

**79th Meeting of the National Cancer Institute (NCI)
NCI Council of Research Advocates (NCRA)
National Institutes of Health (NIH)**

**NIH Campus
Bethesda, Maryland**

Monday, September 9, 2019

Members Present

Dr. Gregory Aune, Acting Chair
Mr. Rick Bangs
Ms. Anjelica Davis
Dr. Sue Friedman (by telephone)

Ms. Danielle Leach
Ms. Jennifer Pegher (by telephone)
Mr. Roberto Vargas

Speakers

Dr. Jaime Guidry Auvil, Director, Office of Data Sharing, Center for Biomedical Informatics and Information Technology (CBIIT), NCI
Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations (OGCR), NCI (by telephone)
Dr. Tony Kerlavage, Director, CBIIT, NCI
Dr. Douglas Lowy, Acting Director, NCI
Dr. Deborah Winn, Acting Director, Division of Cancer Prevention (DCP), NCI
Ms. Amy Williams, Acting Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

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Welcome and Meeting Goals

Dr. Gregory Aune and Ms. Amy Williams

Ms. Amy Williams opened the meeting at 9:50 a.m., welcomed the Council members, and reviewed the meeting agenda. She noted that two members, Dr. Sue Friedman and Ms. Jennifer Pegher, were attending by telephone. New member Ms. Anjelica Davis introduced herself. Dr. Gregory Aune reviewed the conflict of interest rules for the meeting and confirmed that a quorum of members was present.

Budget and Legislative Update

Ms. Holly Gibbons (by telephone)

Ms. Holly Gibbons provided an update on the NCI budget and the next steps in the appropriations process.

- In fiscal year (FY) 2019, Congress paired the budgets for the Labor, Health and Human Services, Education, and Related Agencies (L–HHS) spending bill with the FY 2019 Defense spending bill. This on-time appropriation included a \$2 billion (B) increase for the NIH above the FY 2018 enacted budget, a \$74 million (M) increase for the NCI, and \$400 M for the Cancer MoonshotSM as authorized by the 21st Century Cures Act of 2016.
- The FY 2020 President’s Budget Request, released in March 2019, set levels based on requirements of the Budget Control Act of 2011 (BCA). This request featured a 12 percent reduction for the NIH, a 14.6 percent decrease for the NCI, and an additional \$50 M for the Childhood Cancer Data Initiative (CCDI).
- In August 2019, the President signed the Bipartisan Budget Act (BBA) of 2019, which raised the budget caps from the 2011 BCA for FY 2020 and FY 2021. The 2019 BBA also suspended the Federal debt limit but did not appropriate funds for FY 2020.
- Congress resumed session on September 9, 2019. The House Appropriations Committee has passed 10 out of 12 spending bills; the L–HHS spending bill, which was passed on June 19, 2019, included a \$300 M increase for the NCI and \$50 M for the CCDI. The Senate Appropriations Committee will begin considering the L–HHS bill this week. Congressional leaders have indicated that a short-term Continuing Resolution may be a topic they will need to address.
- Ms. Gibbons reported on an area of increased Congressional interest and public concern, namely the trend of increased electronic cigarette (e-cigarette) use (i.e., vaping). Hearings were held in July 2019 by the House Committee on Oversight and Reform and its Subcommittee on Economic and Consumer Policy on the subject of “Examining Juul’s Role in the Youth Nicotine Epidemic.” As of October 2018, Juul Labs, Inc. (Juul) accounted for 70 percent of the e-cigarette market.
- Since July 2019, incidences of severe lung disease associated with vaping have emerged. The U.S. Centers for Disease Control and Prevention (CDC) issued an advisory on

August 21 about this problem. A total of five deaths have been confirmed from the initial advisory through this meeting date, and the CDC has reported more than 450 confirmed cases of vaping-associated lung disease across 33 states. Congress has considered several potential measures, such as marketing restrictions, in response and is continuing to monitor and provide oversight on this issue.

