DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

7th VIRTUAL JOINT MEETING of the BOARD OF SCIENTIFIC ADVISORS AND NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
5–7 December 2022

Virtual Meeting
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

BOARD OF SCIENTIFIC ADVISORS and
NATIONAL CANCER ADVISORY BOARD JOINT MEETING
BETHESDA, MARYLAND
Summary of Meeting
5–7 December 2022

The Board of Scientific Advisors (BSA) of the National Cancer Institute (NCI) and the National Cancer Advisory Board (NCAB) convened for the 7th Virtual Joint Meeting on 5–7 December 2022. The meeting was open to the public on Monday, 5 December 2022, from 1:15 pm to 4:24 pm; Tuesday, 6 December 2022, from 1:00 pm to 5:36 p.m.; and Wednesday, 7 December 2022, from 1:00 p.m. to 5:02 p.m., and closed to the public on Monday, 5 December 2022, from 12:00 p.m. to 1:02 p.m. The NCAB Chair, Dr. John D. Carpten, Professor and Chair, Department of Translational Genomics, Royce and Mary Trotter Chair in Cancer Research, Keck School of Medicine, University of Southern California, and BSA Chair, Dr. Keith T. Flaherty, Director Clinical Research, Massachusetts General Hospital Cancer Center, Professor of Medicine, Harvard Medical School, presided during the open sessions. Dr. Carpten presided during the closed session. In the open sessions, the BSA considered new requests for applications (RFAs), cooperative agreements (Coop. Agr.), requests for proposals (RFPs), and program announcements with special receipt, referral, and/or review (PARs) of new and re-issue concepts presented by NCI program staff.

BSA Members

Dr. Keith T. Flaherty (Chair)
Dr. Chandrakanth Are
Mr. Timothy Babich*
Dr. Suzanne J. Baker
Dr. Karen M. Basen-Engquist
Dr. Michael John Becich
Dr. Mary C. Beckerle (absent)
Dr. Melissa L. Bondy
Dr. Otis W. Brawley
Dr. Andrew T. Chan
Dr. Nelson J. Chao
Dr. Gloria D. Coronado
Dr. Mark P. Doescher*
Dr. Chyke A. Doubeni
Dr. Shelton Earp
Dr. Jennifer R. Grandis
Dr. Dorothy K. Hatsukami
Dr. Trey Ideker
Dr. Karen E. Knudsen
Dr. Michelle M. Le Beau
Dr. Ana Maria Lopez*
Dr. Karen M. Mustian
Dr. Lisa A. Newman*
Dr. Raymond U. Osarogiagbon*
Dr. Sylvia Katina Plevritis
Dr. W. Kimryn Rathmell
Dr. Erle S. Robertson
Dr. Leslie L. Robison
Dr. Robert D. Schreiber
Dr. David Sidransky (absent)
Dr. Ian M. Thompson, Jr.
Dr. David A. Tuveson
Dr. Cornelia M. Ulrich*
Dr. Samuel L. Volchenboum*
Dr. Robert H. Vonderheide
Dr. Richard C. Zellars

NCAB Members

Dr. John D. Carpten (Chair)
Dr. Francis Ali-Osman
Dr. Nilofer S. Azad
Dr. Anna D. Barker
Dr. Luis Alberto Diaz, Jr.
Dr. Howard J. Fingert
Dr. Christopher R. Friese
Mr. Lawrence O. Gostin (absent)
Dr. Andrea A. Hayes Dixon
Dr. Amy B. Heimberger
Dr. Scott W. Hiebert
Dr. Nikan Khatibi (absent)
Dr. Electra D. Paskett
Dr. Nancy J. Raab-Traub (absent)
Dr. Margaret R. Spitz
Dr. Susan Thomas Vadaparampil
Dr. Ashani T. Weeraratna
Dr. Karen M. Winkfield

President's Cancer Panel

Dr. John P. Williams (Chair)
Mr. Robert A. Ingram (absent)
Dr. Edith P. Mitchell (absent)

*Pending appointment

Alternate *Ex Officio* NCAB Members

Dr. Michael A. Babich, CPSC
Dr. Gwen W. Collman, NIEHS
Dr. Joseph R. Graber, DOE
Dr. Michael Kelley, VA
Dr. Richard Pazdur, FDA (absent)
Dr. Tara A. Schwetz, NIH (absent)
Dr. Craig D. Shriver, DoD
Dr. Kerry Souza, NIOSH (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Monica M. Bertagnolli, Director, National Cancer Institute
Dr. Oliver Bogler, Director, Center for Cancer Training
Dr. Philip E. Castle, Director, Division of Cancer Prevention
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Henry P. Ciolino, Director, Office of Cancer Centers
Dr. James H. Doroshow, Deputy Director for Clinical and Translational Research
Dr. Dan Gallahan, Director, Division of Cancer Biology
Mr. Peter Garrett, Director, Office of Communications and Public Liaison
Dr. Katrina A.B. Goddard, Director, Division of Cancer Control and Population Sciences
Dr. Satish Gopal, Director, Center for Global Health
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Ed Harlow, Special Advisor to the NCI Director
Dr. Toby T. Hecht, Deputy Director, Division of Cancer Treatment and Diagnosis
Dr. Tony Kerlavage, Director, Center for Biomedical Informatics and Information Technology
Dr. Kristin Komschlies McConville, Acting Director, Office of Scientific Operations, NCI at Frederick
Dr. Douglas R. Lowy, Principal Deputy Director, National Cancer Institute
Dr. Glenn Merlino, Scientific Director for Basic Research, Center for Cancer Research
Dr. Tom Misteli, Director, Center for Cancer Research
Dr. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program
Dr. Diane Palmieri, Acting Director, Center for Research Strategy
Dr. Henry Rodriguez, Director, Office of Cancer Clinical Proteomics Research
Mr. Jeffrey Shilling, Chief Information Officer and Chief of Infrastructure and Information Technology Services Branch, Center for Biomedical Informatics and Information Technology
Ms. Donna Siegle, Executive Officer and Deputy Director for Management, Office of the Director
Dr. Dinah S. Singer, Deputy Director, Science Strategy and Development and Acting Director, Center for Strategic Scientific Initiatives
Dr. Sanya A. Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis M. Staudt, Director, Center for Cancer Genomics
Mr. Michael Weingarten, Director, Small Business Innovation Research and Small Business Technology Transfer Programs
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy
Dr. Maureen Johnson, Executive Secretary, Office of the Director

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MONDAY, 5 DECEMBER 2022

I. NATIONAL CANCER ADVISORY BOARD (NCAB) CLOSED SESSION—DR. JOHN D. CARPTEN

"This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c) (6), Title 5 U.S. code and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2)."

There was a discussion of personnel and proprietary issues. Members absented themselves from the meeting during discussions for which there was potential conflict of interest, real or apparent.

Dr. John Carpten adjourned the NCAB Closed Session at 1:02 p.m.

TUESDAY, 6 DECEMBER 2022

II. CALL TO ORDER AND OPENING REMARKS—DRS. JOHN D. CARPTEN AND KEITH T. FLAHERTY

Dr. John D. Carpten called to order the 7th Virtual Joint Board of Scientific Advisors (BSA) and National Cancer Advisory Board (NCAB) meeting. He welcomed members of the Boards, *ex officio* members, President's Cancer Panel members, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Carpten reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion to accept the minutes of the 31 August 2022 NCAB meeting was approved unanimously.

Dr. Carpten called Board members' attention to the future meeting dates listed on the agenda.

III. NCI DIRECTOR'S REPORT—DR. MONICA M. BERTAGNOLLI

Dr. Monica M. Bertagnolli, Director, NCI, welcomed members of both the BSA and NCAB to the 7th Virtual Joint Meeting of these Boards. Dr. Bertagnolli reviewed the agenda, discussed how NCI is planning for the opportunities ahead, and provided updates on the NCI budget and recent activities and ongoing programs. Dr. Bertagnolli began by expressing her continued excitement after her first eight weeks as NCI Director. She remarked that the NCI is an incredible organization with significant depth and breadth, made up of talented, dedicated people. Working with the extramural community is the core of what will help to succeed in helping people with cancer live full and active lives and, ideally, preventing people from ever having to face a cancer diagnosis.

Dr. Bertagnolli next welcomed new BSA members: **Mr. Timothy Babich,** Founder and Director, RUNX1 Research Program; **Dr. Mark P. Doescher,** Professor, Department of Family and Preventive Medicine, College of Medicine, University of Oklahoma Health Sciences Center; **Dr. Ana Maria Lopez,** Professor and Vice Chair, Department of Medical Oncology, Sidney Kimmel Medical College, Thomas Jefferson University; **Dr. Lisa A. Newman,** Professor of Surgery, Chief, Division of Breast Surgery, Weill Cornell Medicine; **Dr. Raymond U. Osarogiagbon**, Adjunct Research Professor, Department of Medicine, Vanderbilt University, Chief Scientist, Baptist Memorial Health Care Corporation; **Dr. Cornelia M. Ulrich,** Chief Scientific Officer and Executive Director, Comprehensive Cancer Center, Huntsman Cancer Institute, University of Utah; and **Dr. Samuel L. Volchenboum,** Associate Professor

of Pediatrics, Director, Pediatric Cancer Data Commons, Pritzker School of Medicine, University of Chicago.

NCI Plans for Opportunities Ahead. Dr. Bertagnolli reminded the Boards that on 2 February 2022, President Joseph R. Biden charged the NCI to lead the reinvigorated Cancer Moonshot℠ initiative, which called for reducing cancer mortality by 50 percent in 25 years and "ending cancer as we know it." She noted that the first part, 50 percent reduction in 25 years, is clear and tangible and that the NCI understands this directive well and has been implementing relevant strategies for years. Successful strides toward meeting this goal have been made with significant support from society. The phrase "ending cancer as we know it" is a more of a general statement, which the NCI recognizes needs more precision to be translated into a plan for action. In recent weeks, NCI leadership convened to draft a set of aspirational statements describing a future in which "cancer as we know it" has been ended. The aim of this process is to establish clearly defined objectives to guide the NCI's work and provide a framework for focus, innovation, measurement of progress, and collaboration with the broadest possible community.

Unlike a conventional internal strategic plan, this intentional framework can evolve as the NCI makes progress and engages new partners. This "roadmap" recognizes the journey required to reach the desired goals and will respond to conditions along the way. Currently, it is being used to take account of current NCI activities directed toward achieving its specific objectives and to identify gaps and opportunities. The roadmap will allow the NCI to track progress and adapt to changing conditions, such as new and potentially disruptive technologies. It also will be a tool to help the NCI manage change and take action when new opportunities arise and will serve as a framework for collaboration. Dr. Bertagnolli noted that the roadmap would be ready for review by the BSA and NCAB by the next meeting.

NCI Budget. Dr. Bertagnolli reported that the NCI currently is operating under a continuing resolution (CR) through December 16; the budget under the CR mirrors the fiscal year (FY) 2022 budget of $6.9 billion (B). Lack of a FY 2023 budget for a long period would produce harmful downstream effects. Dr. Bertagnolli conveyed the NCI's optimism for funding increases, noting that cancer research traditionally has received strong bipartisan support. She noted that Ms. M.K. Holohan, Director, Office of Government and Congressional Relations (OGCR), NCI, will provide further details on the budget and political climate later in the meeting.

The *Annual Plan and Budget Proposal for Fiscal Year 2024*, released in September 2022, outlines promising opportunities that the NCI can implement in FY 2024. The Annual Plan's goal is to end cancer as we know it for all people; it clearly articulates the importance of health equity throughout the NCI's work. The Annual Plan proposes a significant budget increase to capitalize on current opportunities. The NCI's foremost priority is funding the most compelling cancer opportunities that reflect the full breadth of science, including prevention and screening, diagnosis and treatment, and quality of life and survivorship, as well as the foundational biology that underlies all areas of cancer science. Funding for the next phase of the Cancer Moonshot is distributed throughout the entire Annual Plan. The Cancer Moonshot will allow the NCI to accelerate its work, prepare to take advantage of current opportunities, and push boundaries further.

The NCI remains committed to increasing paylines for Research Project Grants, particularly R01s, which are the source of many innovative ideas and significant discoveries in cancer science. Dr. Bertagnolli commented on the significant return on investment provided by the NCI's R01 investigators. It is anticipated that the aspirational goal of 15th percentile by 2025 will be achievable, but it requires funding to support as many ideas as possible. Funding cannot be taken from other important programs since many are interwoven and highly interdependent. Maximal use of resources requires building understanding of the budget across the community and determining how to leverage existing funds. This approach, which accompanies the National Cancer Program, will emphasize the importance of

increases for the NCI across the board rather than directed at any specific component. Clearly articulating this necessity to Congress, Dr. Bertagnolli anticipates, will lead to increased financial support.

Update on Cancer Research Across NCI Programs and NCI Activities. The latest *Annual Report to the Nation on the Status of Cancer* showed that from 2015 to 2019, cancer death rates continued to decline in every major racial and ethnic group in the United States. Incidence rates for many cancers decreased among non-Hispanic, Black/African Americans, Asian Americans, Pacific Islanders, and Hispanic men. The declines in death rates were the steepest in lung cancer and melanoma among men and women. However, death rates increased for cancers of the pancreas, brain, bones, and joints among men and cancers of the pancreas and uterus among women. The overall cancer incidence rates were highest among non-Hispanic American Indian and Alaska Native people, followed by non-Hispanic White/Caucasian and non-Hispanic Black/African Americans. Significant disparities in incidence rates remain: rates for bladder cancer increased among non-Hispanic American Indian and Alaska Natives, and incidence rates for uterine cancer increased among women of every racial and ethnic group except non-Hispanic White/Caucasian women. The incidence of breast cancer, the most common cancer among adolescents and young adults, also increased by an average of 1 percent per year.

