Carpe’ Diem—Making Data Findable and Accessible to Promote Utility

National Cancer Institute sent this bulletin at 01/16/2025 09:30 AM EST

NIH NATIONAL CANCER INSTITUTE www.cancer.gov

Subscribe to the Newsletter

January 2025

Carpe’ Diem—Making Data Findable and Accessible to Promote Utility

It's a brand new year, 2025, and a time of both change moving forward and of noting the progress made to get where we are now. The nation is mourning the recent loss of an incredible icon and humanitarian in former President Jimmy Carter. He was once quoted as saying, "Tremendous progress can be made if we persevere through difficult challenges." I believe in this ideal to its core, and I can see many parallels with our experience at ODS in trying to plan NCI's approach to implementing data sharing and public access policies for research. While a great majority of our cancer community understands and supports the concept that making comprehensive cancer data available for secondary analyses drives novel innovation, improved treatments and is our basic duty to ensure a full public benefit from federally supported research, there remain multiple challenges to achieving our goals. So much of the way science and medicine has been conducted traditionally (individualized experiments or treatments, siloed systems to maintain privacy and IP, handwritten free text notes for care or research) runs somewhat counter to formatting and sharing structured information in ways that others can appropriately interpret and further utilize that information for new and impactful purposes. Although sharing data and resources is part of all science, doing so on a large scale, in consistent ways and ensuring public benefit, is a new "science" all on its own. The NCI ODS is committed to partnering with investigators, administrators and technical innovators to help facilitate solutions in navigating such challenges. One critical focus starts with making existing data and resources findable and accessible, so that it can be mined, reanalyzed and used for new purposes. It's also the way we will learn what research products and formats truly have the most impact on cancer research.

As I sit and reflect on the last year of progress within the NCI's Office of Data Sharing (ODS) and look forward to this new year with great anticipation, my thoughts go straight to the many ways we've worked to make data and resources more findable and accessible for the cancer community. Our Index of NCI Studies is a catalog-style platform designed to facilitate navigating information about key NCI studies, including available data, publications and resources of each, to ultimately promote more widespread use of these high-value research products. Additionally, ODS has partnered with the NIH OD to pilot the creation of study "collections" that enable access to data from 80% of NCI's controlled-access tier omics studies simply by selecting General Research and Health, Medical and Biomedical research uses together, with Disease Specific-Cancer collection coming soon. This reduces the number of asks from over 600 individual study requests down to 2 or 3 for the same studies collated into collections. These collections allow investigators to truly create cohorts of interest across many datasets with similar data user permissions instead of having to read about those hundreds of studies ahead of time and separately request access. There are so many ongoing activities and issues that continue to need addressing, and so NCI ODS is (finally) kicking off the new year with a monthly webinar series that is completely open to the full cancer community. We look forward to partnering with each of you to highlight successes, explore challenges for mutually beneficial solutions and in general work towards making the products of cancer research as impactful as they can be for all patients, survivors and their families. I have no doubt that together, we will bring about tremendous progress for data sharing!

Announcements

NIH Data Sharing Index (S-index) Challenge - Introductory Webinar

Date and Time: January 28, 2025 at 12:00 PM

Webinar registration.

Learn more about anyone the NIH Data Sharing Index (S-index) Challenge, led by the National Eye Institute (NEI) with contributions from multiple National Institutes of Health (NIH) Institutes, Centers, and Offices (ICOs). With a total prize pool of $1 million, this Challenge aims to incentivize and reward data sharing excellence, promoting a new metric for assessing how effectively researchers share valuable data, driving a culture of openness in science.

The FDA has released: Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry and Other Interested Parties.

In accordance with its mission of protecting, promoting, and advancing public health, FDA's Center for Drug Evaluation and Research (CDER), in collaboration with the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Veterinary Medicine (CVM), the Oncology Center of Excellence (OCE), the Office of Combination Products (OCP), and the Office of Inspections and Investigations (OII), is issuing this draft guidance to provide recommendations to industry on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding the safety, effectiveness, or quality for drug and biological products. Submit comments by April 7, 2025.

NIH Initiates Access Planning Efforts within Intramural Research Program

NIH is issuing an Intramural Research Program (IRP) policy to promote access to IRP-supported inventions resulting in drugs, biologics, vaccines, or devices. As of June 1, 2025, organizations applying to NIH for certain commercial patent licenses will be required to submit Access Plans to NIH outlining steps they intend to take to promote patient access to those licensed products. NIH will continue working with industry partners to develop additional resources and guidance in support of these efforts.

More information here.

Questions may be sent to SciencePolicy@od.nih.gov

NIH Issues Agency Implementation Information on *U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*

NIH has issued agency specific information regarding its implementation of the *U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. The policy, which goes into effect May 6, 2025, is a unified federal oversight framework for conducting and managing certain types of federally funded life sciences research on biological agents and toxins.

The implementation information can be found here. NIH will continue to provide updates as

The implementation information can be found here. NIH will continue to provide updates as additional implementation details are finalized.

Questions may be sent to SciencePolicy@od.nih.gov