partly by increased enrollment.
- Prescription drug spending is projected to grow at an average of 6.7% per year for 2016–2025. This follows growth of 12.2% in 2014 and 8.1% in 2015, when spending growth was influenced by the introduction of costly new specialty drugs.

The full report is available at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>.

Centers for Medicare & Medicaid Services

International Cancer Cell Model Initiative

An international project was announced on July 11 to develop a large, globally accessible bank of new cancer cell culture models for the research community. The National Cancer Institute (NCI), part of the National Institutes of Health (Bethesda, MD); Cancer Research UK (London); the Wellcome Trust Sanger Institute (Cambridge, UK); and the Hubrecht Organoid Technology foundation (Utrecht, The Netherlands) will develop the Human Cancer Models Initiative (HCMI), which will bring together international expertise to make an estimated 1,000 cancer cell models.

Louis Staudt, MD, PhD, director of NCI's Center for Cancer Genomics, said, "As part of NCI's Precision Medicine Initiative in Oncology, this new project is timed perfectly to take advantage of the latest cell culture and genomic sequencing techniques to create models that are representative of patient tumors and are annotated with genomic and clinical information. This effort is a first step toward learning how to use these tools to design individualized treatments."

Genetic sequencing data from the tumors and derived models will be available to researchers, along with clinical data about the patients and their tumors. All information related to the models will be shared in a way that protects patient privacy. Scientists will make the models using tissue from patients with different types of cancer, potentially including rare and children's cancers, which are often underrepresented or not available at all in existing cell line collections. The new models will have the potential to reflect the biology of tumors more accurately and better represent the overall cancer patient population.

The HCMI collaborators hope to leverage the advantages of pooled efforts to accelerate development of new models and to make research more efficient by avoiding unnecessary duplication. Mathew Garnett, PhD, group leader at the Wellcome Trust Sanger Institute, said, "New cancer model der-

ivation technologies are allowing us to generate even more and improved cancer models for research. A concerted and coordinated effort to make new models will accelerate this process, while also allowing for rapid learning, protocol sharing, and standardized culturing methods."

National Cancer Institute

HHS Oncology Care Model Selects Physician Groups

The U.S. Department of Health and Human Services (HHS) announced on June 29 that it had selected nearly 200 physician group practices and 17 health insurance companies to participate in a care delivery model that supports and encourages higher quality and more coordinated cancer care. The Medicare arm of the Oncology Care Model includes >3,200 oncologists and will cover ~155,000 Medicare beneficiaries nationwide. The Oncology Care Model began on July 1 and will run through 2021. "The Oncology Care Model encourages greater collaboration and information sharing so that cancer patients get the care they need," said HHS Secretary Sylvia M. Burwell. "This patient-centered care model furthers the goal of the Vice President's Cancer Moonshot to improve coordination, care, and outcomes while spending dollars more wisely."

The Oncology Care Model is one of the first Centers for Medicare & Medicaid Services (CMS) physician-led specialty care models. As part of this model, physician practices may receive performance-based payments for episodes of care surrounding chemotherapy administration to Medicare patients with cancer, as well as a monthly care management payment for each beneficiary. The 2-sided risk track of this model will be an Advanced Alternative Payment Model under the newly proposed Quality Payment Program, implementing provisions from the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015. Practices participating in the 5-y Oncology Care Model will provide treatment following nationally recognized clinical guide-

lines for beneficiaries undergoing chemotherapy, with an emphasis on person-centered care. They will provide enhanced services to beneficiaries who are in the Oncology Care Model to help them receive timely, coordinated treatment. These services may include: (1) coordinating appointments with providers within and outside the oncology practice to ensure timely delivery of diagnostic and treatment services; (2) providing 24/7 access to care when needed; (3) arranging for diagnostic scans and follow-up with other members of the medical team, such as surgeons, radiation oncologists, and other specialists, that support the beneficiary through their cancer treatment; (4) making sure that data from scans, blood test results, and other tests is received in advance of patient appointments so that patients do not need to schedule additional visits; and (5) providing access to additional patient resources, such as emotional support groups, pain management services, and clinical trials.

"CMS is thrilled with how many physician groups chose to be a part of the Oncology Care Model," said Patrick Conway, MD, CMS principal deputy administrator and chief medical officer. "We have nearly doubled the number of participants that we anticipated. It's clear that oncology physicians recognize the importance of this new performance-based, episode-based payment approach to cancer care. As a practicing physician and son of a Medicare beneficiary who died from cancer, I know the importance of well-coordinated care focused on the patient's needs."

More information about the model and participants is available at: <http://innovation.cms.gov/initiatives/Oncology-Care/>.

U.S. Department of Health and Human Services

NCI Launches African-Ancestry Breast Cancer Genetics Study

The National Cancer Institute (NCI) announced on July 6 the start of the largest study to date to investigate the ways in which genetic and biologic

factors contribute to breast cancer risk among women of African ancestry. This collaborative research project will identify genetic factors that may underlie breast cancer disparities. The Breast Cancer Genetic Study in African-Ancestry Populations initiative does not involve new patient enrollment but builds on years of research cooperation among investigators who are part of the African-American Breast Cancer Consortium, the African-American Breast Cancer Epidemiology and Risk Consortium, and the NCI Cohort Consortium. These investigators, who come from many different institutions, will share biospecimens, data, and resources from 18 previous studies, resulting in a study population of 20,000 women with breast cancer.

“This effort is about making sure that all Americans—no matter their background—reap the same benefits from the promising advances of precision medicine. The exciting new approaches to cancer prevention, diagnosis, and treatment ring hollow unless we can effectively narrow the gap of cancer disparities, and this new

research initiative will help us do that,” said Douglas R. Lowy, MD, acting director of NCI. “I’m hopeful about where this new research can take us, not only in addressing the unique breast cancer profiles of African-American women, but also in learning more about the origin of cancer disparities.”

Black women are more likely than white women to die from breast cancer and are more likely to be diagnosed with aggressive subtypes of the disease. The rate of triple-negative breast cancer is twice as high in black women. As part of the study, the genomes of 20,000 black women with breast cancer will be compared with those of 20,000 black women who do not have breast cancer. The genomes will also be compared to those of white women who have breast cancer. In addition, researchers will examine gene expression in breast cancer tumor samples to investigate the genetic pathways involved in tumor development.

The project was awarded as a \$12 million grant shared by Wei Zheng, MD, PhD, of Vanderbilt University (Nashville, TN); Christopher Haiman, ScD, of the University of Southern

California, Los Angeles; and Julie Palmer, ScD, of Boston University (MA). In addition, minority scientists from various institutions are playing important roles in this study. The Southern Community Cohort Study, for example, a contributing study for this grant, represents a 15-y partnership between Vanderbilt and historically black Meharry Medical College (Nashville, TN). The grant will also provide training opportunities for scientists from minority populations.

“This \$12 million grant—in combination with previous investments—should help advance our understanding of the social and biological causes that lead to disparities in cancer among underserved populations,” said Robert Croyle, PhD, director of NCI’s Division of Cancer Control and Population Sciences, which is administering the grant. “A better understanding of the genetic contributions to differences in breast cancer diagnoses and outcomes among African-Americans may lead to better treatments and better approaches to cancer prevention.”

National Cancer Institute