Dr. Bertagnolli commented that the most concerning area not optimally addressed is the need for a very diverse cancer research workforce that achieves maximal engagement required to prevent cancer and help all people with cancer live longer and healthier lives. The workforce is not sufficiently diverse at this time and the cancer research enterprise has to contend with both the standard challenges of maintaining a highly talented and motivated clinical and research workforce and additional trauma from the COVID-19 pandemic. A cancer research workforce that is well supported and protected from burnout and reflects the communities served is essential for success. The Cancer Moonshot Scholars Program was launched to advance cancer science and diversify the pool of researchers and the approaches to cancer research funded by the NCI. The program targets early-stage investigators, particularly those from diverse backgrounds. The NCI expects to fund 45 new R01s from this program over the next 3 years.

The challenges of the COVID-19 pandemic helped the NCI learn some ways to reduce burdens (e.g., cost, distance) so that more people could access cancer care and participate in some types of cancer research, including clinical trials, even while clinical care was disrupted and travel was more difficult. Telehealth has shown great promise and could be a way to overcome inequalities, but much remains unknown about how to use this new approach to achieve better health without exacerbating disparities. In August 2022, the NCI awarded $23 million (M) to establish four Telehealth Research Centers of Excellence (TRACE). These TRACE awards will help the NCI understand how best to address gaps in using telehealth technology and add to the relatively small amount of science currently documenting telehealth as a way to overcome inequities.

During the June 2022 Joint BSA/NCAB meeting, a funding opportunity announcement (FOA) for developing multi-cancer detection (MCD), sometimes called multi-cancer early detection (MCED), assays was presented and approved by the BSA. These technologies could provide a way to detect many types of cancer, including those for which no current screening method exists, in a single blood sample, as well as reduce obstacles that prevent some people from receiving any screenings. In developing these tests, researchers must ensure that they do not exacerbate disparities or promote overdiagnosis, which will require engaging a broad population in clinical research, including researchers not traditionally part of NCI research teams, primary care physicians, cancer patients, and people without cancer. Funding opportunities for the NCI Multi-Cancer Detection Test Vanguard Study have been posted for work through the new NCI Cancer Screening Research Network (CSRN). The plan is to begin enrolling 24,000 healthy people ages 45 to 70 in 2024 to lay the groundwork for a larger study that will enroll up to 225,000 people, the estimated accrual necessary to address the issues of interest. The NCI anticipates funding initial RFAs in FY 2023.

To increase participation in clinical research for this and other efforts, clinical trials must become more accessible and attractive to more people. On 16 November 2022, the NCI hosted the NCI Summit on Increasing Diversity, Equity, and Inclusion in Cancer Clinical Trials with representatives from government and industry and input from across the health care community and academia. Early trials require special infrastructure, some of which has been implemented in later-phase trials but has not yet reached the earlier phases. The recent summit was part of a long-term effort to partner with many outside organizations, such as pharmaceutical collaborators, to invest in practical initiatives that will enhance equity and inclusion across the spectrum of clinical research funded by the NCI.

Dr. Bertagnolli highlighted the Childhood Cancer Data Initiative (CCDI), which was presented in full later in the meeting, as an example of the kind of collaborative teamwork expected from the NCI roadmap. The CCDI provides an opportunity to overcome persistent challenges in childhood cancer research as a goal-directed framework for innovation in problem-solving. Two CCDI workshops were held in November to share insights and expand the community; one focused on current issues and opportunities for electronic health record (EHR) extraction, and the other convened scientific and technical experts to discuss the importance of a national coordinated effort to study and collect data on very rare childhood cancers and the ways a platform like CCDI can help create an infrastructure to speed progress in tumor research. In addition to its stated goals, the NCI expects that the CCDI would develop effective methods of patient and family engagement, data sharing, fostering clinical trials, accruing rare populations, addressing rare tumors, and providing ongoing support for children and their families. Dr. Bertagnolli suggested that CCDI would lead changes to research and health care delivery that would benefit all people.

The NCI has improved the diversity of its Outstanding Investigator Awards, which support accomplished leaders in cancer research who are providing significant contributions toward understanding cancer at a fundamental level and developing applications that can lead to breakthroughs. Only 1 of the 17 awardees in 2021 was a woman; strikingly, 9 of the 24 awardees were women in 2022. The levels of racial and ethnic diversity also have increased; however more remains to be done to ensure that a diverse pool of accomplished investigators is available by helping more people from a variety of backgrounds rise through all levels of cancer research.

Dr. Bertagnolli recognized the current President's Cancer Panel members whose service was ending: Dr. John Williams, Chair; Mr. Robert Ingram; and Dr. Edith Mitchell. She expressed appreciation for their extraordinary work during the pandemic. The Panel's report on bridging the cancer screening gap concluded that more effective and equitable implementation of existing evidence-based cancer screening modalities and guidelines represents a significant opportunity to reduce the burden of cancer and accelerate the decline in cancer deaths.

In closing, Dr. Bertagnolli commented that the NCI should strive to be a research leader in finding new ways to use what is already known to be effective. She emphasized that the work of the NCI centers on people with cancer and has far-reaching impacts on communities. She expressed appreciation to the attendees for their work in helping to guide the NCI's efforts.

Questions and Answers

Dr. Karen Knudsen, Chief Executive Officer, American Cancer Society, Inc., American Cancer Society Cancer Action Network, asked about estimates for the budget required to achieve the 15th percentile on R01s by 2025. Dr. Bertagnolli explained that although she did not have the exact number available, it is included in every budget request. An increase is required to sustain current levels, particularly in times of inflation, so an additional increase is required to achieve the R01 funding goal. NCAB Chair Dr. Carpten noted that former Acting Director Dr. Douglas Lowy had outlined the budget

process at a prior Joint BSA/NCAB meeting and suggested including that outline at each December Joint BSA/NCAB meeting.

In response to a question from NCAB Chair Dr. Carpten seeking additional information on the Cancer Moonshot, Dr. Bertagnolli explained that the new format includes two approaches. The first is to identify specific measurable goals and the effort required to achieve those goals, which is the intent of the roadmap and NCI's response to it. The second is an all-of-government approach to eliminate cancer, coordinated by the NCI Director in line with the 1971 National Cancer Act. She emphasized that the support of the White House will help the NCI achieve its longtime goal by encouraging collaborations with other agencies, such as the Advanced Research Projects Administration for Health (ARPA-H).

Dr. Karen Mustian, Dean's Professor of Oncology and Surgery, Departments of Surgery, Radiation Oncology, and Public Health Sciences, University of Rochester School of Medicine and Dentistry, asked about the reignited Cancer Moonshot and its perspective on screening and cancer control supportive care, emphasizing that ending cancer may mean removing the fear of death from cancer diagnosis. Dr. Bertagnolli agreed that one of the signature goals is to allow people with cancer to live full and active lives free from symptoms. A complementary goal is to support prevention so that people never receive a cancer diagnosis. Dr. Bertagnolli pointed out that everything the NCI does works toward those goals.

Dr. W. Kimryn Rathmell, Hugh Jackson Morgan Professor of Medicine and Biochemistry, Chair, Department of Medicine, Physician-in-Chief, Vanderbilt University Medical Center, asked about new models for work since the beginning of the COVID-19 pandemic. Dr. Bertagnolli explained that work styles are individualized to achieve goals as successfully as possible. For some units, remote work offers the best path to success because the work can be completed remotely and remote work allows a more diverse and engaged workforce. In other units, such as the NIH Clinical Center, clinicians need to be in the hospital to care for patients. NCI leaders are deciding which practices best achieve the unit's work, support their workforce, and allow their people to remain optimally engaged and active. Dr. Bertagnolli emphasized the importance of providing opportunities for meaningful togetherness that include remote workers.

IV. LEGISLATIVE REPORT—MS. M.K. HOLOHAN

Ms. Holohan provided a legislative update covering the outlook for the midterm elections, the FY 2023 appropriations process, and the overall political climate. The most recent reporting indicates that disagreement remained about the balance between defense and nondefense spending. In addition to completing the appropriations process, this lame duck session of Congress also must approve a national defense authorization; legislators often attach funding for their own priorities to such "must-pass" legislation, especially with the majority shifting in the new Congress. Democrats (D) performed better in the midterm election than historic patterns predicted. Republicans (R) gained a majority in the House with a much smaller increase than predicted. This likely will make passing legislation more challenging because a very small number of members can interrupt plans. Ms. Holohan emphasized the importance of securing FY 2023 funding in light of these challenges.

Senior congressional leadership is undergoing a generational change; Representative Hakeem Jeffries (D-New York) will be the new House minority leader, with Representatives Katherine Clark (D-Massachusetts) and Pete Aguilar (D-California) in the second and third positions. Leadership in the Senate is yet to be determined. With the majority change, the Chair of the full Appropriations Committee, Representative Rosa DeLauro (D-Connecticut), will be handing the committee gavel over to her longtime colleague Representative Kay Granger (R-Texas), who already has held this position. Representative DeLauro also chairs the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies and will be succeeded by a GOP appropriator, perhaps Representative Tom Cole (R-Oklahoma), who also has already held this position. In the Senate, the Georgia runoff

election has resulted in the Democrats with 51 senators, which will strengthen their committee representation, nominations, and legislation.

The budget agreement must either be completed by 3 January 2023 (the end of the 117th Congress) or deferred to the next Congress, which also will need to assess the President's budget request for FY 2024in the first few months (budget requests are typically presented to Congress in February). . If Congress cannot agree on FY24 funding levels, we may see a full-year continuing resolution (CR) could occur, but this option has few benefits for any parties involved – e.g., the new majority can't put their imprint on the spending bills and there would be no earmarks for lawmakers. Both parties will have to agree on defense spending and classification of veterans' health care. For FY23, the House Appropriations Committee proposed a $466 M increase in the NCI budget, and the Senate proposed a $290 M increase. Ms. Holohan noted that these numbers represent a majority view rather than bipartisan negotiation, so they may change. Past performance indicates that NIH and the NCI will remain high priorities. One new complication is disagreement over the provision in the defense authorization requiring the military to be vaccinated against COVID-19. The proposed options are to reverse the current requirements or attach the reversal to the defense authorization or the omnibus. Ms. Holohan reminded the Boards that ARPA-H received $1 B in FY 2022, which can be spent over 3 years. Authorizing legislation for ARPA-H may occur in the current or the new Congress, and the content of such legislation is unknown.

The current CR to fund the government expires on 16 December 2022, and the appropriations work will not be finished at that time. A new CR until December 23 is anticipated, but that also probably will not allow enough time for completion. Ms. Holohan expressed that the NCI is cautiously optimistic that the budget would be settled before the new Congress, which would be more beneficial for retiring and senior appropriators.

Questions and Answers

In response to a question from NCAB Chair Dr. Carpten, Ms. Holohan clarified that the NCI and NIH budgets would remain as they are if additional CRs occur.

Dr. Ashani Weeraratna, Bloomberg Distinguished Professor of Cancer Biology, E.V. McCollum Chair of Biochemistry and Molecular Biology, Johns Hopkins Bloomberg School of Public Health, Co-Program Leader, Cancer Invasion and Metastasis, Sidney Kimmel Cancer Center, Johns Hopkins School of Medicine, asked whether increased salaries for trainees are under consideration. Ms. Holohan confirmed that Congress is very interested in workforce development, a mechanism that the NCI protects. Dr. Bertagnolli pointed out that salaries for fellows are set by Congress, not the NCI, and providing additional funding from faculty grants is not allowed. From her perspective and work in this field, she agreed that salaries for fellows are too low and reiterated the importance of building the biomedical research workforce.

V. THE NCI'S CHILDHOOD CANCER DATA INITIATIVE—DRS. WARREN A. KIBBE AND GREGORY H. REAMAN

Dr. Warren A. Kibbe, Chief, Translational Biomedical Informatics, Department of Biostatistics and Bioinformatics, Chief Data Officer, Duke Cancer Institute, Duke University School of Medicine, presented an update on the Childhood Cancer Data Initiative (CCDI). He began by stating that the CCDI has a broad mission to support the community of pediatric cancer researchers, advocates, families, hospitals, and networks committed to generating, using, and sharing data to improve treatments, quality of life, and survivorship of every child with cancer.

CCDI's foundational goals are to gather data from every child, adolescent, and young adult diagnosed with a childhood cancer, regardless of where they receive their care; create a national strategy of appropriate clinical and molecular characterization to speed diagnosis and inform treatment for all types of childhood cancers; and develop a platform and tools to bring together clinical care and research data that will improve preventive measures, treatment, quality of life, and survivorship for childhood cancers.

The BSA *ad hoc* Working Group in Support of the CCDI developed recommendations in eight areas: Aggregate and generate broad categories of data; develop infrastructure; engage with experts; empower patients and families; ensure appropriate policy and funding; develop a strategy for survivorship; ensure diverse patient representation; and enable improved patient outcomes and treatment. The CCDI represents one of the NCI's first initiatives focused on pediatric cancer as a whole. The effort is based on data aggregation, harmonization, interoperability, and sharing across the ecosystem of pediatric cancer research and care.

CCDI's working framework involves establishing and evolving a data infrastructure, bringing together existing and novel data to fill gaps, learning from the data to make new discoveries and establish new cohorts, and establishing working groups to provide insight and community alignment. The BSA *ad hoc* CCDI Working Group's report was published in January 2020, and the most recent update to the BSA and NCAB was presented in June 2021. Working groups were established during this time. A presentation of priority areas and a symposium were held in FY 2022. Workshops on EHR data and rare tumors are scheduled for FY 2023. The NCI is actively planning next steps to align with community feedback.

