Project Data Sphere to Make Cancer Clinical Trial Data Publicly Available

By Karyn Hede

In the mid-1980s, the emerging semiconductor industry had a problem. Many competing standards and manufacturing practices were a costly drag on progress. U.S. chipmakers realized that solving common problems and developing industry-wide standards would benefit everyone. They created Sematech, a joint venture that helped solve thorny technical challenges and yielded industry-wide efficiencies that no company could have accomplished alone. By the mid-1990s, the group globalized and today represents more than half the worldwide semiconductor manufacturers.

Call 2013 the year that large pharmaceutical companies began to share in earnest. It started in 2012 when drug makers joined forces to create Transcelerate Biopharma, an independent entity that many of the world’s largest pharmaceutical companies supported, including Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson and Johnson, Pfizer, Roche’s Genentech division, and Sanofi. The new organization will cooperate in precompetitive intelligence, such as creating standardized clinical trial formats, to reduce the cost of conducting human trials, the most costly aspect of bringing a new medicine to market.

Realizing that data sharing was changing, Charles Hugh-Jones, vice president of medical affairs at Sanofi Oncology, proposed sharing comparator-arm data gleaned from completed cancer clinical trials. He already had the attention of pharmaceutical company CEOs through his involvement in Transcelerate, but what really got the process moving were connections he made with tech company executives involved in the CEO Roundtable on Cancer, a nonprofit organization that George H. W. Bush started to address issues facing cancer research. Hugh-Jones spent several months hashing through technical and proprietary issues that have hampered efforts to share data. He developed Project Data Sphere, which within weeks will go live with cancer trial data from an expected five to seven pharmaceutical companies.

The goal, according to Hugh-Jones, is to have Project Data Sphere grow into an interactive platform where investigators can learn from the collective successes and failures of previous trials with the help of powerful analytic tools, which the statistical software giant SAS Institute offered to the project free.

“The reality is that we have to do better,” said Hugh-Jones. “You’ve got to get beyond a 5% success rate in bringing new oncology drugs to market. But it’s an economic issue as well. People are realizing there just isn’t the money to keep pumping into trials either at a commercial or at a governmental level.”

To kick-start the effort, Hugh-Jones persuaded his Sanofi colleagues to contribute the comparator-arm data from three completed trials: the phase III trial for cabazitaxel, now approved for metastatic prostate cancer; the phase III trial of iniparib, a PARP inhibitor that failed its trial for treatment of breast cancer; and the phase III TAX 327 paclitaxel trial for hormone-refractory prostate cancer, as well as potentially results of another trial in the prostate cancer arena. To address privacy concerns, Sanofi will strip identifiers such as name, address, and date of birth from the data sets, Hugh-Jones said.

“We’re not asking them for their crown jewels immediately, but we are asking people to get used to the process of de-identification,” said Hugh-Jones. “Multiple companies are producing data.”

He would not release company names but said that many participate in Transcelerate. Their main motivation for participation seems to be the potential to save money through conducting more cost-effective trials. But Hugh-Jones sees a larger purpose in attracting technology savvy to identify meaningful patterns in the data that others have missed or that can’t be seen without the multiplicative power of big data. “What Project DataSphere does is allow you to link data, skills, technology and ideas, all of which may come from disparate sources,” he said.

This is not the first attempt to make cancer research data accessible online. The National Cancer Institute’s now-defunct CaBig project spent more than $350 million to build a shared computing platform and open-source software tools to standardize data exchange. But user uptake was slow and the project was deemed unsustainable. Hugh-Jones hopes to avoid issues of user acceptance by starting simple.

The Synapse technology platform sponsored by the nonprofit Sage Bionetworks, which already serves the Cancer Genomics Hub, a large-scale data repository and user portal for NCI, will host Project DataSphere.

Kyle Ellrott, a University of California, Santa Cruz, software engineer who serves as data manager for the Cancer Genome Atlas Project cross-tumor comparison project and has had experience with both Synapse and CaBig, said that the Synapse
Cancer Research: Evaluating the Sequester’s Impact

By Charlie Schmidt

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causing nearly 80,000 deaths per year, cancer remains the nation’s second-leading killer after heart disease. Even so, federal support for the National Institutes of Health, which supports most U.S. cancer research, has shrunk by 20% over the last decade when adjusted for inflation. It was in that context that the federal government, which could not agree on deficit-reduction legislation earlier this year, allowed a worst-case alternative to go into effect March 1. Known as budget sequestration, or the sequester, it unleashed $85 billion in federal spending cuts that now shave 5.1%, or another $1.6 billion, off the 2013 NIH budget. That translates to a $250 million loss to the National Cancer Institute, which has already grappled with stagnant budgets averaging $4.9 billion for the last 6 years. The sequester also cuts other federal spending on cancer research, including drug approvals at the U.S. Food and Drug Administration (FDA), which will lose $209 million.

Now scientists face the demoralizing task of administering those cuts, which are expected to affect basic science in cancer and clinical trials focused on public health more than commercial drug development. Reactions to the sequester vary: To some, it’s a severe financial loss, whereas others say that the greater effect is the added uncertainty for research planning.

Specifics about how the cuts will be implemented remain uncertain. Some details have emerged, each emblematic of the troubled economics of cancer research today. “It’s a gloomy situation,” said Sandra Swain, M.D., president of the American Society of Clinical Oncology. “Centers that depend more on philanthropy will be OK, but that won’t be true for scientists who depend on public grant funding.”

Agency Consequences

As an epicenter for cancer research, NCI is particularly vulnerable. NCI officials were reluctant to comment about the sequester, referring only to a March 15 statement from director Harold Varmus, M.D., who said that “modest but significant cuts” would be made to virtually all extra- and intramural programs, including noncompetitive grant renewals, cancer centers, and research contracts. Varmus said that NCI did not anticipate more drastic steps, such as employee furloughs or salary reductions. But as in other years that begin with congressional and FDA staff, Grossman said that “modest but significant cuts” would be made to virtually all extra- and intramural programs, including noncompetitive grant renewals, cancer centers, and research contracts. Varmus said that NCI did not anticipate more drastic steps, such as employee furloughs or salary reductions. But as in other years that begin with continuing resolutions, new and continuing grants would be paid at 90% of expected levels, he said.

FDA has not released a statement about the sequester, and officials would not comment. According to Steven Grossman, who directs the Washington, D.C.-based Alliance for a Stronger FDA—a group that lobbies on behalf of the agency’s stakeholders—FDAs short-staffed drug approval offices will lose another $47 million. On the basis of his discussions with congressional and FDA staff, Grossman said that the Center for Drug Evaluation and Research will focus its priorities on drugs closest to approval. “It doesn’t appear that the number of approvals scheduled for this year will be affected,” he said. “But pre-Investigational New Drug meetings will be delayed, as will those for phase I and II trials. So the sequester will definitely slow the approval process down in the long run.”

Extramural Programs Lose Out

The sequester also affects cancer centers at public universities. For instance, the Ohio State University Comprehensive Cancer Center (OSUCCC) in Columbus will cut roughly 200 graduate and postdoctoral positions, according to director Michael