92nd Meeting of the National Cancer Institute (NCI)
Council of Research Advocates (NCRA)
National Institutes of Health (NIH)

Virtual Meeting
June 26, 2024

Members Present

- Mr. Yelak Biru
- Dr. Vickie Buenger
- Mr. Marty Chakoian
- Ms. Annie Ellis, *Chair*
- Mr. Nathaniel Ferre
- Ms. Joya Delgado Harris
- Mr. Lee Jones
- Dr. Brittany McKelvey
- Mr. Robert Riter
- Ms. Kristen Santiago
- Ms. Jacqueline Smith
- Mr. Kevin Stemberger
- Dr. Nicole Willmarth

Speakers

Ms. Holly Gibbons, Deputy Director, Office of Government and Congressional Relations, NCI
Dr. Andrew Kurtz, Program Director, Center for Strategic Scientific Initiatives, NCI
Dr. Michelle Mollica, Deputy Director, Office of Cancer Survivorship, NCI
Dr. Kimryn Rathmell, Director, NCI
Ms. Amy Williams, Director, Office of Advocacy Relations (OAR); Executive Secretary, NCRA, NCI

Contents

Welcome and Opening Remarks

Ms. Annie Ellis and Ms. Amy Williams

Ms. Williams opened the meeting at 12:15 p.m. Eastern Time (ET), welcomed Council members and attendees, provided brief opening remarks, and reviewed the day's agenda.

Ms. Ellis called the meeting to order, reviewed the conflict-of-interest rules, read the public comment statement, and confirmed that a quorum of members was present.

Cancer Grand Challenges

Dr. Andrew Kurtz

Ms. Ellis introduced Dr. Kurtz, who is the Program Director of NCI's Center for Strategic Scientific Initiatives and the co-lead for Cancer Grand Challenges (CGC). Ms. Ellis noted that Mr. Yelak Biru and Ms. Joya Delgado Harris serve on the CGC Advocacy Panel.

- Dr. Kurtz shared the history of CGC, which is a partnership between NCI and the private charity Cancer Research UK (CRUK). Between 2011 and 2021, NCI led the Provocative Questions Initiative. This initiative hosted small workshops with the extramural cancer research community to develop new research questions and led to R01 and R21 funding opportunities for single investigator teams. Over the initiative's 10-year history, 35–50 awards were funded each year. In comparison, the CRUK Grand Challenge was launched in 2015, combining the problem development process of the Provocative Questions Initiative with a team science approach to study larger issues that could not be addressed by individual investigators. Between 2017 and 2019, the CRUK Grand Challenge funded seven project teams.
- In 2020, NCI and CRUK partnered to expand CRUK's Grand Challenge initiative through a collaborative funding initiative called CGC. The goal of CGC is to set ambitious challenges in cancer research and provides awards up to $5 million per year over five years ($25 million total) that support multinational research teams. CGC is guided by an international scientific committee that provides input on the challenges developed and the research teams funded. For the first phase of the partnership, NCI and CRUK agreed to co-fund three rounds of awards with up to four awards per round.
- Dr. Kurtz explained that the challenges developed by CGC must address important and complex problems in cancer research. These problems can be related to understanding, preventing, detecting, and/or treating cancer that can be addressed through basic, translational, clinical, and/or population research. These problems can be new for the cancer field or persistent problems that have existed for many decades. In all cases, these challenges require intellectual inputs from multiple investigators from international multidisciplinary teams. Importantly, these problems are timely, especially in areas where researchers are poised to make significant progress in the near term. Previous challenges funded by CGC are on its website.
- Dr. Kurtz shared examples of CGC awardees. The eDyNAmiC project was funded in 2022 and characterized extrachromosomal DNA (ecDNA), which are small circular pieces of DNA associated with aggressive cancers and cancer progression. The CANCAN project was also funded in 2022, and it focused on understanding the clinical subtypes and reversing cancer-

related cachexia, which is a decline in muscle mass and motor function. PROSPECT is a currently funded award characterizing molecular changes caused by various environmental exposures across an individual's lifetime and how these changes may be associated with early-onset cancers like colorectal cancer. Another current project is SAMBAI, which is understanding the mechanism through which genetics, biology, and social determinants affect cancer risk and outcomes among the global African diaspora. All these projects involve 10–15 researchers.