Dr. Kibbe highlighted efforts to build a data infrastructure portfolio, including the National Childhood Cancer Registry, Molecular Targets Platform, CCDI participant index, index of NCI studies, Clinical Trial Data Commons, application programming interfaces for federation, a data submission pipeline, and new analytic tools and computational methods. Efforts related to aggregating and generating a data portfolio include the Molecular Characterization Initiative, data and tools supplements, clinical data, and a rare pediatric tumor cell atlas. Efforts related to learning from and using the data portfolio include the Childhood Cancer Data Catalog, National Childhood Cancer Registry Pediatric Explorer, grant and contract supplements, and EHR Data Extraction Pilots.

Dr. Gregory Reaman, Scientific Director, CCDI, discussed the initiative's priorities and next steps. He began by emphasizing the importance of considering and refining individual data touchpoints, from pre-diagnosis through survivorship. He briefly highlighted CCDI's priorities, which relate to patient identifiers, data models and standards, consent, and baseline data collection.

Dr. Reaman outlined the CCDI's next steps, which include continuing to expand data ecosystem capabilities, with a focus on tools and a portal for access and broad use; establishing the CCDI ultra-rare tumor protocol, including comprehensive clinical and molecular characterization; and developing consortia or networks to oversee and explore studies on feasibility of EHR extraction to support research. Two related workshops—"Advancing a National Initiative for Rare Cancers in Children, Adolescents, and Young Adults" and "The Importance of Electronic Health Record Data in Clinical Care and Research"—were held in November 2022.

Dr. Reaman explained that the foundational phase was focused on developing a framework of critical activities to fill major areas of need in the pediatric research community and to support future efforts. The discovery and expansion phases will establish opportunities to extend foundational efforts to make them work together and create feasibility studies in the wider community.

Questions and Answers

Dr. Andrea Hayes Dixon, Dean, Howard University College of Medicine, Vice President of Clinical Affairs, Chief of Surgery, Howard University Hospital, asked about the challenges to applying common language to data from multiple networks. Dr. Reaman explained that clinical data are submitted every 6 months, and data will be aligned as needed. Additional mechanisms for data alignment might be needed in the future as enrollment efforts are expanded.

Dr. Leslie L. Robison, ALSAC Endowed Chair in Epidemiology, Chair, Department of Epidemiology and Cancer Control, St. Jude Children's Research Hospital, Associate Director, St. Jude Comprehensive Cancer Center, inquired about plans to convey CCDI's progress and activities to the broader scientific community. Dr. Kibbe noted that the CCDI publishes a monthly newsletter. He added that the engagement committee is committed to work in this area. Dr. Reaman also noted that a manuscript featuring information on the CCDI is under review, and several abstracts are in preparation.

VI. STATUS OF THE ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)—DR. RENEE WEGRZYN

Dr. Renee Wegrzyn, Director, ARPA-H, presented an update on the status of ARPA-H. Dr. Wegrzyn informed the members that the mission of ARPA-H is to accelerate better health outcomes for everyone. She explained that ARPA-H is intended to augment the existing ecosystem by pursuing the highest risk projects that cannot be funded through other mechanisms. ARPA-H was established in response to the new availability of complex technologies, as well as the presence of massive economic and social disruptions. Powerful biological factors include pandemics and emerging biotechnologies. ARPA-H program managers will design, build, and launch solutions to create the best version of the health future. Dr. Wegrzyn encouraged the participants to imagine how ARPA-H could be harnessed for bold pursuits in medicine and health care.

ARPA-H was established as an independent component of the U.S. Department of Health and Human Services (HHS) within the NIH and the Director reports directly to the HHS Secretary. ARPA-H was granted an initial budget of $1 B, with plans to increase exponentially over the next several years. No internal research laboratories are in place, and the agency is disease-agnostic. Program managers will drive ideas and decision-making, and a lean and nimble management structure is in place.

Dr. Wegrzyn explained that teams represent individual measures toward the larger goal. The teams will coordinate with program managers to ensure that they are incorporating the best technologies. Performance will be assessed regularly, and resources will be reallocated among teams as needed. "Graduation" will occur when the challenge is solved. Dr. Wegrzyn also explained that ARPA-H is part of a larger ecosystem of federal agencies (e.g., NIH, U.S. Food and Drug Administration [FDA], Centers for Medicare & Medicaid Services [CMS], Health Resources and Services Administration), academic and industry partners, nongovernment organizations, health care providers, patient groups, and the public.

The ARPA-H program life cycle involves designing programs, building a performer team, executing and measuring, learning and growing, and commercializing and transitioning. Dr. Wegrzyn explained that the program manager is the sole decision-maker in the process and is informed by insights from a subject-matter review panel. Stakeholders will be made aware of changes during this process. The transition community will be engaged at the end of the process to determine next steps. Dr. Wegrzyn outlined the initial focus areas: health science futures (i.e., expanding what is technically possible), scalable solutions (i.e., reaching everyone quickly), proactive health (i.e., keeping people from becoming patients), and resilient systems (i.e., building integrated health care systems).

The program managers will be appointed for 3 to 6 years and will be diverse in terms of geography, demographics, experience, and topic. Program managers can be recruited from government,

academic, and industry entities. Dr. Wegrzyn explained that she possesses direct hiring authority. Common traits of program managers include recognized expertise, serious drive, insatiable curiosity, no fear of failure, interdisciplinary track record, and technical honesty. Program managers can be problem-solvers, dreamers, tinkerers, rookies, status quo challengers, and sages.

ARPA-H's approach for defining problems is based on the Heilmeier Catechism and includes the following questions: (1) What are you trying to do? What health problem are you trying to solve? (2) How does this get done at present? Who does it? What are the limitations of present approaches? (3) What is new about our approach? Why do we think we can be successful at this time? (4) Who cares? If we succeed, what difference will it make? (5) What are the risks that may prevent you from reaching your objectives? What are the risks the program itself may present? (6) How long will it take? (7) How much will it cost? (8) What are our midterm and final exams to check for success? (9) To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed? (10) How might this program be misperceived or misused, and how can we prevent that from happening?

Dr. Wegrzyn emphasized that solutions are not research grants. Success is defined by survival in the wild, separating the improbable from the impossible, and delivering better health care to all people. Program managers will use flexible contracting vehicles, including cooperative agreements, contracts, and other transactional authorities, to create these solutions. Additionally, she noted that ARPA-H's Project Accelerator Transition Innovation Office (PATIO) is focused on increasing the odds of survival in the wild at each step of the life cycle. PATIO will provide resources to program managers to help with efforts related to assessing the market, identifying possible performers, performing due diligence, de-risking, driving adoption, helping with protection of intellectual property and company formation, transitioning investments, and providing access to key customers and investors.

The ARPA-H website and social media channels have been launched, with a landing site for program managers and a submission form for ideas. Dr. Wegrzyn underscored the importance of promoting community representation and engagement. Current stakeholders include members of Congress, staff, and intragovernmental partners; university administrators and faculty; and patient advocacy organizations and professional associations.

Next, Dr. Wegrzyn spoke about ARPA-H's role in the context of the Cancer Moonshot. She explained that ARPA-H can appoint a champion to identify internal efforts that are aligned with the Cancer Moonshot, engage stakeholders on behalf of the government, and collaborate with leaders across the U.S. government. Program managers can leverage infrastructure and implementation pathways, translate ongoing research efforts into capabilities for researchers or patients, and solve problems prioritized in the Cancer Moonshot that cannot be solved otherwise.

Dr. Wegrzyn concluded by highlighting examples of programs that could address strategic priorities of the Cancer Moonshot; these examples included at-home screening tests for colon cancer, wearable devices that report environmental exposure risk, tools to measure and modulate microenvironments to prevent metastasis, advocacy capabilities through EHRs, artificial intelligence tools for digital histopathology, and approaches to ensure equitable access to cancer-related health care.

Questions and Answers

Dr. Margaret R. Spitz, Professor Emeritus, Department of Medicine, Dan L. Duncan Cancer Center, Baylor College of Medicine, asked how the program managers will be reviewed and selected. Dr. Wegrzyn briefly outlined the candidacy process and explained that application materials will be assessed by a technical team within ARPA-H. Selected candidates will be invited to give a presentation and participate in an interview. After hiring, program managers will be equipped with a team to begin the market assessment and develop a call for proposals within the first 3 months.

Dr. Christopher R. Friese, Elizabeth Tone Hosmer Professor of Nursing, Director, Center for Improving Patient and Population Sciences, Associate Director for Cancer Control and Population Sciences, University of Michigan Rogel Cancer Center, University of Michigan, referenced a recent report indicating that the NCI research portfolio does not address scientific areas in cancer equitably across racial and ethnic groups. He offered to share the report with Dr. Wegrzyn to inform the development of the ARPA-H portfolio.

Dr. Ulrich underscored the importance of considering geographic diversity, particularly regarding rural populations. She also wondered about strategies for workforce management in a high-turnover environment. Dr. Wegrzyn clarified that program managers will not be required to relocate to the ARPA-H headquarters. The program managers will travel regularly to engage with stakeholder communities directly. Dr. Bertagnolli added that the partnership between ARPA-H and the NCI will enhance efforts related to workforce management.

Dr. Michael John Becich, Chairman and Distinguished University Professor, Department of Biomedical Informatics, Professor of Pathology, Computing/Information, Clinical/Translational Sciences, and Bioengineering, Associate Vice Chancellor for Informatics in the Health Sciences, Co-Director, Center for Commercial Application (CCA) of Healthcare Data, Associate Director, Hillman Cancer Institute (HCI), Associate Director, Clinical and Translational Science Institute (CTSI), University of Pittsburgh School of Medicine, noted that translating basic scientific research into commerce and industry remains a major barrier. Dr. Wegrzyn noted that PATIO will provide mentorship in this area, and approaches will be tailored to each team. She added that support from federal partners, such as CMS and the FDA, also will be beneficial.

Dr. Knudsen asked whether feasibility of downstream implementation and translation will be considered in program selection and whether subsets of the portfolio will be committed to addressing cancer-related problems. Dr. Wegrzyn explained that implementation will be considered throughout the program life cycle. She added that the program is enthusiastic about pursuing cancer-related topics, but such a requirement is not in place.

Dr. Doescher sought clarity on the technical team and selection process. Dr. Wegrzyn clarified that a mission office director will be hired for each mission area; hiring efforts are in progress. Currently, Dr. Wegrzyn is reviewing program manager applications; new program managers also will be involved in the selection process.

VII. RECOGNITION OF RETIRING BSA MEMBERS—DR. MONICA M. BERTAGNOLLI

On behalf of the NCI, Dr. Bertagnolli recognized the contributions made by members of the BSA whose terms of office have ended. She expressed appreciation for their service and dedication over the course of their terms. Those retiring BSA members are: **Dr. Michael John Becich,** Chairman and Distinguished University Professor, Department of Biomedical Informatics, Professor of Pathology, Computing/Information, Clinical/Translational Sciences, and Bioengineering, Associate Vice Chancellor for Informatics in the Health Sciences, Co-Director, CCA of Healthcare Data, Associate Director, HCI, Associate Director, CTSI, University of Pittsburgh School of Medicine; **Dr. Mary C. Beckerle,** Chief Executive Officer, Huntsman Cancer Institute, Jon M. Huntsman Presidential Endowed Chair, Distinguished Professor of Biology and Oncological Sciences, Associate Vice President of Cancer Affairs, The University of Utah; **Dr. Melissa L. Bondy,** Chair and Professor, Department of Epidemiology and Population Health, Co-Director, Center for Population Health Sciences, Associate Director for Population Sciences, Stanford Cancer Institute; **Dr. Robert D. Schreiber**, Andrew M. and Jane M. Bursky Distinguished Professor, Director, Center for Human Immunology and Immunotherapy Programs, Department of Pathology and Immunology, Washington University School of Medicine; **Dr. Ian M. Thompson, Jr.,** President, CHRISTUS Santa Rosa Medical Center Hospital, Texas Urology

Group; and **Dr. David A. Tuveson,** Roy J. Zuckerberg Professor, Director of the Cancer Center, Cold Spring Harbor Laboratory.

VIII. FUTURE DIRECTIONS FOR THE DIVISION OF CANCER CONTROL AND POPULATION SCIENCES—DR. KATRINA A. B. GODDARD

Dr. Katrina A. B. Goddard, Director, DCCPS, NCI, provided an overview of the future directions for the DCCPS and discussed the cancer control and population sciences research framework, the current status of the DCCPS, and future opportunities in cancer control. Dr. Goddard invited the Boards to review the DCCPS 2022 annual report titled *2022 Overview and Highlights: New Reflections on Cancer Control* for further details. She explained that a cancer diagnosis begins a journey that takes hard work and determination to successfully complete. Cancer control enables more people to have successful cancer outcomes so that they can live longer and healthier lives. Cancer control helps the DCCPS to achieve its mission to reduce the burden of the cancer journey.

Cancer Control and Population Sciences Research Framework. This DCCPS framework has broad categories for generating knowledge, producing outcomes, and improving population health. Generating knowledge using tools and resources involves surveilling and monitoring populations; studying etiology and identifying and assessing risk factors; developing and evaluating interventions; and improving care delivery and implementation strategies. This knowledge is applied to reduce the cancer burden across the cancer control continuum. The first step is prevention, or behavioral research, which is intended to reduce the risk of developing cancer. For detection, efforts have focused on developing polygenic risk scores that predict progression and prognosis of disease. In terms of treatment, work has been addressing understanding expectancies and cancer pain and symptom management. Regarding survivorship, efforts have focused on primary care. To improve outcomes, this framework encompasses individual health and well-being, system performance, population benefits, and equity. Many of the cancer control interventions are developed through either the NCI's intramural or extramural programs and are specific to the individual level. DCCPS incorporates additional interventions to help support individuals and systems in accomplishing desired health outcomes, such as maintaining a healthy diet.