- Ms. Gibbons discussed the status of legislation of interest and Congressional visits to the NCI. She highlighted that in FY 2019, the NCI began implementing the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act of 2018. To date, three activities have been completed: issuing a request for applications (RFA) focused on improving outcomes for pediatric, adolescent, and young adult cancer survivors in January 2019; hosting the Enhancing Biobanking for Childhood Cancers meeting on May 13, 2019; and issuing a grant supplement award to the Children's Oncology Group's Biospecimen Bank.
- Ms. Gibbons outlined recent and upcoming Congressional events related to cancer research in which the NCI participated and will be supporting, including the Glioblastoma Awareness Day reception on July 17, 2019; the 10th Annual Childhood Cancer Summit scheduled for September 20, 2019; and the Men's Health Network prostate cancer briefing scheduled for September 25, 2019.
- The NCI had visits from the Congressional Cancer Survivors Caucus on July 18, 2019, and on August 29, 2019, Rep. David Trone visited NCI's Frederick National Laboratory for Cancer Research, which is in his district. On September 5, 2019, 16 bipartisan Congressional staffers visited and toured several NCI and NIH facilities.

Discussion

- Ms. Davis asked about current hiring limitations on Federal employees and the effect of executing NCI programs. Ms. Gibbons responded that Congress is not addressing this issue directly in the current appropriations process. The NIH has a hiring control committee; thus, the NIH is still able to hire employees after a review process, which is managed by the agency or operating division level.
- Mr. Rick Bangs asked if any oversight occurs on selecting the topics of Congressional cancer briefings and whether these rotate across different cancers. Ms. Gibbons responded that the NCI is invited to participate by groups that happen to be hosting a briefing on an ad hoc basis. The OGCR solicits NCI experts to provide research updates at these briefings.
- Mr. Roberto Vargas inquired about emerging policy areas of Congressional interest, in addition to the CCDI and the youth vaping issue. Ms. Gibbons responded that removing barriers to colorectal cancer screening, including addressing a Medicare loophole around coinsurance for colorectal screening when polyps are removed, has high bipartisan sponsorship. Additionally, a bill supporting palliative care and palliative care research was passed in the House of Representatives and also has high bipartisan sponsorship.

- Ms. Pegher expressed appreciation for the OGCR's work and noted that many cancer research advocates will visit Capitol Hill for the Rally for Medical Research on September 19, 2019.

NCI Prevention and Early Detection Update

Dr. Deborah Winn

Dr. Deborah Winn described some concepts of cancer prevention and provided an update on NCI's research programs in cancer prevention, two extramural—DCP and Division of Cancer Control and Population Sciences (DCCPS)—and one intramural, Division of Cancer Epidemiology and Genetics (DCEG). She also reported on recent prevention initiatives: the internal Early Detection and Screening Initiative and the Board of Scientific Advisors (BSA) Working Group on Prevention.

- Dr. Winn elaborated on the three cancer prevention concepts: primary, to reduce cancer incidence by avoiding carcinogen exposure and promoting the ability to resist cancer; secondary, to limit the progression of a disease process already begun that could lead to cancer; and tertiary, mitigating the effects of cancer and the consequences of cancer treatment. She detailed examples of the interventions for cancer prevention and how they can be incorporated along the continuum of cancer prevention research.
- Dr. Winn pointed out the major benefit of screening, as well as the potential harms of screening, and explained that precision cancer prevention identifies individuals who would benefit most from prevention approaches, such as those with high genetic risk, heavy exposures to carcinogens, or predisposing illnesses.
- Dr. Winn remarked that the scientific scope of the DCP is focused principally on the secondary and tertiary prevention concepts, developing interventions to target cancer pathways in identified populations at risk for cancer and training future cancer prevention and control leaders through the Cancer Prevention Fellowship Program.
- The DCP has a robust preclinical, clinical, and biomarker development pipeline that extends from drug development to post clinical trial research. Dr. Winn detailed the major prevention programs involved in agent and drug development, the PREVENT Cancer Preclinical Drug Development Program (commonly called PREVENT); Phase 0–2 trials, the Cancer Prevention Clinical Trials Network (commonly called CP-CTNet); and Phase 3 trials in prevention and symptom management, supported within the NCI Community Oncology Research Program (NCORP). She noted that large prevention trials convert to observational studies to support biomarker development.
- Dr. Winn highlighted that the Cancer MoonshotSM–funded Pre-Cancer Atlas of the Human Tumor Atlas Immuno-Oncology Translation Network analyzes premalignant conditions, and the DCP Early Detection Research Network (EDRN) is involved in discovering and validating biomarkers for early detection of several cancers. Two DCP initiatives focused on specific cancer sites—the U.S.–Latin America–Caribbean Clinical

Trials Network and the Barrett's Esophagus Translational Network—also were described, as were nutritional science efforts.

