

NEWS

project has had a good working relationship with programmers from the start.

“If you are only looking at the website Synapse, you are missing about half of what’s available,” said Ellrott. In the background, a host of open-source software allows processing designed to standardize data from the disparate sources and allows what Ellrott, who is not involved in the DataSphere project, called an analyst-friendly data repository. But for researchers, the project

ultimately aims for simplicity and a seamless ability to work on collaborative projects, with many investigators working in tandem.

“We are keeping it simple,” said Stephen Friend, M.D., Ph.D., CEO of Sage Bionetworks. “Our approach is to let the projects grow the platform instead of making it strong and put the projects onto a platform.”

Hugh-Jones said that the technology, legal framework, de-identification

standards, and data analysis tools are all now in place awaiting the data, and the project will launch in beta on May 31, with a public launch planned later this summer.

“There’s a realization that no individual company can conquer cancer alone,” said Hugh-Jones. “We need to be doing something different, and I think everyone is realizing that.”

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Cancer Research: Evaluating the Sequester’s Impact

By Charlie Schmidt

Causing nearly 580,000 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 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—FDA’s 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

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Caligiuri, M.D. OSUCCC treats more than 6,000 patients per year and derives half its \$200 million annual budget from NCI and other NIH-based support, with the rest coming from OSU revenues, industry, and philanthropies. With its reliance on NIH, OSUCCC has had to contend with inflation-adjusted losses for years. Nevertheless, during the last decade, the center hired hundreds of new faculty with expectations of NIH grant funding. Now Caligiuri worries that funding will plunge, further burdening the center's resources, he said, and taking an emotional toll on scientists who can't get their work done.

Clinical Trials Make Do With Less

Moreover, the sequester will affect clinical trials at OSUCCC, Caligiuri said, specifically the phase I and II trials performed through contracts with NCI outside the Cooperative Groups program. "The NCI has had to put limitations on the number of cancer patients that could be accrued to clinical trials under the N01 (phase II) contract," he said. "That limit has been lowered over the last several years. I suspect this might be even more ominous if sequestration sticks." NCI officials corroborated this statement, adding that with its increasingly strained resources, the institute can cover the cost of only a limited number of recruits under its phase II contracts. Cancer centers are encouraged to boost trial enrollment as much as possible, the official said, but they should look elsewhere to cover clinical trial costs that the NCI cannot support.

Likewise, Laurence Baker, D.O., a professor at the University of Michigan Health System, said that declining funding

equates with more stringent criteria for selecting trials performed by the NCI-supported Cooperative Groups, including the Southwest Oncology Group, of which he is outgoing director. Sources for this story describe an increasingly tense atmosphere as NCI officials consider which types of trials to drop. One possibility concerns large trials in estrogen receptor-positive metastatic breast cancer. An executive summary from the NCI-sponsored Estrogen Receptor-Positive Clinical Trial Planning Meeting, for instance, referred to that vulnerability by stating that there was "no space for an additional large randomized adjuvant trial of hormonal therapy" and that the Cooperative Groups should use "smaller preoperative studies and neoadjuvant trials space to evaluate endocrine response."

A senior NCI official responded by e-mail that this summary statement "does not represent official NCI policy" on trials involving such illnesses, adding that after the meeting "a concept for a randomized

"It's a gloomy situation. Centers that depend more on philanthropy will be OK, but that won't be true for scientists who depend on public grant funding."

[phase II/III trial in estrogen receptor-positive metastatic breast cancer] was approved." Still, the overarching view among stakeholders is that NCI clinical trials are under growing pressure to streamline and

focus on studies with practice-changing potential. The sequester, Caligiuri said, merely accelerates this ongoing transition. How much



Sandra Swain, M.D.

that's overtly harmful is debatable. Though she decries the sequester's effect on cancer research, Swain nevertheless acknowledges that too many trials may have not have aimed high enough with respect to changing

treatment paradigms and that budget pressures might make cancer researchers "more thoughtful and careful about what they're doing."

Reflecting on the sequester's impact, Baker takes a broad view, emphasizing that a lot of waste occurs in cancer research. "Do I think a 5% reduction will adversely affect progress? No, I don't. What affects progress, in my opinion, is the continual budget uncertainty that makes it so difficult for us to plan."

Eric Winer, M.D., a professor at Harvard Medical School and director of the Breast Oncology Center at the Dana-Farber Cancer Institute in Boston, concurs that \$250 million represents a small portion of what the government invests in cancer research but that its loss is nonetheless misguided. "We can do a tremendous amount with that money," he said. "And now we have new targeted therapies that are ready to be explored. This is the time to step on the accelerator and really speed the pace of research, not slow it down."

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