Dr. Goddard highlighted examples of success stories in cancer control. Tobacco control is the result of decades of research and involves comprehensive interventions at all levels, from individual to societal. Interventions and strategies addressing barriers to colorectal cancer screening have been implemented in clinical practice to help support patients and health care systems. DCCPS partnered with other NCI divisions, offices, and centers to improve the uptake of human papillomavirus (HPV) vaccinations. Efforts included providing administrative supplements to existing grants to help the NCI-Designated Cancer Centers (Cancer Centers) to develop strategies that could be implemented within their catchment areas. Today, there is vast improvement in the uptake of HPV vaccines, and the national campaign is on a trajectory to meet 2030 targets. Immunotherapy interventions are now available, and use of these agents over the past decade has significantly increased worldwide. Policy action frameworks have been developed in Europe, for example, to help clinicians and researchers have discussions with policymakers about providing patients with access to these therapies to enable translating the scientific evidence into what can be implemented within health care systems.

Current Status of the DCCPS. Currently, 33 initiatives that span the cancer control and population sciences research framework are active. Surveillance, Epidemiology, and End Results (SEER) is a flagship program in population surveillance and monitoring that has been ongoing for several decades. SEER expanded in 2021 to include almost 50 percent of the cancer cases in the United States. In terms of etiology and risk factor identification, DCCPS-supported cohorts, including environmental

exposure cohorts, have been ongoing for multiple decades and have contributed to understanding key risk factors for various cancer types.

In support of intervention development and evaluation, DCCPS recently published a FOA on adolescent tobacco cessation. This FOA is addressing a critical time in life when many individuals will make the decision to begin smoking tobacco products. The Cancer Intervention and Surveillance Modeling Network (CISNET) modeling program has been ongoing for two decades and is evaluating preventive screening interventions, aligning with the U.S. Preventive Services Task Force evaluations. Several initiatives on colorectal cancer screening, HPV vaccine uptake, tobacco control policies, and the Implementation Science Centers in Cancer Control (ISC^3) compose the research on care delivery and implementation strategies.

DCCPS has active initiatives and partnerships NCI-wide, including a new concept co-developed with the Center to Reduce Cancer Health Disparities (CRCHD) focusing on health equity centers, to be introduced later in the meeting. DCCPS has numerous active initiatives with partners across the federal government, as well as other NIH Institutes and Centers (ICs). Dr. Goddard notes that these various partnerships have enabled DCCPS to support an additional $40 M in co-funding for NCI-assigned research grants.

As of 2022, DCCPS had 550 active investigator-initiated awards (e.g., R01, R37) within its research portfolio. Over the past 10 years, the cancer-control workforce pipeline has been strong, with 23 percent of R01 and R37 grants awarded to early-stage investigators. Population science monitoring and methods and technology research grants are least represented in the DCCPS portfolio.

Dr. Goddard expressed appreciation to Dr. Paul Jacobson, Associate Director, DCCPS, for his work in developing and growing the Healthcare Delivery and Implementation Science Research program over the past 7 years. Dr. Jacobson will be retiring at the end of December.

Future Priorities. Dr. Goddard explained that DCCPS leadership has spent the past year focusing on future priorities and has solicited input from various stakeholders. She noted three main principles that influenced its decision-making process. Adapt and remain nimble and flexible to recognize and act on emerging opportunities and community input. Build and leverage the strong foundation that the division has achieved. Create new opportunities to enable bold and innovative possibilities that are currently infeasible or impractical for a single investigator alone. Dr. Goddard detailed six crosscutting areas of focus that encompass these three principles; some key points and strategies are summarized below.

1. **Health equity** is focusing on attaining the highest level of health for all people, is distinct from health disparities, and requires investment at each step of the cancer control framework.
2. **Data gaps in cancer control** (e.g., social determinants of health [SDoH] data, patient-reported information) exist and are inhibiting the field's ability to conduct research. Overcoming these gaps requires effective strategies, including promoting FAIR (Findable, Accessible, Interoperable, Reusable) principles, fostering partnerships, and creating an infrastructure for storing and accessing data.
3. **Research in modifiable risk factors**—including smoking, obesity, physical activity, and alcohol use—has been a strength of the DCCPS. Research has identified 11 known risk factors that account for 44 percent of cancer deaths. Strategies to advance this research include identifying effective interventions and understanding if improvements alter risk.
4. **Climate change** is one example of an emerging opportunity to incorporate into the DCCPS portfolio, and climate disasters are becoming increasingly common and impactful. Across the

climate change exposure pathway, changes in air quality, water quality, sun and heat exposure, and food quality all affect cancer risks.

5. **Policy research** has enabled societal level policy changes, but focused on specific areas. Successful research will expand the types of policies that are being evaluated, build an evidence base to inform policy, and evaluate the impact of policies once they have been implemented.
6. **Digital health** and its tools can effectively improve patient safety, the quality of care, adherence to guidelines, interactions between clinicians and patients, and the patient experience. Strategies to advance digital health include training and workforce force development, investigating and addressing barriers to equity, and collaborating with federal partners.

In closing, Dr. Goddard emphasized that population-based strategies with an equity lens are essential to realize the full potential of medical discoveries and innovations that are developed throughout the NCI.

Questions and Answers

Dr. Karen M. Winkfield, Executive Director, Meharry-Vanderbilt Alliance, Ingram Professor of Cancer Research, Professor of Radiation Oncology, Vanderbilt University School of Medicine, asked how DCCPS is addressing the economics of health care when it comes to the underinsured and cancer screening, as well as connections to diagnostics. Dr. Goddard explained that economic analysis is within the purview of DCCPS and noted that funding of economics research by NIH has been inconsistent but highlights an opportunity to expand in this area. She agreed on the need to focus on getting people through all the steps of a comprehensive program her division might design.

IX. RFA/COOP. AGR. AND PAR CONCEPTS—NEW AND RE-ISSUE—NCI PROGRAM STAFF

Division of Cancer Biology/Division of Cancer Prevention

Cancer Immunoprevention Network (CIP-Net) (New RFA/Coop. Agr.)— Drs. Lillian Kuo and Altaf Mohammed

Dr. Altaf Mohammed, Program Director, Division of Cancer Prevention (DCP), NCI, presented the new RFA concept to establish CIP-Net, which was developed in collaboration with the Division of Cancer Biology (DCB). Dr. Mohammed explained that tumorigenesis is a continuum of a dynamic interaction between emerging aberrant cell clones and host tumor immune surveillance, from the earliest stage of tumor formation to the establishment of invasive cancers. Better understanding of early oncogenic processes and immune cell malignancy can provide insight into the immune pathways and basic mechanisms responsible for driving progressive tumor growth and weakening the host defense mechanisms.

Members were informed that the scientific objectives of CIP-Net are to support a deeper understanding of basic mechanisms of immunoprevention, discover novel immunoprevention strategies, and foster a community of cancer immunoprevention researchers. The RFA builds on Cancer Moonshot Immuno-Oncology Translational Network (IOTN)'s progress toward the Cancer Moonshot Immunology Working Group goal to prevent cancers before they occur. This research meets an emerging scientific opportunity to complement recent immunoprevention clinical trials by building a research pipeline of discovery science in basic mechanisms of immunoprevention. This initiative directly addresses the recommendations in the BSA *ad hoc* Working Group on Prevention report to encourage novel and innovative research designs to expedite progress in precision prevention.

CIP-Net will utilize the UG3 and UH3 funding mechanisms. The UG3 will enable the discovery and investigation of novel immune pathways, mechanisms, and innovative targets for immunopreventive intervention. Projects will be milestone driven, with the UG3-to-UH3 transition evaluated by NCI staff. The UH3 will encompass validation and deeper mechanistic interrogation of pathways, development, or preclinical testing to evaluate mechanisms, efficacy, and potential side effects.

Dr. Lillian Kuo, Program Director, DCB, NCI, explained that CIP-Net also will include a U24 resource coordinating center. The scientific objectives are to enhance CIP-Net data, resource sharing (e.g., biospecimens), and collaborations; provide bioinformatic and analytical support; increase awareness through scientific communications and meetings; conduct scientific outreach to build immunoprevention bridges across complementary cancer research communities; and foster career development of junior investigators. CIP-Net preclinical projects are expected to develop promising immunoprevention candidates that will advance into the NCI DCP PREVENT Cancer Preclinical Drug Development Program (PREVENT) and Cancer Prevention Clinical Trials Network (CP-CTNet) programs. The overall goal is to build this cancer immunoprevention research continuum starting with the UG3/UH3 research projects and complementing existing NCI research programs, such as the Human Tumor Atlas Network (HTAN).

Subcommittee Review. Dr. Robert H. Vonderheide, Director, Abramson Cancer Center, Vice Dean, Cancer Programs, Perelman School of Medicine, Vice President, Cancer Programs, University of Pennsylvania Health System, John H. Glick, MD Abramson Cancer Center Director's Professor, Perelman School of Medicine, University of Pennsylvania, expressed the Subcommittee's enthusiasm and support for the concept, which is filling a critical gap in immunoprevention research. Dr. Vonderheide commented that this RFA is a $48 M proposal to establish a network in cancer immunoprevention, which is a research area that is outpaced by immunotherapy in the NCI research portfolio. He expressed his excitement for the focus on revealing new biology in early malignancy, which is an area not otherwise funded. The two divisions (DCB and DCP) stewarding this RFA and using the UG3/UH3 mechanisms are employing strategic approaches likely to improve success. The Subcommittee appreciates NCI staff responses to its requests to clarify and refine specific definitions for prevention and immunoprevention research and to provide research examples. The Subcommittee is enthusiastic about the ability of CIP-Net to intersect with other DCB and DCP programs and initiatives and recommended including a go/no-go decision step in the drug development process.

The first-year cost for the one-time issuance is estimated at $4.25 M for five to six UG3/UH3 awards over three receipt dates, with a total cost of $48.25 M for of 10 to 12 UG3/UH3 awards combined with collaborative supplements in years 2–4.

Questions and Answers

Dr. Luis Alberto Diaz, Jr., Head, Division of Solid Tumor Oncology, Grayer Family Chair in Medicine, Department of Medicine, Memorial Sloan Kettering Cancer Center, called attention to a conference of interest, the American Association for Cancer Research (AACR) Special Conference: Precision Prevention, Early Detection, and Interception of Cancer. Dr. Diaz commented that this RFA is being proposed at an opportune time and is likely to attract interest in the research community. He suggested reviewing broad initiatives on early detection.

Motion. A motion to approve the DCB/DCP's new RFA/Coop. Agr. entitled "Cancer Immunoprevention Network (CIP-Net)" was approved unanimously.

Divison of Cancer Control and Population Sciences

Addressing the Needs of Cancer Survivors in Primary Care (New RFA/Coop. Agr.)— Dr. Michelle Mollica

Dr. Michelle Mollica, Deputy Director, Office of Cancer Survivorship, DCCPS, NCI, presented a new RFA concept on addressing the needs of cancer survivors in primary care. Dr. Mollica noted that the NCI considers an individual a cancer survivor from the time of diagnosis, through the balance of life, including those living with and without cancer. More than 18 million cancer survivors live in the United States, with 6 million surviving 5 years beyond a diagnosis. Recent research has demonstrated that more than two-thirds of cancer survivors receive care in primary care settings. Achieving high-quality care, delivered to improve outcomes and align with current evidence, is a critical goal from the time of diagnosis and beyond.

Dr. Mollica informed members that many organizations have solicited a shared model of survivorship care, in which components of care are shared among primary care providers and oncologists. Even though primary care providers and practices are willing to and several are providing care to survivors, they are confronted with substantial barriers, such as 1) limited access to actionable information on diagnosis and treatment history and 2) recommendations for follow-up care. Most often it is unclear as to who is responsible for specific components of care for survivors. Regular communication and coordination with oncology providers is lacking. The number of survivors living with cancer who have been treated with newer therapies and experience unique symptoms is growing. Current efforts to improve primary care for survivors have been limited, particularly those related to systematically implementing guidelines, survivorship care plans, effective interventions, and training. These challenges speak to the need for effective and sustainable strategies for transforming primary care for cancer survivors, which this concept will address.

The goal of this RFA is to stimulate the development and testing of practice and health system interventions that support and promote high-quality primary care for cancer survivors during and/or after the treatment period. Utilizing the U01 mechanism, the RFA aims to foster an ongoing collaborative care approach between primary care practices and oncology specialists. Applications should focus on assisting primary care providers in better delivering services that are germane to primary care, including effective management of common chronic conditions, promoting healthy lifestyle behaviors for survivors, and adhering to screening and surveillance guidelines.

Regarding evaluation criteria, all applications must extend beyond engaging individual primary care providers or integrating primary care into a cancer center workflow and should focus on primary care provider practices or health systems providing primary care. Research must include primary care providers delivering care to any adult survivor from the time of diagnosis forward, including any cancer stage. Applications should also incorporate meaningful endpoints (e.g., health care utilization) that show a strong interest in populations that experience disparities in health outcomes.

Subcommittee Review. Dr. Chandrakanth Are, Jerald L. and Carolyn J. Varner Professor in Surgical Oncology and Global Health, Associate Dean for Graduate Medical Education, University of Nebraska Medical Center, expressed the Subcommittee's support for the concept. Dr. Are noted some key reasons this research is essential. First, many patients are successfully surviving. Second, cancer care is becoming more advanced and more complex. Third, health care in general is becoming more fragmented. This RFA aims to improve coordination between the specialists and primary care physicians, thus reducing health care fragmentation. Dr. Are emphasized the importance of having a clinical lead who also has administrative experience but explained that the goal is not for the primary care provider to be an oncologist. The Subcommittee expressed that this RFA intends to reduce the time burden of primary care providers, seamlessly integrating survivor care into their workflows, and to make providing services

easier. Additionally, the Subcommittee recommended adding language to the RFA text to highlight how primary care physicians improve patient care by helping one another.