- Dr. Winn pointed out that the DCCPS, which is population-based, is greatly concerned with risk factor modification, including evaluating the effects of various measures to encourage behavior change and healthy lifestyles. Two DCCPS Behavioral Research Program cancer prevention initiatives are the Smoking Cessation at Lung Examination (SCALE) trial focusing on screening long-term smokers and innovative interventions, and the Cancer Center Cessation Initiative established to enhance the capacity of NCI-Designated Cancer Centers (Cancer Centers) to deliver tobacco cessation treatments to cancer patients who smoke.
- Dr. Winn emphasized that as of FY 2018, the NCI had 40 active grants with a primary or secondary focus on e-cigarettes that are helping to address the increasing use of e-cigarette use among U.S. high school students and that the DCCPS participates in trans-NIH initiatives focusing on obesity in the U.S. adult population.
- DCCPS' secondary cancer prevention activities focus on human papillomavirus (HPV) testing to screen for cervical cancer across U.S. and international sites. Several new cancer screening initiatives, including the Population-based Research to Optimize the Screening Process (commonly called PROSPR) and Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science (commonly called ACCSIS) have been funded recently.
- Dr. Winn called attention to DCCPS efforts addressing the disparity between rural and urban cancer mortality, which has increased in recent decades. Multiple newly funded rural research initiatives are in place, such as the RFA on Improving the Reach and Quality of Cancer Care in Rural Populations, Cancer Center supplements to enhance research capacity in rural cancer control, and the Colorectal Cancer Screening Implementation Project Across Southwestern American Indian Tribes.
- Dr. Winn explained that the DCEG, NCI's intramural component, conducts transdisciplinary epidemiologic and genetics research and has the mission to discover the causes of cancer and the means for prevention. The Division conducts unique high-risk research and studies that require a national programmatic approach and/or a timely response to emerging public health issues.
- Different from the NCI extramural programs—DCP and DCCPS—the DCEG's prevention research continuum consists of etiology, translation, and implementation. One such example is in HPV research establishing HPV as the necessary cause of cervical cancer and as a risk factor for other cancers.
- The DCEG, in collaboration with other NCI Divisions, the Bill & Melinda Gates Foundation, the World Health Organization International Agency for Cancer Research, and Fundación Inciensa (Costa Rica) is conducting an international HPV trial. The study is comparing the effectiveness of one versus two doses of the HPV vaccine in both low- and high-resource regions and has 10,000 enrolled participants.

- Dr. Winn announced two new NCI initiatives on prevention that began in FY 2019. In the Internal Early Detection and Screening Initiative, NCI Acting Director, Dr. Douglas Lowy has challenged staff to identify high-influence opportunities and to think creatively to accelerate advancements in early detection and screening. Dr. Winn and other members of the NCI Scientific Program Leadership are directing this effort and plan to present their report to Dr. Lowy in late September 2019.
- In March 2019, the NCI established the BSA Working Group on Prevention and charged the group with considering how best to utilize the NCI resources in developing and sustaining a cancer prevention and early detection research program. The Working Group will consider a wide scope of potential ideas and is scheduled to begin its activities mid-September. Dr. Winn noted that the OAR could convey to the Working Group any ideas or topics the NCRA would like to be addressed.

