researchers to share their results (available at http://iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx). They recommend specific strategies aimed at expanding access for other researchers and the public while protecting patient privacy and creating safeguards for sponsors' intellectual property. The IOM, the health arm of the National Academy of Sciences, assembled a committee of 14 experts in medical research and health policy to compile the report.

"Sharing allows others to reproduce published findings and carry out secondary analyses—and maximizes the contributions of participants and the effort and funding for trials," said committee chair Bernard Lo, MD, president of the Greenwall Foundation in New York, NY, and former director of the Program in Medical Ethics at the University of California, San Francisco, at a press conference. "We think that the question today is not whether you share clinical trial data, but instead, what types of data do you share, when do share it, and how do you share it?"

Those details should be included in a data-sharing plan submitted when registering a clinical trial, the IOM report recommends. Upon study completion, summary results should be made available within 12 months, and complete data within 6 months of publication or no later than 18 months after the close of the trial. Full data on products submitted for regulatory approval should be published 30 days after approval, or within 18 months if the application for approval is abandoned.

To encourage investigators to make data available, various stakeholders could require data sharing as part of their agreements with researchers. For example, funders and sponsors could require it as a condition of funding, and medical journals could ask for a data-sharing plan when a manuscript is submitted for publication.

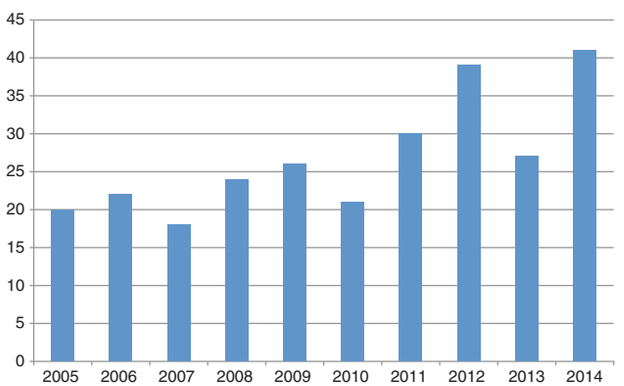
Investigators should also detail who should have access to the data and when, the committee recommends.

The committee notes several significant obstacles to achieving its recommendations, including developing compatible technology platforms to store and manage information. Success also hinges on establishing a sustainable funding model.

"Currently, a small subset of sponsors and funders of trials bear the full cost of clinical trial data sharing," said Lo. "That's not a sustainable or fair model. We recommend that those who benefit from sharing clinical trial data should also bear a fair share of the cost." ■

BY THE NUMBERS

Drugs Approved by the FDA, 2005–2014



In 2014, the FDA approved 41 novel new drugs, the most since the agency approved 53 in 1996, and ahead of its yearly average of 25 from 2005 through 2013. Nine of the 41 new drugs were approved for the treatment of cancer, and four of those were considered to be first-in-class agents: blinatumomab (Blincyto; Amgen), pembrolizumab (Keytruda; Merck), olaparib (Lynparza; AstraZeneca), and idelalisib (Zydelig; Gilead).

FDA

NOTED

- Cambridge, MA–based **Foundation Medicine announced that it will "enter into a broad strategic collaboration" with Roche,** giving the Swiss pharmaceutical giant an ownership stake in the company of up to 56%. Roche's total investment will exceed $1 billion. Foundation Medicine develops assays to determine molecular alterations in a patient's cancer and match them with targeted therapies and clinical trials.
- **Myriad Genetics of Salt Lake City, UT, is giving up efforts to prevent other companies from offering tests for *BRCA1* and *BRCA2* mutations,** bringing several lawsuits to an end. Myriad has reached settlements with LabCorp, Invitae, and Pathway Genomics and is in talks with Ambry, Quest Diagnostics, GeneDx, and Counsyl.
- **The American Lung Association released its 13th annual "State of Tobacco Control" report,** which concluded that little happened on the state or federal levels in 2014 to reduce tobacco use (see www.stateoftobaccocontrol.org). No state passed a comprehensive smoke-free law or significantly increased tobacco taxes, and no state earned an "A" grade for providing access to quit-smoking treatments.
- A published analysis found that **many women with breast cancer lack knowledge of their disease's characteristics, including tumor stage, grade, and receptor status** (Cancer 2015 Jan 26 [Epub ahead of print]). Only 20% to 58% of 500 women surveyed reported the characteristics correctly.
- **The American Society of Clinical Oncology (ASCO) for the first time named its Advance of the Year: the transformation of treatment for adults with chronic lymphocytic leukemia.** The Advance of the Year was part of its *Clinical Cancer Advances 2015: ASCO's Annual Report on Progress Against Cancer* (see www.cancerprogress.net/cca).
- **Human Longevity, Inc. (HLI) announced a multiyear agreement with Genentech to conduct whole-genome sequencing on tens of thousands of deidentified tissue samples.** Based in La Jolla, CA, HLI aims to build the world's most comprehensive, integrated human genotype and phenotype database.

For more news on cancer research, visit *Cancer Discovery* online at http://CDnews.aacrjournals.org.