The first-year cost for the one-time issuance is estimated at $5 M for six U01 awards, with a total cost of $25 M for 5 years.

Questions and Answers

Dr. Howard J. Fingert, Consultant, suggested that the NCI consider engaging industry experts, such as medical affairs groups, that develop programs for continuing care of clinical participants after a study has ended. Dr. Fingert also highlighted examples in other countries where the overall care of patients was improved by the assistance of care navigators, who were assigned to help the general practitioners better understand how to identify, follow up, and care for patients once they leave specific clinical protocols.

Dr. Doescher indicated that, based on his experience working with rural Tribes in the United States, it would be ideal to have nurse navigators or care coordination navigation champions at the primary care level who can spend critical time collecting sensitive information from oncology groups. He also emphasized exploring a mechanism that encourages active involvement of oncology teams where they reside (i.e., in the community).

Dr. Ulrich suggested engaging key health care providers and paying careful attention to health disparities that could be further exacerbated, such as health literacy and access to care.

Dr. Andrew T. Chan, Chief, Clinical and Translational Epidemiology Unit, Massachusetts General Hospital (MGH), Director of Epidemiology, MGH Cancer Center, Daniel K. Podolsky Professor of Medicine, Harvard Medical School, commented on the importance of having the primary care provider as a champion for cancer survivorship and suggested including other health care professionals, such as nutritionists, as part of the primary care team.

Dr. Shelton Earp, Director, University of North Carolina (UNC) Lineberger Comprehensive Cancer Center, Director, UNC Cancer Care, The University of North Carolina at Chapel Hill, commented that care can vary by region of the country and noted that the rates of endometrial cancers are rising faster than other cancers. Dr. Earp suggested including gynecologists in the primary care team, along with internists.

Dr. Chyke Doubeni, Professor, Department of Family and Community Medicine, Associate Director, Diversity, Equity, and Inclusion, The Ohio State University Comprehensive Cancer Center, Chief Health Equity Officer, Wexner Medical Center, Director, Center for Health Equity, The Ohio State University, commended the NCI for sponsoring this RFA to support the role of primary care in cancer survivorship care. He emphasized not solely relying on primary care providers for the success of the program but better understanding all that is necessary for such success.

Dr. Volchenboum remarked on the opportunity to involve survivors of pediatric cancers because of the current efforts being done in conjunction with the Cancer Moonshot and the CCDI, especially the technology being developed that could help enable survivorship coordination. Dr. Mollica explained that, after discussions of the scope, the NCI decided to focus this RFA on adult survivors of cancer and to include adult survivors of childhood cancers as well.

Dr. Knudsen noted that even in an integrated health system, cancer survivors can have challenges moving beyond the oncology clinic when the time comes. She suggested examining a model for the transition of cancer survivors from oncology care to primary care.

Motion. A motion to approve the DCCPS' new RFA/Coop. Agr. entitled "Addressing the Needs of Cancer Survivors in Primary Care" was approved unanimously.

The Impacts of Climate Change Across the Cancer Control Continuum (New PAR)— Dr. Curt DellaValle

Dr. Curt DellaValle, Program Director, DCCPS, NCI, presented a new PAR concept on the impacts of climate change across the cancer control continuum. Dr. DellaValle informed members that NIH has a history of soliciting research on climate change, and that the NIH Climate Change and Health Initiative recently published several FOAs. The intent of this PAR is to leverage the existing efforts and framework. Climate change is a process of long-term shifts in weather patterns, largely from anthropogenic (i.e., human-caused) processes. These long-term changes have environmental impacts (e.g., heat waves, wildfires, droughts, flooding, extreme weather events) that affect exposure pathways over time, resulting in consequences for health across the cancer control continuum from etiology to survivorship. Recent reviews examining the impact of climate change in cancer have consistently identified threats from changing carcinogenic exposures, alterations to food supplies and diet, and behavioral factors, as well as disruptions to health care systems.

The aims of this PAR are to 1) stimulate and support climate change and cancer risk and control research and 2) create a portfolio that addresses questions on cancer etiology and control with respect to climate change. This PAR will support R01 and R21 mechanisms and is intended to promote observational and intervention research to understand and address the impacts of climate change on cancer risk, cancer control, and survivorship. It is anticipated that this research will advance the understanding of the impacts of climate change on cancer etiology and outcomes, mitigate the potential impacts of cancer care, address cancer health inequalities, and spur needed interdisciplinary collaborations.

Subcommittee Review. Dr. Bondy expressed the Subcommittee's strong support and enthusiasm for the concept, which is addressing critical research for the NCI. Dr. Bondy remarked that the NCI and NIH are recognizing the impact of climate change on cancer control as a major issue that has the potential to affect the U.S. population, regardless of region. The effects of extreme weather and climate change are not well understood. The Subcommittee appreciates the NCI staff responses to their request to have a more directed granting opportunity and to reorder the RFA text. The Subcommittee recommended collaborating with other NIH ICs and other federal agencies, such as the U.S. Environmental Protection Agency, to expand the NCI climate change initiative for a broader impact.

Motion. A motion to approve the DCCPS' new PAR entitled "The Impacts of Climate Change Across the Cancer Control Continuum" was approved unanimously.

Understanding Expectancy in Cancer Symptom Management (New PAR)—Dr. Rebecca Ferrer

Dr. Rebecca Ferrer, Program Director, DCCPS, NCI, presented a new PAR concept on understanding expectancies in cancer symptom management. With advances in treatment, the number of cancer survivors in the United States is growing and thus translates to more people experiencing cancer-related symptoms. These symptoms include pain, fatigue, nausea, cognitive effects, emotional distress, and poor sleep. Despite evidence-based protocols, many patients have unmet symptom management needs. Stark and pervasive disparities in symptom management affect patients from medically underserved groups. Harnessing expectancies may help address these unmet needs.

Dr. Ferrer explained that expectancies include beliefs about treatment efficacy, prognostic beliefs, perceived likelihood of symptoms and side effects of cancer, and cancer treatments. Clinicians routinely leverage the expectancy effect in cancer care, often intuitively, rather than being systematically informed by an evidence-based of expectancy-generating factors. For example, expectancies may be generated

when a clinician expresses confidence, empathy, encouragement, optimism, or vagueness. The expectancies of caregivers and clinicians also influence patient outcomes. The magnitude of cancer symptom treatment–efficacy resulting from expectancy versus active treatment is not well known and has been shown to vary depending on treatment and symptoms. Disparities in expectancy effects exist, and these effects are likely unevenly distributed to medically underserved racial and ethnic groups; however, research on expectancy effects among medically underserved groups is limited.

The purpose of this PAR is to support the systematic study of expectancy-generating factors and measure their effects on expectancies and symptom outcomes. Projects will identify potential factors that can be engaged to change target expectancies and subsequent outcomes. Because expectancy effects are variable, projects should also consider potential moderators elucidating the types of symptoms, treatments, and patients that may control these causal links.

Subcommittee Review. Dr. Leslie Robison expressed the Subcommittee's support for the concept. Dr. Robison remarked on how this research is addressing often-overlooked nontherapeutic aspects and strategies for improving cancer-related symptoms that can negatively affect the outcome and quality of life of cancer patients. The Subcommittee is confident that scientific and rigorous investigation of the mind–body connection can inform clinical practice and the design and implementation of approaches to improve cancer care going forward. In addition, the Subcommittee commends the broad scope of this PAR to focus on the individual cancer patient as well as health care providers, physicians, nurses, family members, and caregivers. The NCI program staff was encouraged to clearly define or provide examples of the goals of the targeted expectancies, the clinical trial designs that will fulfill the requirements, specific symptoms or symptom clusters that might be considered of high priority, and deceptive versus nondeceptive interventions.

Questions and Answers

Although expectancies is a psychological term used by psychologists in behavioral studies, Members suggested defining the term within the context of this PAR on managing cancer symptoms or considering using a less vague, more salient term.

Motion. A motion to approve the DCCPS' new PAR entitled "Understanding Expectancy in Cancer Symptom Management" was approved unanimously.

WEDNESDAY, 7 DECEMBER 2022

X. CALL TO ORDER AND OPENING REMARKS—DRS. JOHN D. CARPTEN AND KEITH T. FLAHERTY

Dr. Carpten called Members to order on the final day of the 7th Virtual Joint Board Meeting of the BSA and NCAB and welcomed members of the Board, *ex officio* members, President's Cancer Panel members, liaison representatives, staff, and guests.

XI. MULTIPLE MYELOMA AND DISPARITIES—DR. IRENE GHOBRIAL

Dr. Irene Ghobrial, Lavine Family Chair of Preventative Cancer Therapies, Dana–Farber Cancer Institute, and Professor of Medicine, Harvard Medical School, presented an update on clinical health disparities in multiple myeloma. Dr. Ghobrial explained that multiple myeloma is organ damage resulting from the presence of malignant cancer cells in bone marrow. Patients also exhibit four features that are associated with end-organ damage linked to myeloma progression: calcium elevation, renal insufficiency, anemia, and bone lesions. Multiple myeloma has an incidence rate of approximately 35,000 cases per year in the United States and always is preceded by one of two conditions: monoclonal gammopathy of

undetermined significance (MGUS) or smoldering multiple myeloma (SMM). Approximately 10 percent of patients with SMM will develop multiple myeloma; in certain high-risk populations of patients with SMM, the chances of developing multiple myeloma within 2 years are roughly 50 percent. MGUS is prevalent in approximately 3 percent of the U.S. population aged 50 and older; Black and African American populations and people with a first-degree relative who has been diagnosed with any B-cell malignancy have approximately two- to threefold chance of developing MGUS or having multiple myeloma.

Multiple myeloma is the most common blood cancer in Black and African American populations. This elevated risk can be attributed to increased incidence rates of the precursor conditions, rather than a more rapid disease progression. Currently, one of every five patients diagnosed with multiple myeloma is Black or African American, and this prevalence is expected to increase. Multiple myeloma also is more common in younger Black and African American patients, but because of decreased access to quality health care and other underlying conditions, this patient population is less likely to be diagnosed than other populations. Despite recent treatment advances, Black and African American patients do not have equitable access to combination drug therapy, chimeric antigen receptor (CAR) T-cell therapy, bone marrow transplants, or clinical trials. Survival of Black and African American patients with multiple myeloma is approximately half that of White/Caucasian patients. Several studies demonstrate that, compared with White/Caucasian patients, Black and African American patients with multiple myeloma exhibited equal outcomes when they received equitable care. According to limited germline sequencing data, Black and African American patients demonstrate a higher prevalence of the translocations t(11;14), t(14;16), and t(14;20); a lower prevalence of the deletions 1q gain and 13q and 17p; and lower genetic signatures that usually accompany a better prognosis.

Dr. Ghobrial advocated increasing early screening and treatment of multiple myeloma, especially since high-risk patients often are not screened and treatment often is delayed until patients exhibit evidence of organ damage. Multiple myeloma can be detected early and accurately using blood tests. Dr. Ghobrial emphasized that this "watchful waiting" paradigm must change, and that early screening and intervention efforts should be implemented. One such effort is the Dana–Farber Cancer Institute–led Predicting Progression of Developing Myeloma in a High-Risk Screened Population (PROMISE) study, a nationwide effort to screen high-risk patients, including people of African descent, for MGUS and SMM. Dr. Ghobrial is principal investigator, and Stand Up to Cancer, the Broad Institute, and Massachusetts Institute of Technology are collaborators. The aim is to understand why multiple myeloma precursor conditions are more prevalent and present earlier in certain populations. These efforts involve a genetics and genomics team to develop novel diagnostic biomarkers, an epidemiology team to establish new risk stratification tools, an imaging and therapeutics team to generate new tools to prevent disease progression, and a bone marrow niche team to study dysregulation of the immune system using single-cell sequencing.

Patients enrolled in PROMISE must be 30 years of age or older and must either self-identify as African American or be a first-degree relative of a patient with blood cancer. Enrollment is completed online, and patients receive a kit to perform a scheduled blood collection. When test results are positive for MGUS or SMM, patients are informed over the telephone and provided with guidance related to care. Patients with negative test results are informed via email and invited to be screened again in 3 years. The COVID-19 pandemic delayed efforts of the PROMISE study, but recent outreach at the federal, state, and local levels has been successful. Representatives of the study attended the 2022 Indiana Black and Minority Health Fair and enrolled 177 participants, including one patient who was diagnosed with multiple myeloma and able to receive care within the week. During the pandemic, outreach efforts also included virtual educational sessions and other events to build trust with communities across the country. Globally, the PROMISE study currently has 12,592 enrolled participants who have submitted more than 10,000 samples for screening, with a positivity rate of 12.6 percent. More than 6,000 participants are located in the United States and are responsible for submitting more than 250 samples for screening.

Study recruitment efforts are ongoing in South Africa and the United States, and arrangements to establish outposts in such locations as Ghana, Israel, and Kenya are being made.