Discussion

- Mr. Bangs remarked that by definition, early detection occurs when patients have no symptoms. In bladder cancer, however, many patients with hematuria (i.e., blood in the urine) are diagnosed with urinary tract infection instead. This misdiagnosis translates to worse outcomes. Dr. Winn commented that early detection is becoming more nuanced through precision medicine, in which patients are stratified by level of risk. People with persistent hematuria, for example, should be classified as higher risk for cancer. Biomarker or other early screening tests should be given to such patients.
- Mr. Bangs observed that cancer specialists could improve their execution of smoking cessation interventions. Dr. Winn agreed and explained that the NCI began a supplement for Cancer Centers to begin smoking cessation programs. The DCCPS is adept at focusing on system-, provider-, and people-based approaches to behavior change. Participants agreed that such programs address an important need.
- Dr. Aune commented on prevention in the population of survivors, particularly the childhood cancer survivor population. This population is a high-risk and high-exposure group with a genetic predisposition to developing cancer. Dr. Winn pointed out that it is possible to examine the NCI's portfolio on prevention among survivors. She provided the example of young women with high chest radiation exposure who have a higher risk profile for breast cancer and begin screening at age 25. More of these specific high-risk groups need to be identified.
- Dr. Winn noted that the NCI has extensive interaction with other NCI Institutes and Centers on nutrition and physical activity. In the past 2 years, the NCI has begun collaborating with the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) on pancreatic cancer research.
- Ms. Davis asked about collaborations with the CDC's Colorectal Cancer Control Program. Dr. Winn conveyed that the NCI has ongoing relationships with both the CDC's Division of Cancer Prevention and Control and its Office of Public Health

Genomics. Ms. Davis also asked if discussions are occurring about implementing a screening program if the colonoscopy screening age is officially dropped to 45. Dr. Winn explained that the Cancer Intervention and Surveillance Modeling Network (CISNET) statistical modeling group is studying the population effects for a revised colorectal cancer screening age. The DCCPS would focus on how best to implement screening of younger populations.

- Mr. Vargas explained that a San Francisco initiative is building partnerships with local health providers to communicate with diverse populations the value of early screening. He asked whether the NCI is investing in capacity building for community-based groups to engage low-income communities to increase screening uptake. Dr. Winn responded that Cancer MoonshotSM efforts are written to include community engagement and the involvement of underserved communities.
- Ms. Danielle Leach asked if NCI's OAR is advertising the current opportunity to extramural cancer prevention stakeholders, beyond the NCRA, to provide input on the NCI's prevention portfolio. Ms. Williams indicated that the OAR can reach out to organizations about cancer prevention.
- Dr. Winn commented that the work of the NCI's internal Early Detection and Screening Initiative already has helped to identify research gaps. She elaborated that Dr. Lowy wants the Initiative to identify gaps and opportunities specified for particular cancers.
- Mr. Bangs suggested that the BSA Working Group on Prevention consider a targeted strategy to particular populations in its approach for soliciting public comment from the research community.
- Mr. Vargas expressed appreciation for the NCI's focus on the disparity between rural and urban cancer mortality. He cited four NCI grants in FY 2019 totaling \$2.2 M, plus additional Cancer MoonshotSM supplements in this area. Mr. Vargas asked whether the NCI has an interest in increasing its investment for rural populations. Dr. Winn responded that Dr. Robert Croyle, Director, DCCPS, has focused heavily on this topic for the past 2 years. She emphasized that the Cancer Center supplements for rural cancer control and other initiatives for rural populations will remain a high priority within the DCCPS.

NCI Director's Update

Dr. Douglas Lowy

Dr. Lowy provided an update on the current status of the grant applications, NCI budget planning, NCI's Annual Plan & Budget Proposal for Fiscal Year 2021, including two cancer treatment success stories, and updates to NCI programs and staff. Dr. Lowy welcomed Ms. Davis, President, Fight Colorectal Cancer, to the NCRA and congratulated Ms. Leach on her new position as Chief of Community and Government Relations for the National Brain Tumor Society.

