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PEOPLE

Kenneth C. Anderson, MD, director of the Lebow Institute for Myeloma Therapeutics and Jerome Lipper Myeloma Center at Dana-Farber Cancer Institute in Boston, MA, will become president of the American Society of Hematology on December 6. Serving a 1-year term, he will succeed Charles S. Abrams, MD.

Anderson's research focuses on the biology and treatment of plasma cell disorders. Outside the laboratory, he works to identify new opportunities for mentorship and role models for the next generation of hematologists and to strengthen international leadership to improve the care of patients with blood disorders. He has published more than 1,100 peer-reviewed manuscripts, textbook chapters, and books. He has also served as editor-in-chief of *Clinical Cancer Research,* a journal of the American Association for Cancer Research (AACR).

On December 1, **Nancy E. Davidson, MD,** became executive director of clinical oncology at the Fred Hutchinson/University of Washington (UW) Cancer Consortium in Seattle. The current president of the AACR, Davidson previously served as director of the University of Pittsburgh Cancer Institute in Pennsylvania. In her new role, she will bridge cancer treatment; clinical, translational, and basic research; and public health research programs of the consortium members: Fred Hutchinson, UW School of Medicine, UW School of Public Health, Seattle Children's Hospital, and Seattle Cancer Care Alliance.

A world-renowned physician-scientist, Davidson has published key findings on the role of hormones in gene expression and cell growth in breast tumors. She has also guided national trials of potential therapies and has helped increase understanding of the value of angiogenesis inhibitors for treating metastatic disease.

HHS Expands Rules for Clinical Trial Reporting

The federal government has adopted new policies to clarify and expand the reporting requirements for clinical trials and to make the data available more quickly to researchers and the public. Noting that previous rules were ambiguous and often ignored, federal officials vowed to enforce the new requirements and pull public funding from studies that do not comply.

The new rules from the U.S. Department of Health and Human Services (HHS) and the NIH, which take effect on January 18, 2017, outline the requirements for registering and submitting summary results to ClinicalTrials.gov for all publicly funded trials. Key changes include mandatory registration of trials that test experimental and early-stage therapies, and posting results for trials of unapproved drugs.

The rules also clarify the definition of an Applicable Clinical Trial and provide a checklist of mandatory data requirements for registration, such as information about the design and outcome measures and recruitment eligibility criteria. In addition, more information must be submitted on completed trials, including demographic characteristics of participants and details of any adverse events that affect more than 5% of patients. The key points are described in *The New England Journal of Medicine* (N Engl J Med 2016 Sept 16 [Epub ahead of print]).

"Sharing results is society's responsibility toward the volunteers who agree to participate in trials," said NIH Director Francis Collins, MD, PhD, at a press conference, "but we as a community have had a disappointing track record at making those results available."

Under the existing rule, researchers must submit results of federally funded research within a year of completing a trial, but that often doesn't happen. Collins cited a recent study showing that among trials conducted at 51 U.S. academic medical centers, 43% had not published their results within 2 years of completion (BMJ 2016;352:i637). A separate review of 400 studies found that 30% had not reported results within 4 years (PLoS ONE 2014;9:e101826).

Officials anticipate a flood of new trial registrations as a result of the ruling, said Collins, and the FDA is making plans to strengthen enforcement.

Sponsors of publicly funded studies that do not comply will face stiff penalties, including fines and withdrawal of funding for future trials, noted FDA Commissioner Robert Califf, MD, during the news conference. The FDA plans to fold compliance and enforcement activities into its existing Bioresearch Monitoring program, through which it collects clinical trial information during site inspections.

"We are already at a number of these trial sites on a routine basis," Califf noted. "Once people realize how serious this is, we don't think that we will have a lot of problems with compliance. No one wants to be on the 'wall of shame' for failing to report their results." *–Janet Colwell* ■

Better Outcomes with Precision Medicine

According to final results from the prospective MOSCATO-01 trial, tailoring treatment to the genetic makeup of a patient's tumor improves progression-free survival (PFS), compared with previous nontargeted therapy. Lead investigator Jean-Charles Soria, MD, PhD, of the Institut Gustave Roussy in Villejuif, France, reported the data at the Molecular Analysis for Personalized Therapy conference in London, UK, in September.

Soria and his colleagues biopsied a total of 949 patients for this study. A diverse range of advanced cancers were represented, including bladder carcinoma, head and neck squamous cell carcinoma, and bile duct cancer; all patients had received a median of three prior therapies for their disease. In 844 cases, the tumor tissue samples were of sufficient quality to undergo extensive molecular analyses, including DNA sequencing with a customized 75-gene panel, comparative genomic hybridization to assess copy-number variations, and RNA sequencing.

The investigators looked at whether the PFS achieved with targeted therapy was better than that seen with prior standard treatment. "Our primary

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