Dr. Ghobrial highlighted recent findings of the PROMISE study of a published report of 2,439 African American and 3,086 first-degree family study participants and the Mass General Brigham Biobank. An analysis of patient samples using mass spectrometry was able to detect MGUS more accurately than serum protein electrophoresis. Mass spectrometry also enabled the detection of an MGUS-linked monoclonal protein in a significant number of cases (20 percent of samples). Patients with detectable amounts of this protein were diagnosed with a novel precursor condition, termed monoclonal gammopathy of indeterminate potential (MGIP). The prevalence of MGIP and MGUS increased with the age of participants and also was higher in the African American study population than in other participants. Using the mass spectrometry technique, 13 percent of people aged 50 and older were positive for MGUS and 15 percent were positive for MGIP. Patients with monoclonal gammopathies had significantly worse survival and increased association with all-cause mortality when compared with control patients. Dr. Ghobrial briefly reviewed unpublished preliminary data indicating that the mass spectrometry screening might be useful for the early detection of several B-cell malignancies and, possibly, even autoimmune diseases.

Dr. Ghobrial described additional efforts related to risk stratification among patients diagnosed with multiple myeloma precursor conditions. Using whole-exome sequencing of patients with SMM, her group identified three genomic alterations associated with rapid progression to myeloma: myelocytomatosis oncogene alterations, mitogen-activated protein kinase pathway mutations, and DNA repair mutations. Another study involved whole-genome sequencing of circulating tumor cells to identify DNA translocations and characterize clonal evolution within MGUS and SMM patient samples. Whole-genome sequencing of circulating tumor cells was as effective at detecting translocations and copy number abnormalities associated with multiple myeloma as fluorescence *in situ* hybridization, which has been performed using invasive bone marrow biopsies as part of routine myeloma screening for the previous 50 years. Dr. Ghobrial also highlighted efforts to understand compositional changes in the immune system that occur with multiple myeloma. Single-cell RNA sequencing identified transcriptional changes in bone marrow and peripheral blood cells in both SMM and MGUS samples. Efforts are underway to identify transcriptional changes that are hallmarks of malignancy.

Dr. Ghobrial closed with a description of intervention efforts for patients diagnosed with precursor conditions. SMM patients who receive a combination treatment of lenalidomide and dexamethasone have improved survival when compared with control patients. Current and future efforts include interventions in MGUS patients, immunotherapy, and precision interceptions to target particular genetic signatures, as well as traditional and mRNA vaccines. Dr. Ghobrial highlighted the Immuno-PRISM (or PRecision Intervention Smoldering Myeloma) study, a randomized Phase 2 platform study of treatment with bi-specific antibodies in patients with high-risk SMM. She noted that the first six patients have responded positively to the antibody treatment, which is being given in the absence of chemotherapy or other drugs. Another study, the CAR-PRISM study, will be recruiting participants in the near future to investigate the use of ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy,in patients with high-risk SMM.

Questions and Answers

Dr. Otis W. Brawley, Bloomberg Distinguished Professor of Oncology and Epidemiology, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, noted the substantial number of people in Atlanta, Georgia, who have been diagnosed with multiple myeloma and have no access to treatment. The NCI could consider sponsoring studies to show that a significant number of Americans have cancer that is treatable but receive less than the optimum treatment or no treatment.

Dr. Friese noted the significant progress in understanding multiple myeloma but added that the progress has not been equitable. A better understanding of the structural issues that lead to patients' being unable to afford treatment and targeted interventions to ensure that patients receive therapies are both needed.

When asked about plans for collecting data related to cost of treatment for multiple myeloma, Dr. Ghobrial stated that her group currently is conducting a study on the benefits of early treatment, explaining that, in many cases, patients are diagnosed only at the later stages of the disease; at that point, they often are unable to work. Early detection and treatment would enable people to avoid many financial barriers encountered later on in the progression of the disease.

In response to a question from Dr. Becich about ways to collaborate with patient advocacy organizations, such as the Multiple Myeloma Research Foundation (MMRF), Dr. Ghobrial responded that PROMISE has worked closely with MMRF, the International Myeloma Foundation, and Stand Up to Cancer to collect patient data for both MGUS and SMM. PROMISE also is collaborating with Cancer Research United Kingdom and the Leukemia & Lymphoma Society on translational myeloma research efforts, including bringing clinical trials to local community cancer centers.

Dr. Chan asked about broadening the early detection and treatment approach to include other forms of cancer and about ensuring equitable enrollment in clinical trials related to MCED screening. Dr. Ghobrial affirmed that efforts are underway to expand the PROMISE program into all blood cancers. Her group is interested in developing immune-cell sequencing as an MCED, in addition to evaluating the commercially available MCED techniques. She explained that the PROMISE program could aid in efforts to integrate MCED detection into blood cancer diagnoses in a way that is equitable across all populations.

XII. *AD HOC* WORKING GROUP REPORT ON STRATEGIC APPROACHES AND OPPORTUNITIES FOR RESEARCH ON CANCER AMONG RACIAL AND ETHNIC MINORITIES AND UNDERSERVED POPULATIONS—DRS. ELECTRA D. PASKETT, CHYKE A. DUOBENI, AND ELENA MARTINEZ

Dr. Elena Martinez, Professor, Herbert Wertheim School of Public Health & Human Longevity Science, University of California San Diego, reminded the BSA and NCAB members that the NCAB *Ad Hoc* Subcommittee on Population Science, Epidemiology, and Disparities had convened the *Ad Hoc* Working Group on Strategic Approaches and Opportunities for Research on Cancer Among Racial and Ethnic Minorities and Underserved Populations (Working Group) to advise on strategic approaches and opportunities for research on cancer among racial and ethnic minorities and underserved populations. The Working Group was charged with identifying and evaluating the current status of—and barriers to progress on—cancer research on racial and ethnic minorities and underserved populations, as well as potential strategic approaches to better support such research. These population groups included Black or African American, Hispanic/Latino, American Indian/Alaska Native, Asian/Pacific Islander, rural, older adult, LGBTQ+, and adolescent and young adult (AYA) populations.

Dr. Martinez, Dr. Chyke Doubeni, and Dr. Electra D. Paskett, Marion N. Rowley Professor of Cancer Research, Director, Division of Cancer Prevention and Control, Department of Internal Medicine, College of Medicine, The Ohio State University, served as co-chairs of the Working Group. Dr. Martinez acknowledged and expressed appreciation to the Working Group members—including the Executive Secretary, Dr. Philip E. Castle—for their efforts. Dr. Martinez noted that the first Working Group meeting took place in July 2021, continued monthly to discuss progress, and featured speakers from various NCI centers and divisions, including the Center for Research Strategy (CRS), DCCPS, and CRCHD. The co-chairs presided during the monthly Working Group meetings and also met monthly to discuss the agenda and next steps.

Data Methods and Analysis. Dr. Martinez presented an outline of the Working Group's report and reviewed background information and the methodology used to produce the data and analysis. She reviewed the concept of multilevel frameworks, which are developed to guide interventions and other strategies to enhance cancer outcomes and achieve equity among populations that experience disparities. The Working Group examined research across the cancer control continuum (i.e., etiology, prevention, detection, diagnosis, treatment, survivorship) to identify gaps where attention is warranted. Crosscutting areas of research included communications, surveillance, health disparities, decision-making, implementation science, health care delivery, epidemiology, and measurement.

Dr. Martinez expressed appreciation to the CRS project team, Drs. Christine Burgess, Health Scientist Administrator; Joshua Collins, Scientific Program Analyst; and Diane Palmieri, Acting Director, for their contributions to evaluating the NIH cancer research grant portfolio and identifying cancer research relevant to the populations of interest. The CRS team leveraged machine learning algorithms to evaluate all NIH grants from FY 2021 and identify all FY 2021 cancer research grants (i.e., NIH cancer comparator). From this group of grants, the team identified specific cancer research project proposals and projects of interest to relevant populations using appropriate Research, Condition, and Disease Categorization (RCDC) system categories. The resulting list of grants was shared with the Working Group to obtain feedback on which grants were truly relevant, and a final list of projects was compiled. Grants were categorized along the cancer research continuum using International Cancer Research Partnership (ICRP) Common Scientific Outline (CSO) codes. Grant exclusion criteria included award supplements; international and domestic training and career grants; P30 awards to Cancer Centers; NCI Community Oncology Research Program (NCORP) awards; international projects (e.g., Fogarty International Center grants, Center for Global Health grants, grants with foreign countries in the title); and subproject cores.

Dr. Martinez elaborated on the RCDC system, which NIH utilizes in its reporting process to categorize funding in biomedical research for each fiscal year. Automated text mining of projects produces a weighted list of RCDC concepts (referred to as a project index) from the RCDC Thesaurus. RCDC categories are weighted with lists of concepts that define a research area, condition, or disease. Category concepts are matched to project indices to produce the category project listing. Dr. Martinez discussed the categorization of research along the cancer continuum using ICRP CSO codes, which are determined using a machine learning model and are used to apply a common language for discussing, comparing, and presenting cancer research portfolios. Applications and base projects can be assigned to more than one category. CSO codes include "biology"; "etiology"; "prevention"; "early detection, diagnosis, and prognosis"; "treatment"; and "cancer control, survivorship, and outcomes research." In some cases, the information in an application is insufficient to assign that grant to a particular category.

NIH Portfolio Results. Dr. Paskett presented the results of the FY 2021 portfolio analysis. After initiating the search process with roughly 9,650 cancer-related FY 2021 NIH base projects (75 percent NCI-funded), approximately 7,300 base projects (74 percent NCI-funded) remained when exclusions had been removed. This collection of projects, the NIH cancer research portfolio or NIH cancer comparator, was further refined using RCDC categories and concepts to generate FY 2021 NIH cancer research portfolios for each population of interest. Dr. Paskett presented a list of FY 2021 extramural base projects for populations of interest from all ICs, as well as the total number of base projects administered by the NCI for each population. For example, of 310 total NIH grants related to Black or African American populations (4.23 percent of 7,327 total NIH cancer grants), 246 were administered by the NCI (4.55 percent of 5,412 total NCI cancer grants). Thus, 246 of 310 (or 79 percent) of all FY 2021 NIH cancer grants related to Black or African American populations were administered by the NCI.

Dr. Paskett highlighted Table 1 (FY 2021 Extramural Base Projects for Populations of Interest), which includes NIH portfolio base projects classified within ICRP CSO categories across the cancer continuum. Of the 7,327 total NIH cancer grants, 42.7 percent were classified as biology; 12.9 percent as

etiology; 6.1 percent as prevention; 19.7 percent as early detection, diagnosis, and prognosis; 41.1 percent as treatment; 9.8 percent as cancer control, survivorship, and outcomes research; and 8.2 percent were not categorized. By contrast, of the 310 NIH cancer grants that focused on Black or African American populations, 26.5 percent were classified as biology; 37.4 percent as etiology; 18.7 percent as prevention; 24.8 percent as early detection, diagnosis, and prognosis; 14.8 percent as treatment; 31.0 percent as cancer control, survivorship, and outcomes research; and 10.0 percent were not categorized. When compared with the total NIH cancer portfolio, grants focused on the populations of interest were less likely to be classified under the biology or treatment CSO codes.

Dr. Paskett summarized the Working Group's findings. The Working Group report uncovered an imbalance in research funding relative to the distribution of cancer diagnosis, morbidity, and death in the United States. Relative to the overall NIH portfolio, investment was small for research focused on racial and ethnic minorities, rural populations, and the other groups evaluated, and this underrepresentation existed across both the continuum of science and the human life span. Within identified research associated with populations of interest, proportionally more projects in population sciences and fewer biological and clinical research studies were observed. Many projects draw on a limited number of underserved population groups, constraining the applicability of the current knowledge base. Information was lacking for some population groups because of limited disaggregated data in those groups (e.g., Pacific Islander population); populations being understudied (e.g., LGBTQ+ population); or the population group not being identified as a distinct group within the current research inventory at NIH (e.g., AYA, older adults). Dr. Doubeni emphasized that these factors considerably limited the Working Group's ability to complete the charge to the same degree for all population groups.

Summary of Recommendations. Dr. Paskett summarized the Working Group recommendations. Specific recommendations in the areas of funding, data collection, monitoring and evaluation, and reporting were provided. These are to (1) expand or initiate RFAs, FOAs, investigator-initiated awards (e.g., R01s, P01s), and supplement opportunities with an intentional focus on eliminating disparities and inequities in the funded grant portfolio; (2) adopt and standardize a checklist for NIH grants to identify populations that are included, and develop standards for reporting disaggregated data for all races and ethnicities; (3) develop effective and efficient strategies for tracking, monitoring, and evaluating the federal investment in advancing cancer health equity to address the gaps in health disparities identified in the report; and (4) create an annual report of activities in this area and provide congressional briefings on the state of cancer health equity.

Broader recommendations in the areas of implementation strategy, frameworks for inclusive research, resources, uniform measures, intentionality, and ongoing NCI training efforts also were provided. These are to (1) establish a set of guiding principles and priorities to move the Working Group recommendations into action; (2) utilize a framework for research that relates to the practice of inclusive cancer research and includes implementing strategies to increase funding to diverse and underrepresented investigators; (3) ensure that a portion of grants is focused on the underserved and underrepresented populations included in this report; (4) implement a set of core elements to facilitate the analysis and reporting of progress in research across the continuum by each of the populations included in this report; (5) accelerate research by offering funding opportunities in areas across the cancer continuum that specifically enhance the understanding of why disparities in cancer outcomes exist for certain groups and how to eliminate these disparities and achieve health equity in these groups; and (6) realize the goal of increasing diversity at all levels of the cancer workforce.

Questions and Answers

Dr. Hayes Dixon asked about grants to support young investigators, which Dr. Paskett agreed to include in the Working Group's recommendations.

Dr. Doescher commented on the need for data-sharing agreements to accommodate Tribal sovereignty in the case of patients being treated in an Indian Health Service, Tribal, or Urban Indian Health Program setting. He also emphasized the need to clarify definitions (e.g., urban) in the analyses of research portfolios; Dr. Paskett agreed and added that the RCDC code "Rural" was used in the analysis.