- Dr. Lowy reported that from FYs 2014 to 2018, the NCI R01 grant applications increased by about 50 percent, whereas NIH R01 grant applications increased by only about 5 percent. Although the NCI budget has substantially increased over this period, it has not been at the pace of the increase in applications, which has resulted in a smaller percentage of awards being funded, translating to reduced paylines.
- Dr. Lowy further conveyed that the funding success rates for NIH grant applications increased from 19 to 22 percent, but decreased from 15 to 11 percent for the NCI. He noted three factors attributing to the increase in NCI grant applications: increase in unique principal investigator applicants, an increase in multi-principal investigator applications, and a substantial increase in applications in response to Program Announcements with Special Receipt, Referral, and/or Reviews (commonly called PARs).
- Dr. Lowy announced the new NCI blog—“NCI Bottom Line: A Blog About Grants & More”—expected to launch on September 12, 2019, which is intended to keep the extramural community informed and engaged about NCI grants and funding policy.
- Dr. Lowy described some of the information contained in the NCI Annual Plan & Budget Proposal for Fiscal Year 2021, also known as the Bypass Budget or the Professional Judgment Budget Proposal, in which the NCI communicates its goals and priorities directly to Congress. A detailed copy of the FY 2021 Annual Plan can be accessed from the NCI website.
- Dr. Lowy explained that the NCI FY 2021 Bypass Budget is 7.5 percent greater than the House Appropriations Committee FY 2020 budget and 12 percent greater than the President’s proposed FY 2020 budget for the NCI. He explained that this proposed budget increase of approximately \$6.9 B represents the amount necessary to substantially increase paylines and funding success rates. The NCI anticipates the R01 application success rate would return to the 15th percentile at this proposed funding level, notwithstanding any new increases in application rates beyond what is projected.
- The FY 2021 Annual Plan also highlights three areas exemplifying NCI’s progress in cancer research—the immune system and microbiome, implementation science, and artificial intelligence—as well as cancer treatment success stories. Dr. Lowy described two such stories, including that of a pediatric Molecular Analysis for Therapy Choice (MATCH) trial patient featured on the Annual Plan’s cover, who had an unresponsive fibrosarcoma caused by a tyrosine receptor kinase fusion gene rearrangement and was successfully treated with larotrectinib, which was approved by the U.S. Food and Drug Administration (FDA) in November 2018.
- With the advent of new FDA approved drugs to multiple myeloma as well as the recent improvements in patient survival and mortality rates, Dr. Lowy emphasized that the incidence and mortality rates, which were once twice as high for African American patients as for Caucasian patients, are almost identical between these two groups. In addition, an NCI analysis reveals that costly new treatments are successfully reaching

patients with limited means because the trends in mortality remain the same between rich and poor U.S. counties. Dr. Lowy next described the research of NCI-supported principal investigators also featured in the 2021 Annual Plan who are focusing on cancer health disparities, implementation research for cancer health disparities, and artificial intelligence for cancer screening.

- Regarding NCI's new and ongoing programs, Dr. Lowy reported that the NCI—particularly Dr. James Doroshow, Deputy Director, Clinical and Translational Research—was directly involved in providing evidence to support the Centers for Medicare & Medicaid Services' decision on national coverage for chimeric antigen receptor (CAR) T-cell therapy for Medicare beneficiaries.
- The NCORP has a key role in cancer prevention research, screening, treatment, and cancer care delivery. Almost 50 percent of the adult MATCH trial patients were enrolled at NCORP Sites. The NCI has increased its support for NCORP by \$30 M per year and for the clinical trials cooperative groups by \$20 M per year.
- The NCI, particularly Dr. Dinah Singer, Deputy Director, in collaboration with Dr. Francis Collins, Director, NIH, has worked on implementing the NCI Cancer MoonshotSM Public Access and Data Sharing Policy.
- Congress has taken notice of issues related to intellectual property (IP) in academic settings from foreign entities. To address this increased interest and IP issues, Dr. Michael Lauer, Deputy Director for Extramural Research, NIH, plans to present on this topic at the December 2019 Joint Meeting of the BSA and NCAB.
- Dr. Lowy announced recent leadership appointments: Dr. Singer to Deputy Director, Scientific Strategy and Development; Ms. Joy Wiszneauckas to Director, Committee Management Office; Mr. Eric Cole to Deputy Executive Officer, NCI; and Ms. Anne Lubenow to Chief of Staff, Office of the Director.
- The NCI is currently recruiting for directors for DCP, the Center for Global Health, Office of Cancer Survivorship, and Division of Cancer Biology and for associate director of the Cancer Therapy Evaluation Program. In closing, Dr. Lowy admired the work of NCI acting directors in positions with current leadership vacancies.

Discussion

- Dr. Aune inquired about NCI's ability to keep up with the demand in grant applications based on funding availability. Dr. Lowy responded that the NCI has engaged in discussion with other NIH Institutes and Centers (ICs), but most of the funding will still come through the NCI. Dr. Lowy noted the change in the wording of the Cancer Center

Core Grant applications to clarify that this grant is equal in stature to awards from other ICs.

