

Bertagnolli to Serve as NCI Director

President Joe Biden announced on August 10 his intention to appoint Monica Bertagnolli, MD, as the 16th (and first woman) director of the National Cancer Institute (NCI). She currently serves as the Richard E. Wilson Professor of Surgery in surgical oncology at the Harvard Medical School, as well as a surgeon at the Brigham and Women's Hospital and a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at the Dana-Farber Cancer Institute (all in Boston, MA). She has championed collaborative initiatives to transform the data infrastructure for clinical research and is the founding chair of the Minimal Common Oncology Data Elements (mCODE) Executive Committee. She is a past president and chair of the board of directors of the American Society of Clinical Oncology and has served on the board of directors of the American Cancer Society and the Prevent Cancer Foundation.

"I look forward to working with Dr. Bertagnolli to advance the President's call to end cancer as we know it," said Secretary Xavier Becerra, U.S. Health and Human Services, referring to the President's renewed Cancer Moonshot initiative. "Her decades of cancer research expertise around patient-centered care and her work to create more inclusive clinical trials will be instrumental as we accelerate the rate of research and innovation to fight cancer."

The White House

TerraPower Announces Funding Raised for Nuclear Technologies

Terrapower (Bellevue, WA) announced on August 15 the close of an equity raising effort that yielded >\$750 million. The effort was led by TerraPower founder Bill Gates and by SK Inc./SK Innovation (Seoul, South Korea). Additional funding will come from other investors. According to a press release from TerraPower, this effort will enhance the company's

"groundbreaking work in advanced nuclear energy technologies and nuclear medicine."

"TerraPower is committed to solving some of the toughest challenges that face this generation through innovation," said TerraPower President and CEO Chris Levesque. "Whether it's addressing climate change with carbon-free advanced nuclear energy or fighting cancer with nuclear isotopes, our team is deploying technology solutions, and investors across the world are taking note." TerraPower's recent growth has been driven in part by a U.S. Department of Energy (DOE) Advanced Reactor Demonstration Program (ARDP) award and the construction of the Natrium demonstration plant at a retiring coal facility in Wyoming. Part of the ARDP award requires a match of 50% of project costs, up to \$2 billion.

The TerraPower Isotopes (TPI) program is "supporting the transformation of the fight against cancer by advancing the next generation of isotopes." Across a range of partnerships, the program is focusing on isotopic materials harvested from DOE storage to be used in targeted α therapy. The press release noted that TPI has "unique access to ^{225}Ac and is working to provide this isotope to the pharmaceutical community for the development of drugs that target and treat cancer." TerraPower's radiochemistry laboratory also supports other radioisotope development initiatives within the company as part of its nuclear innovation mission. For more information on the TPI, visit: <https://www.terrapower.com/wp-content/uploads/2022/03/2022-TPI-Isotopes.pdf>.

New European Data Law and FDA

In a perspective article published on August 9 by the U.S. Food and Drug Administration (FDA), Heather Messick, JD, an international policy analyst, looked at the current and likely future effects of the General Data Protection Regulation (GDPR), a law enacted by the European Union (EU) in 2018

requiring that organizations put in place certain measures to collect, use, or store personal data originating from persons in the European Economic Area (the 27 EU member states plus Iceland, Norway, and Lichtenstein) to ensure that the data are protected, even if transferred out of the area. The GDPR defines personal data as: "any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, online identifier, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that person." Of note, coded data, referred to in the law as "pseudonymised data," are considered to be personal data and subject to the protections of the law. Messick outlined a number of concerns for the FDA in its current interactions with the EU, particularly in clinical and other scientific trials, New Drug Applications/Biologic License Applications, and adverse event reporting. The FDA is assessing implications for collaborative medical research involving sites in EU member states and the United States. In March, the EU and the United States agreed "in principle" on a new data agreement for cross-border transfers of personal privacy data for commercial purposes. The FDA will continue to monitor both requirements and interpretations of the GDPR in the coming year. The complete perspective article is available at: <https://www.fda.gov/international-programs/global-perspective/how-european-data-law-impacting-fda>.

U.S. Food and Drug Administration

NIH Centers of Excellence for Telehealth in Cancer Care

The National Cancer Institute (NCI) announced on August 18 that it will award \$23 million to 4 academic institutions to establish centers of excellence to conduct research on the role of

telehealth in delivering cancer-related health care. The 5-y awards will establish the NCI Telehealth Research Centers of Excellence (TRACE) initiative, which is being supported by the Cancer Moonshot program to accelerate the rate of progress against cancer.

“One of the Cancer Moonshot goals is to make the cancer experience less burdensome for patients and their families and caregivers,” said Katrina Goddard, PhD, director of the NCI Division of Cancer Control and Population Sciences. “We are awarding these centers of excellence to better understand how telehealth can contribute to improved health outcomes across the cancer care continuum.”

The research being undertaken by the 4 centers will study the role of telehealth in fields from prevention to screening, diagnosis to treatment, and survivorship. Each center will be led by an academic institution that has assembled diverse teams of researchers to conduct large trials in real-world clinical settings such as hospitals, cancer centers, oncology practices, and primary care offices. The centers will be

led by the New York University Grossman School of Medicine (NY), Northwestern University (Evanston, IL), the University of Pennsylvania (Philadelphia), and Memorial Sloan Kettering Cancer Center (New York, NY)

In addition to developing innovative ways to use telehealth in cancer care, the centers will focus on identifying and addressing telehealth-related disparities among vulnerable populations, including racial and ethnic groups, rural residents, older adults, people who are uninsured or have low incomes, people who are socially isolated, and people who have limited digital literacy. All participating centers are also committed to training the next generation of telehealth-focused researchers.

National Cancer Institute

DOE Medical User Group Meetings

The Department of Energy (DOE) Isotope Program held its Annual Medical Isotope User Group Meetings in a virtual format in September and October. The meetings, which focused on

emerging α and β emitters, are organized to facilitate free discussion and collaboration among users of specific isotopes and to encourage information exchange about their applications in medicine. The webinar-style sessions featured brief presentations by leading researchers showcasing progress in these emerging fields, followed by interactive panel discussions. The ^{225}Ac User Group Meeting was held on September 1 and was moderated by Cathy Cutler, PhD, from the Brookhaven National Laboratory (Upton, NY). The ^{211}At User Group Meeting was held on September 6 and moderated by Yawen Li, PhD, from the University of Washington School of Medicine (Seattle). On September 19, the ^{134}Ce User Group Meeting was moderated by Stosh Kozimor, PhD, from the Los Alamos National Laboratory (NM). The final event, the ^{212}Pb User Group Meeting was moderated by Matt O’Hara from the Pacific Northwest National Laboratory (Richland, WA).

U.S. Department of Energy