Dr. Gloria D. Coronado, Mitch Greenlick Endowed Scientist in Health Disparities Research, Kaiser Permanente Center for Health Research, asked about the Working Group's recommendations for tracking and reporting minority representation in clinical trials. Dr. Paskett responded that tracking and reporting on representation in clinical trials were not considered in the Working Group report but should be a topic of focus in the future. Dr. Doubeni added that the Working Group's recommendations around inclusive research would be important for the NCI to track. Dr. Bondy added that the Working Group had discussed the incorporation of a checkbox to help identify NIH grant submissions related to populations of interest.

Motion. A motion to accept the Report of the NCAB *ad hoc* Working Group on Strategic Approaches and Opportunities for Research on Cancer Among Racial and Ethnic Minorities and Underserved Populations" was approved was approved with 14 ayes, 0 nays, and 1 abstention. The vote was later changed to "unanimous" as it was clarified that only NCAB members were eligible to vote.

XIII. RFA/COOP. AGR., AND PAR CONCEPTS—NEW AND RE-ISSUE—NCI PROGRAM STAFF

Division of Cancer Control and Population Sciences/Center to Reduce Cancer Health Disparities

Advancing Cancer Control Equity Research Through Transformative Solutions (New RFA/Coop. Agr.)—Dr. April Oh

Dr. April Oh, Senior Advisor, Implementation Science and Health Equity, DCCPS, NCI, presented a new RFA concept on advancing cancer control equity research through transformative solutions, which was developed in collaboration with the CRCHD. Despite considerable advances in cancer research, disparities persist. Black/African American women are nearly two times more likely to be diagnosed with, and die from, triple-negative breast cancer and multiple myeloma than other women, partly due to late-stage diagnoses. Women in rural areas are twice as likely to die from cervical cancer, driven, in part, by social determinants of health (SDOH). Without addressing these complex social, economic, and environmental drivers, cancer control interventions will have minimal impact on reducing these disparities or advancing equity. Advancing cancer control equity is connected to an understanding of SDOH. Researchers have illustrated that upstream social structures, inequalities, and social determinants have a multilevel impact on living environments as well as on behavioral, psychologic, and health care risk factors, and, ultimately, cancer disparities.

This RFA aims to address cancer control equity research gaps by integrating four areas of science: SDOH, community engagement, capacity-building, and multilevel interventions. The purpose is to advance cancer control equity research by using community engagement to develop interventions that target the multilevel pathways affecting SDoH; develop measures, evaluate, and assess community-level SDOH community engagement and cancer control equity process and outcomes; and build capacity among diverse scholars and community partners to implement interventions that incorporate the lived experiences of those who may face cancer inequalities.

The NCI is proposing a U19 research center design comprising four cores: administrative; research; methods, measures, and data; and capacity building. Each center will be designed around the proposed cancer control health equity research theme. Each center will conduct at least one large-scale SDOH intervention trial relevant to its research theme that intervenes on one or more SDOH. A pilot

project will be conducted to inform the SDOH intervention. This RFA also will support one U24 coordinating center to advance the synthesis of cancer control equity research products and practices developed across the research centers. Evaluation criteria will consist of short-term (years 1 and 2) accomplishments, including delivery of capacity-building activities and reach to underserved populations, and long-term (years 3 through 5) goals related to the dissemination of tools and interventions.

Subcommittee Review. Dr. Brawley expressed the Subcommittee's enthusiasm and strong support for the concept, which is proposing projects to elucidate ways to provide adequate care to humans. Dr. Brawley called attention to similar research by the Southwestern Oncology Group (commonly called SWOG) revealing that equal treatment yields equal health outcomes for people in equal standing. This RFA aims to catalyze new research in this area. The Subcommittee thinks that the U19 mechanism is appropriate for this concept and appreciates the NCI staff responses to their concerns on interacting with other NCI and NIH initiatives.

The first-year cost for the one-time issuance is estimated at $10.5 M for four U19 awards and one U24 award, with a total of $52.6 M for 5 years.

Questions and Answers

Dr. Bertagnolli commented that the reignited Cancer Moonshot is engaging an all-of-government approach, noting that the NCI does research and that this research must lead the way, which speaks to the implementation. This cancer control equity research is one area that the NCI can have significant impact for health.

Dr. Doubeni suggested ensuring that community-engaged research in the context of this RFA aligns with the Centers for Disease Control and Prevention's Principles of Community Engagement and other groups doing similar research, such as the National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Awards Program.

In response to a question from Dr. Mustian about the research centers' modeling other networks (e.g., NCORP), Dr. Oh explained that the intent is for the U19 centers to function as a network, with the coordinating center facilitating cross-collaborations on specific scientific areas, such as measures development and multilevel interventions.

Dr. Lopez suggested encouraging investigative teams to explore diseases beyond cancer that are likely to be affected by the SDoH-related interventions, and Dr. Ulrich emphasized incorporating ways to engage the broader community to rapidly benefit from the expertise of the U19 centers.

Motion. A motion to approve the DCCPS'/CRCHD's RFA/Coop. Agr. entitled "Advancing Cancer Control Equity Research Through Transformative Solutions" was approved unanimously.

Division of Cancer Prevention

Discovery and Development of Natural Products for Cancer Interception and Prevention (New RFA/Coop. Agr.)—Dr Altaf Mohammed

Dr. Mohammed presented a new RFA concept for the discovery and development of natural products for cancer interception and prevention, which is co-sponsored by the NCI DCP and DCTD, and NCATS. Cancer prevention and interception remains the most promising strategy for cancer control for reducing cancer incidence and mortality. The need for more effective and safer cancer interception and prevention agents remains high. In natural product discovery research, a new discovery program for cancer interception and prevention is needed. The natural products field continually reviews grants investigating the same agents, primarily due to a lack of innovation and targeted natural products. Discovery research, especially for prevention, is inherently high risk and high reward, and the potential

for identifying a notable drug is relatively low. Reduced resources and fewer opportunities for discovery research expansion are significant challenges that should be addressed.

Currently, no NCI programs or initiatives support natural product discovery research activities at the level necessary. The unique resources available from the NCI and NCATS, such as quality control and informatic expertise, compensate for many of the deficiencies of historical discovery approaches. No other program in the scientific community, including those facilitated by pharmaceutical companies, is doing this work. Given the high level of attrition in this field, the need to expand the base of discovery is critical.

The NCI is proposing this RFA to use the UG3/UH3 bi-phasic mechanism to support the discovery and development of novel, safe, nontoxic, and efficacious natural products for cancer interception and prevention. The NCI has one of the world's largest, most diverse collections of natural product extracts, with more than 500,000 collected from various plant, marine, and microbial sources. The NCI Program for Natural Products Discovery (NPNPD) is a Cancer Moonshot–funded program designed to stimulate research in natural products. NPNPD is producing a library of 1 million partially purified natural product fractions that will be readily available to the research community for use at no cost.

NCATS, with its cutting-edge technologies, frequently collaborates with NIH and external investigators to perform complex screening programs. The opportunity exists to integrate the novel resources and expertise of the NCI and NCATS for the discovery of natural products with useful cancer-prevention activity.

This RFA is soliciting UG3 research proposals of milestone-driven studies for target selection and verification (preclinical and clinical); assay development and validation; prototype high-throughput screening, and pilot screening. The UH3 phase may be awarded for the full-scale high-throughput screening and assessment of the screened natural product's mechanism of action *in vitro* and *in vivo*. Promising agents with *in vivo* efficacies and low toxicities can enter the NCI PREVENT pipeline for advanced preclinical development. Successful agents will advance to clinical trials through the DCP CP-CTNet program. Dr. Mohammed highlighted examples of potential molecular targets for cancer interception that play key roles during early stages of tumorigenesis, including microsomal prostaglandin E synthase-1.

Subcommittee Review. Dr. Erle S. Robertson, Harry P. Schenk Endowed Chair Professor, Vice-Chair, Department of Otorhinolaryngology, University of Pennsylvania School of Medicine, expressed the Subcommittee's support for the concept, which is addressing an unmet need of applying platform technologies to prevention research. The Subcommittee appreciates the NCI staff responses to its concerns to clearly define the NCI's role in the available resources of the NPNPD and the criteria for transitioning from a UG3 to UH3 grant.

The first-year cost for the one-time issuance is estimated at $2.25 M for four UG3 awards and resources and subsequently two UH3 awards in years 4–5, with a total of $23.35 M for 6 years.

Questions and Answers

Dr. Chan asked how this program would ensure that natural products with less clear molecular mechanisms, but that are still effective agents, advance within the discovery pipeline. Dr. Mohammed noted that most natural products do not have one single target and will have off-target effects. The strategy is to select a clinically relevant target, perform target validation for interception, and screen the agents. The principal investigators will be asked to propose relevant clinical targets to screen.

In response to questions from Dr. Vonderheide regarding the track record indicating that the compounds in the NPNPD are viable and the rationale for developing natural products to investigate interoception, Dr. Castle explained that the initial aim is to leverage NCATS' prior efforts with natural products; he noted that other chemical libraries can be considered in the future. Dr. Barry R. O'Keefe, Director, Molecular Targets Program, Center for Cancer Research (CCR), NCI, highlighted some recent accomplishments of the NPNPD. An anti-cancer agent developed in collaboration with Baylor University and Texas Children's Hospital identified a new natural product that was effective and capable of shrinking tumors. Anti-SARS-COV-2 agents (biologics, small proteins, and peptides) successful in Phase 1 studies recently advanced to the clinic. Recent discoveries of natural product novel kinase inhibitors for use with fibrolamellar hepatocellular carcinoma are in development in the CCR. Dr. O'Keefe noted that 80 percent of the molecules and natural product fractions contained in the NPNPD previously screened for cytotoxicity and deemed active were not active when the crude extracts were tested; most of the chemistry being observed now was not determined in those earlier assays. It is anticipated that chemical diversity of the NPNPD library will provide insight into new targets addressed in chemoprevention.

Dr. Tuveson suggested exploring new methods, such as click chemistry, to identify which proteins are interacting with the natural products being developed and to leverage the expertise of the NCI RAS Initiative team, which is utilizing similar methods.

Motion. A motion to approve the DCP's RFA/Coop. Agr. titled "Discovery and Development of Natural Products for Cancer Interception and Prevention" was approved unanimously.

Division of Cancer Treatment and Diagnosis

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) (Re-issue RFA/Coop. Agr.)—Dr. Lori A. Henderson

Dr. Lori A. Henderson, Program Director, DCTD, NCI, presented a re-issue RFA concepr for continuing the BMT CTN. Established in 2001 and jointly sponsored by the NCI and the National Heart, Lung, and Blood Institute (NHLBI), the primary leading IC, the BTM CTN has emerged as the national leader in designing and successfully conducting hematopoietic stem cell transplantation (HCT) clinical trials. The BTM CTN has several unique attributes. The Network conducts Phase 2/3 HCT and adoptive cell therapy trials of malignant and nonmalignant blood disorders, which are not performed elsewhere. The BMT CTN currently has 75 affiliate members and convenes an open forum, the State of the Science Symposium. The Network endorses trials that are affiliated with other NIH-funded programs, such as the NCI National Clinical Trials Network (NCTN), the AIDS Malignancy Consortium, and the NHLBI's Sickle Cell Disease Network. Several pharmaceutical companies also leverage the Network and provide substantial financial support to evaluate promising cell therapies and drugs in trials. Disease targets include leukemia, myelodysplasia, lymphoma, multiple myeloma, and HIV-associated cancers.

Dr. Henderson highlighted accomplishments and significant research findings of this current funding cycle. The BMT CTN has addressed key issues in graft-versus-host disease, donor availability, post-transplant infection, conditioning and maintenance therapy for disease control, organ and regimen-related toxicities, and quality-of-life studies. As of 31 August 2022, the Network had launched 60 trials: 52 are relevant to the NCI's mission; 35 have been completed; and 22 are ongoing. It has also accrued 7,500 patients across active trials, and the results are informing clinical practices. BTM CTN investigators had 148 publications, with primary results from 42 trials disseminated to date. The BMT CTN Phase 3 randomized trial (0702), which compared single autologous transplant with and without consolidation therapy with tandem autologous transplant, provided evidence that the current state of care is the best option for treating multiple myeloma patients. The Network collaborated with the Dana–Farber Cancer Institute to conduct a Phase 3 randomized trial evaluating the clinical benefit of combination treatment of lenalidomide-bortezomib-dexamethasone versus dexamethasone and high-dose treatment with autologous

HCT in multiple myeloma patients. The results demonstrated that with dexamethasone therapy, transplant can be delayed without harm, thus creating the ability to individualize patient care.

A recent external evaluation of the program concluded that the BMT CTN had made exceptional progress, and the reviewers unanimously recommended that such a program should continue to be supported. This re-issuance will support (1) a research agenda defined by the 2021 State of the Science Symposium priority research topics, including preventing or reducing regimen-related toxicities and relapse; (2) six clinical trials; and (3) three NCTN collaborative studies focusing on B-cell lymphoma, amyloidosis, and classical Hodgkin's lymphoma.

Subcommittee Review. Dr. Rathmell expressed the Subcommittee's enthusiasm and support for the re-issue concept, which supports clinical trials not supported elsewhere. The Subcommittee lauded the productivity and success of the BMT CTN and concurred with the external reviewers' program evaluation.

The first-year cost for the one-time re-issuance is estimated at $3.9 M (NCI component) for 18 UG1 awards and one U24 award, with a total cost of $27.3 M (NCI component) and $81.1 M (NIH total) for seven years.

Questions and Answers

Dr. Hayes Dixon recommended providing an update on the BMT CTN's research progress toward the middle of the funding cycle.