- Mr. Bangs expressed concern that the NCI is able to fund fewer grants of very high quality because of fiscal constraints. Dr. Lowy indicated that the NCI has made Congress aware of this issue.
- Ms. Pegher explained that the American Association of Cancer Institutes (AACI) is engaged in ongoing discussions with Congressional staffers involved in crafting the Labor–HHS appropriations bills. She expressed that the investigator’s perspective is important to communicate to Congress. Dr. Lowy thanked the AACI for its strong letter supporting the FY 2021 Annual Plan.
- Mr. Vargas appreciated that NCI’s FY 2021 Annual Plan has highlighted community engagement and disparities research. He asked whether increased investment is being made in intervention research to address, and not simply describe, the disparities. Dr. Lowy noted that in 2018 the NCI initiated a Specialized Program of Research Excellence award mechanism specifically focused on cancer disparities. Dr. Lowy encouraged the cancer research community to investigate and consider ways to try to overcome the rural/urban cancer disparity so that the gap does not continue to widen.
- Mr. Vargas asked whether collaborative investments have been made to support team science among NIH ICs. Dr. Lowy responded that the NCI does perform project-based research with other Institutes; for example, the NCI and NIDDK are collaborating on liver and pancreatic cancer research.
- Ms. Leach expressed concern that Cancer MoonshotSM funding is anticipated to be reduced by half in the next year. Dr. Lowy conveyed that the number of new Cancer MoonshotSM initiatives are reduced for FY 2020 based on the 21st Century Cures Act funding structure. He expressed concern that a fiscal cliff in 2024, when Cancer MoonshotSM funding ends, will result in a decrease in overall cancer research support. The NCI has been discussing measures to address this abrupt change in funding, and Congress has taken this issue into serious consideration in their FY 2020 appropriation bills.
- Dr. Lowy explained that CISNET modeling of lung cancer data led to recommendations on eligibility for lung cancer screening. CISNET linked mortality data with the Surveillance, Epidemiology, and End Results Program (SEER) database. Mortality rates for non-small cell lung cancer have dropped independently of racial background.

Childhood Cancer Data Initiative Update

Dr. Tony Kerlavage and Dr. Jaime Guidry Auvil

Drs. Tony Kerlavage and Jaime Guidry Auvil reviewed the CCDI's origins, goals, progress updates, and next steps.

- Dr. Kerlavage explained that at the February 2019 State of the Union Address, the President proposed \$500 M for childhood cancer research to be appropriated over 10 years. In subsequent weeks, the White House convened several meetings with patients, parents, and advocates. Then-NCI Director Dr. Norman Sharpless and Dr. Lowy joined the Vice President to meet with stakeholders to discuss how increased funding might accelerate progress against childhood cancer.
- The CCDI's goals are to (1) maximize all opportunities to improve treatments and outcomes for children with cancer; (2) build a connected infrastructure to enable sharing from multiple repositories; (3) identify opportunities to make data work better for patients, clinicians, and researchers; and (4) develop and enhance tools and methods to extract knowledge from the data.
- Dr. Guidry Auvil reported that support for pediatric cancer research by the NCI and NIH increased between 2014 and 2018. The NCI already has several programs devoted to studying childhood and adolescent and young adult (AYA) cancers and survivorship. The data collected by these programs usually have been formatted to answer very specific questions, and they are stored in different repositories maintained by the NCI, NCI grantees, children's hospitals, or cancer care centers.
- Dr. Guidry Auvil noted a few childhood and AYA cancers for which data are particularly important. The 5-year relative survival rate for acute lymphocytic leukemia has greatly improved since the 1970s, but a significant number of patients still do not respond to treatment. Limited progress has been made in increasing the 5-year survival rate of childhood brain and nervous system cancers.
- Successes in childhood cancer have resulted largely from very toxic therapies given to growing children, which lead to serious long-term side effects. Secondary cancers cause death for about 75 percent of childhood cancer survivors; additionally, from 60 percent to more than 90 percent of survivors develop at least one chronic health condition. The CCDI is positioned to address these issues.
- At the CCDI symposium held in Washington, D.C., July 29–31, 2019, pediatric oncologists, data scientists, ethicists, and advocacy stakeholders met to share their perspectives on data management for cancer research studies. The symposium featured four areas of focus: prioritizing scientific and clinical research data needs; creating meaningful data sets; developing infrastructure to enable federation among repositories; and developing tools and methods to extract knowledge from data.

- Dr. Kerlavage communicated the next steps for the NCI CCDI. A summary of the ideas related to cancer data sharing solicited from the research community is now available on the NCI website. A post-symposium webinar is scheduled for October 8, 2019, and is intended for a broad audience. The NCI will publish a position paper in fall 2019 on the CCDI approach.
- NCI leadership and the newly forming BSA CCDI Working Group will focus on three areas: creating and maintaining a resource catalog for data, biospecimens, and tools; connecting pediatric data repositories and registries holding NCI-funded data; and defining criteria for “ideal” data sets through connecting existing data and collecting new data.
- Dr. Kerlavage indicated that although the NCI will provide resources and the environment to make data sharing possible, the research community should identify ways they can change their approaches to facilitate the sharing and use of data. He outlined principles of data sharing success, which include using digital identification, interoperability, and exposing data and models through an application program interface.

Discussion

- Ms. Leach sought clarity on the age definition for AYA cancers. Dr. Guidry Auvil clarified that the NCI refers to AYA patients as up to and including age 39.
- Mr. Vargas asked how the NCI plans to overcome institutional barriers to incentivize data sharing. Dr. Kerlavage responded that childhood cancer is a sensible field to push sharing because of the incentive to help children and the need to get enough statistical strength to make meaningful discoveries about these rare conditions. Dr. Kerlavage was pleased that at the end of the July symposium, participants conversed about collaborating to share data. Micro-attribution for data sourcing combined with digital identification to track usage will be important methods to retain investigator credit in a sharing environment.
- From the perspective of both a 30-year survivor of Hodgkin’s lymphoma and a pediatric oncologist, Dr. Aune shared that 90 percent of patients who survive this disease currently endure complications and most, if not all, will face a chronic health condition by age 50. He inquired about options the NCI provides to promote data sharing besides the proposed \$50 M per year allocation. Dr. Kerlavage explained that the \$50 M per year will help the CCDI to achieve its goals faster as the NCI moves forward on its data sharing focus areas. The NCI is committed to developing core data repository infrastructure to the maximum extent allowed by the budget.
- In response to a question from Dr. Aune, Dr. Kerlavage conveyed that extracting data from electronic health records (EHRs) and interfacing with existing EHR systems is one of the CCDI’s biggest challenges. The NCI is exploring methods to connect SEER data

with other data types. The NCI is collaborating with the U.S. Department of Energy to develop deep learning methods for automated extraction of information from pathology reports.

Closing Remarks

Dr. Gregory Aune and Ms. Amy Williams

Ms. Williams thanked the participants for their engaged attendance at this meeting. She noted that the NCRA will communicate follow-up items in preparation for the next meeting.

Dr. Aune expressed appreciation to NCRA retiring member Mr. Vargas for his service and valuable input. Mr. Vargas reflected that during his time with NCRA, he has brought the perspective of leveraging science to partner with stakeholders, such as community health systems and policymakers. He supported the continuation of this perspective at the NCRA.

Dr. Aune summarized the meeting's presentations and asked NCRA members to provide closing comments.

Mr. Vargas was pleased that cancer prevention efforts were discussed and that the NCI is increasing the investment in childhood cancer survivorship. He thanked Dr. Aune for his advocacy for childhood cancer survivorship research and expressed support for the increased attention being given to the rural/urban cancer disparity.

Ms. Leach commented that the NCI has been dedicated to working with advocates and expressed enthusiasm for the speed at which the STAR Act and the CCDI have been implemented.

Dr. Aune emphasized that patients want better treatments. Data such as the single-year 5 percent decrease in melanoma mortality show that basic science research over many years is beginning to significantly disrupt certain cancers.

The meeting adjourned at 3:21 p.m.

Certification

I hereby certify that foregoing minutes are accurate and complete.

November 18, 2019

Date

Gregory J. Aune, MD, PhD

Dr. Greg Aune, Chair
NCI Council of Research Advocates

11/19/19
Date

Amy Williams
Amy Williams, Executive Secretary