Motion. A motion to concur on the DCTD's Re-issue RFA/Coop. Agr. entitled "Blood and Marrow Transplant Clinical Trials Network (BMT CTN)" was approved with 24 ayes, 0 nays, and 1 abstention**.**

Office of the Director

SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer-Focused Technologies Toward Commercialization (Re-issue RFA)—Dr. Jonathan Franca-Koh

Dr. Jonathan Franca-Koh, Program Director, SBIR Development Center, NCI, presented the re-issue RFA concept for the SBIR Phase IIB Bridge Awards to accelerate the development of cancer-focused technologies toward commercialization. The SBIR and Small Business Technology Transfer (STTR) programs are congressionally mandated. Federal agencies with extramural research and development (R&D) budgets of $1 B or more are required to set aside a total of 3.65 percent for SBIR/STTR. This set aside is referred to as "America's Seed Fund" and is the primary program at NIH supporting innovative small businesses. Congress recently reauthorized the SBIR/STTR program for an additional 3 years. In 2018, the NCI SBIR Development Center commissioned an economic evaluation to review Phase II awards made between 1998 and 2010. The results showed that the overall economic impact of 690 awards was $26.1 B, which included the sales of the products and services, tax revenue, and labor income.

Congress structured the SBIR program into phases: Phase I, a proof-of concept study, provides up to $400,000 for 6 to 12 months, and Phase II provides $2 M over 2 years and requires both R&D and commercialization plans. Many promising technologies and their companies experience a funding gap to reach the next key value inflection point. For early-stage companies, it can be challenging to attract investment because of the risks. Without further funding, technologies can wane or face significant delays. To address these challenges, the NCI launched the Bridge IIB Award in 2009 to support technologies that have undergone rigorous due diligence and can attract investment. The Bridge Award provides up to $4 M in funding over 2 to 3 years to support technology validation and clinical translation. Companies that have completed the SBIR Phase II from any federal agency are eligible, with clinical trials optional. The main objectives are to help companies achieve critical milestones, promote

partnerships with key players in their ecosystem, and leverage federal funding to attract private investment that equals or exceeds NCI funds.

Since the program's inception, the NCI has made 49 awards, totaling $126 M. Companies have leveraged the NCI's investment to raise more than $500 M in matching funds from investors, including leading venture capitalists, strategic partners, and angel investment groups. Project types span the NCI portfolio to include devices, imaging, diagnostics, and therapeutics. Of the 49 awards, 19 products have been launched. Dr. Franca-Koh highlighted one Bridge Award case study. Oncoceutics Inc. (now Chimerix) received a Bridge Award in 2018 to develop a small-molecule targeting dopamine receptor D2 and mitochondrial protease ClpP. The award supported a Phase 2 clinical trial testing this agent, known as ONC201, for gliomas. ONC201 subsequently received FDA fast-track and orphan designation. ONC201 significantly increased survival of a patient diagnosed with diffuse intrinsic pontine glioma at age 6, who had a 1 percent 5-year prognosis of surviving.

An external evaluation of the program from 2016 to 2020 found that it successfully met the goals of assisting companies in reaching milestones, establishing partnerships, and attracting private investments. The external reviewers noted that the matching fund requirement was a key feature and that the program supports vital early-development activities that are beyond the scope of a traditional Phase II SBIR grant. This re-issue concept would support the continuation of promising cancer-focused SBIR Phase II projects and an increased budget limit of $4.5 M.

Subcommittee Review. Dr. Tuveson expressed the Subcommittee's support for the re-issue concept, explaining that this program is advancing academic discoveries into new therapies, diagnostics, and computational approaches. The Subcommittee emphasized the strong translational aspects of the program and thanked the NCI SBIR Development Center staff for providing a detailed history of the NCI SBIR/STTR program during their review.

The first-year cost for the one-time re-issuance is estimated at $12 M for six SBIR Phase IIB Bridge Awards, with a total of $60 M for 5 years.

Questions and Answers

Dr. Karen M. Basen-Engquist, Professor, Department of Behavioral Science, Division of Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center, asked to what extent population health and behavioral technologies were incorporated into the SBIR/STTR program. Dr. Franca-Koh explained that the SBIR/STTR program funds digital health and software-based projects focusing on population health, as well as grants promoting diverse representation in clinical trials, but he could not provide a specific percentage relative to the total awards.

Dr. Fingert inquired about the statistics of companies receiving the Phase IIB Bridge Award and not advancing the products to commercialization. Dr. Franca-Koh pointed out that the NCI SBIR program cares about patient impact and monitors those data and noted that the congressional mandate intends that the awards make positive contributions to the U.S. economy.

Dr. Doubeni suggested establishing a process for diversifying the representation of researchers who benefit from the SBIR program.

Motion. A motion to concur on the Office of the Director's Re-issue RFA/Coop. Agr. entitled "SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer-Focused Technologies Toward Commercialization" was approved unanimously.

XIV. ONGOING AND NEW BUSINESS—DRS. JOHN D. CARPTEN AND KEITH T. FLAHERTY

NCAB *Ad Hoc* Global Cancer Research Subcommittee. Dr. Francis Ali-Osman, Margaret Harris and David Silverman Distinguished Professor of Neuro Oncology, Professor Emeritus of Neurosurgery, Duke University Medical Center, Chair of the NCAB *ad hoc* Global Cancer Research Subcommittee, presented the report of the 5 December 2022 meeting. Dr. Ali-Osman explained that Dr. Satish Gopal, Director, Center for Global Health (CGH), updated the Subcommittee on implementation of the *CGH 2021–2025 Strategic Plan*. The current task is to advance the CGH and prioritize cancer within global health across the primary goals of research, research training, dissemination, and partnerships. In technology development, the CGH evolved and re-issued its Affordable Cancer Technologies Program, which supports late-stage testing and validation of cancer control technologies in low-and middle-income countries (LMICs). For extramural research training, the CGH is using the D43 award mechanism to support building global cancer research training networks and to encourage LMIC institutions to develop institutional research training partnerships with Cancer Centers. Regarding intramural research training, CGH resumed its Short-Term Scientist Exchange Program in fall 2022, with four scientists from LMICs supported by the NCI's CCR and Division of Cancer Epidemiology and Genetics (DCEG). After the presentation, the Subcommittee discussed the significant progress and repositioning of the CGH under Dr. Gopal's leadership. The emphasis on capacity-building and training in LMICs was viewed as essential and critical to the conduct of cancer research in these countries. The Subcommittee encouraged the CGH to continue to develop its partnerships to further advance the NCI global cancer research agenda.

Dr. Ali-Osman reported that the Subcommittee was provided an update on the 2021 Global Oncology Survey of NCI-Designated Cancer Centers from Ms. Elise Garton, Health Specialist, CGH, NCI, and Dr. Patrick Loehrer, Distinguished Professor, Joseph W. and Jackie J. Cusick Professor of Oncology, Global Oncology Program Leader, Indiana University School of Medicine. The survey was conducted in collaboration with the Cancer Centers, NCI Office of Cancer Centers, American Society of Clinical Oncology, American Society of Preventive Oncology, and AACR. The key findings were that 67 of 71 Cancer Centers responded to the survey, and the majority reported involvement in global oncology; the NIH was the largest source of funding for these activities, followed by charitable, philanthropic, and donated funds. NIH-funded grants focused on biology and etiology, whereas non-NIH-funded projects investigated cancer control, survivorship, and outcomes research. Last, Dr. Ali-Osman noted that the Subcommittee briefly considered leveraging opportunities in the reignited Cancer Moonshot for increased visibility and, potentially, resources for the CGH and the NCI global cancer research agenda. These discussions are in the early stages, and more specific initiatives will be presented at future meetings.

Questions and Answers

Dr. Dorothy K. Hatsukami, Associate Director of Cancer Prevention and Control, Forster Family Chair in Cancer Prevention, Masonic Cancer Center, Professor, Department of Psychiatry and Behavioral Sciences, University of Minnesota, asked about the Subcommittee's vision for developing the infrastructure within LMICs to support local research hubs for capacity-building training in those countries. Dr. Ali-Osman called attention to a prior CGH program that sponsored such a hub composed of two or three LMICs. He noted that this would be an opportune time to revisit this model and discuss funding, which the CGH is planning to do.

Motion. A motion to accept the report of the 5 December 2022 NCAB *ad hoc* Global Cancer Research Subcommittee meeting was approved unanimously.

NCAB *Ad Hoc* Population Science, Epidemiology, and Disparities Subcommittee. Dr. Paskett, Chair of the NCAB *ad hoc* Population Science, Epidemiology, and Disparities Subcommittee, presented the report of the 5 December 2022 meeting. Dr. Paskett explained that Subcommittee spent the majority of its time in the meeting reviewing and discussing the report of the

NCAB *ad hoc* Working Group on Strategic Approaches and Opportunities for Research on Cancer Among Racial and Ethnic Minorities and Underserved Populations. This report was presented to the Boards earlier in the day and then approved by the NCAB. Dr. Paskett had no further updates to report and noted that the Subcommittee will decide on the next topic to consider and will revisit the list the members had previously generated.

Questions and Answers

Members suggested funding opportunities for trainees in population science and outreach to research communities and special populations as topics the Subcommittee could consider.

Motion. A motion to accept the report of the 5 December 2022 NCAB *ad hoc* Population Science, Epidemiology, and Disparities Subcommittee meeting was approved unanimously.

NCAB Clinical Investigations Subcommittee. Dr. Nilofer S. Azad, Professor of Oncology, Co-Director, Developmental Therapeutics Program, Co-Leader, Cancer Genetics and Epigenetics, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Chair of the NCAB Clinical Investigations Subcommittee, presented the report of the 5 December 2022 meeting. Dr. Azad noted that the Subcommittee's mission is: 1) to advise the NCAB on clinical trials focused on detection, prevention, diagnostics, management, and treatment; 2) responsible for a broad range of concerns aimed at improving the investigation of cancer in humans; and 3) advise the NCAB and the NCI on the NCTN program. In preparation for the re-competition of the NCTN program, the NCI and NCTN leadership developed a survey to assess the health and conduct of the program for the performance period of March 2019 to July 2022. The Subcommittee heard a presentation on the NCTN performance survey from Dr. Margaret Mooney, Associate Director, Cancer Therapy Evaluation Program, DCTD, NCI. Dr. Mooney first summarized that the NCTN program launched in 2014 as a reconfiguration of the cooperative groups and was established to harmonize processes, promote collaborations, and invigorate the NCI clinical trials' portfolio. The NCTN is composed of several centralized functions. These include an NCI Central Institutional Review Board, a Cancer Trials Support Unit, a Radiation Therapy and Imaging Core Center, NCI Disease Steering Review Committees, and a Common Data Management system. Each NCTN Group has its own Lead Academic Participating Site, Operations Center, Statistics and Data Management Center, and Tumor Bank.

Dr. Azad highlighted the main findings of the NCTN survey. The results indicated that program satisfaction improved between December 2016 and August 2022. Areas for improvement include enrollment and retention of diverse patient populations, efficient completion of trials, and efficient activation of trials. Suggestions for improving opportunities for junior investigators included limiting individuals to chairing only one study at a time, considering term limits for committee chair roles, and providing further guidance and mentorship. Accruals in NCTN trials significantly decreased during the initial period of the COVID-19 pandemic, and new processes were implemented, including applying telehealth for study visits and obtaining consent remotely. Overall, feedback on the NCTN was positive, and the Subcommittee discussed providing input on the NCTN program recompetition RFA that is soon to be released.

Dr. Azad noted that the Subcommittee and participants further elaborated on multiple issues emerging from the survey, and a common consensus was that additional funding will be necessary for the NCTN program. The Subcommittee discussed performing additional data analysis of the costs for conducting trials and agreed on the need to focus on ways to improve access to clinical trials to patients who have different socioeconomic challenges.

Questions and Answers

Dr. Winkfield highlighted some potential groups to engage in the conversations of NCTN clinical trial enrollment, including the Robert A. Winn Diversity in Clinical Trials Award Program, which is focused on improving workforce diversity with respect to clinical trials, as well as inclusive participation in trials.

When asked about data streamlining and data quality, Dr. Azad noted that the Subcommittee is planning to consider ways to implement standard operating procedures for some of the central functions of the NCTN, including data collection and protocol writing. Because all NCTN studies are monitored by the same entity, the opportunity exists to review data quality over time and propose any changes.

Motion. A motion to accept the report of the 5 December 2022 NCAB Clinical Investigations Subcommittee meeting was approved unanimously.

Other Business. Dr. Carpten noted that the BSA concept review report has been posted on the secure BSA-only website and, as requested, prior reports have been archived for future access. For future Division, Office, Center reports, members suggested including any challenges or issues on which the Boards could provide insight, and framing the presentations accordingly.

Future Agenda Items. The BSA and NCAB members suggested future presentations on the NCI approach for increasing R01 pay lines to the 15th percentile by 2025; proposed legislation regarding research publications and immediate open access and the potential effects on NCI-funded investigators; and implementation of the NIH 2023 Data Management and Sharing Policy. Members reiterated interest in updates on NCI-Frederick and the Cancer Immune Monitoring and Analysis Centers. Members were also asked to forward any additional suggestions for potential future agenda items to the respective Board chairs and Dr. Paulette Gray.

XV. ADJOURNMENT—DRS. JOHN D. CARPTEN AND KEITH T. FLAHERTY

Drs. Carpten and Flaherty thanked Board members, staff, visitors, and observers for attending the meeting. There being no further business, the 7th Virtual Joint Meeting of the BSA and NCAB was adjourned at 5:02 p.m. on Wednesday, 7 December 2022.

Date	Keith T. Flaherty, M.D., Chair, BSA
Date	John D. Carpten, Ph.D., Chair, NCAB
Date	Paulette S. Gray, Ph.D., Executive Secretary