- Dr. Kurtz highlighted a fifth team that was awarded in this most recent round and will be fully funded by CRUK. The project is called KOODAC and is addressing the challenge of developing therapies for pediatric solid tumors.
- Dr. Kurtz clarified that as a private charity, CRUK relies on funding support from other donors and partners. As a US federal agency, NCI does not participate in fundraising efforts.
- Dr. Kurtz explained that CGC-funded projects must have a minimum of one patient advocate with a clearly defined role, though many projects have multiple patient advocates. These advocates should represent people affected by cancer as a group and not just provide their individual viewpoint or that of any advocacy organization. The research teams should collaborate with their advocates throughout the project, so that this interaction can add clear value to the project and advance progress toward solving the challenge.
- Dr. Kurtz shared the CGC-developed definitions related to patient advocacy. These terms are not used by NCI for its own research activities. "Involvement" is when patient advocates use their experiences with cancer to shape the research and have a voice that is reflected in the scientific strategy. "Engagement" is when patient advocates are involved in sharing information and knowledge about the research, either with other patient advocates or the public who are not directly involved with CGC research. Both activities are distinct from "patient participation," which is when patients are part of a research study or a clinical trial but do not work directly with the researchers on the actual project.
- Dr. Kurtz explained that the CGC Advocacy Panel comprises an international group of patient advocates that assists the program to develop strategies to involve patient advocates in CGC research. The panel provides feedback on CGC teams' proposed approaches for involvement and engagement and engages with patient advocates on the funded teams throughout the projects.
- Dr. Kurtz shared a patient engagement example from the CRC-funded team called Team OPTIMISTICC, which is an acronym for OPportunity To Investigate the Microbiomes Impact on Science and Treatment In Colorectal Cancer. Patient advocates from Team OPTIMISTICC hosted nine educational webinars that were informal conversations between the researchers, other patient advocates, and the public. These webinars covered topics such as lifestyle factors that can impact the microbiome (e.g., diet, antibiotics), prevention and screening of colorectal cancer, and novel treatment strategies for colorectal cancers, including vaccines and immunotherapies. This webinar series is a great example of how patient advocates made research more impactful by making it accessible to a broad audience.

Discussion

- Ms. Ellis asked Ms. Delgado Harris and Mr. Biru to share thoughts about their experience serving on the CGC Advocacy Panel. Ms. Delgado Harris said that connecting with more patient advocates and people with an international perspective has allowed the advocates to learn from each other and share best practices. Each of the CGC-funded teams has patient advocates who are passionate and not afraid to speak up on specific issues. Mr. Biru said that the patient advocates on the panel are not meant to represent a particular cancer or advocacy organization. The three main roles for the panel are to create and implement a training program for the patient advocates on CGC-funded research teams, ensure that research teams think of patients first when planning and conducting their research, and act as a resource for the patient advocates on the CGC-funded teams during their five-year funding period.

- Ms. Delgado Harris noted that the CGC Advocacy Panel assesses CGC funding application plans for patient advocate involvement and provides feedback on how they can improve, which has been a great learning experience for researchers. Mr. Biru shared an example of a research team that incorporated the panel's feedback, and the resubmission was one of the most patient-centered research plans that incorporated strong involvement and engagement plans.
- Mr. Lee Jones serves as a patient advocate for Team OPTIMISTICC and has participated on teams submitting proposals to CGC, including a project about cancer-related cachexia. In his experience, it is difficult for patient advocates to be involved with basic and preclinical research teams. Most researchers in general have no experience working with patient advocates and do not always understand the benefit of this partnership. Mr. Jones encouraged any NCRA members to consider participating in CGC as an advisory panel member or on a research team.
- Dr. Kurtz explained that CGC solicits applications in two phases. First, CGC announces the challenge and requests research teams submit a short application of their research idea. From these idea submissions, CGC leadership chooses approximately a dozen finalists to submit a full application. CGC staff, including the advocacy panel, work closely with the finalists to develop their applications and ensure the research plan has effective patient advocacy plans.
- Ms. Kristen Santiago asked whether a patient advocate who is part an institution that is already funded by CGC is allowed to serve as a team member or an advocacy panel member. Dr. Kurtz said that there are no restrictions on patient advocates joining CGC, but there is a policy that patient advocates cannot serve on multiple teams.
- Mr. Marty Chakoian asked about collaboration between patient advocates on different research teams. Dr. Kurtz said that there is an annual CGC Summit, which is an opportunity for all the teams, including the patient advocates, to gather, network, and present on their research. Patient advocates have used this opportunity to discuss their work and learn from each other. Mr. Biru and Ms. Delgado Harris discussed the Cancer Advocacy Café, which is a quarterly meeting of the CGC patient advocates where they share their experiences and learn from each other.
- Dr. Nicole Willmarth asked about the time commitment required to participate as a CGC Advocacy Panel member or as a patient advocate on a research team. Mr. Jones shared his experience with developing a proposal for CGC, which was very time-consuming. Conversely, serving as a patient advocate on a research team is less of a time commitment; there are a few meetings a month and some time is required to review documents and papers. As advocacy panel members, Mr. Biru and Ms. Delgado Harris said that the first few months were a significant time commitment because it involved reviewing proposals, providing comments, and having internal meetings with the other panel members.

- Dr. Vickie Buenger remarked that the information being shared by patient advocates during the annual summit or quarterly meetings should be captured and published as a white paper. It would be useful to publish this information in a scientific journal for researchers, but other platforms may be needed to share this information with patient advocates. Dr. Kurtz agreed and noted that the some of the CGC patient advocates, like Dr. Laura Porter from Team OPTIMISTICC, have published about their advocacy experiences, and the CGC team is considering how to capture and disseminate key takeaways from the annual summit meeting.
- Ms. Williams noted that Dr. Kurtz was invited to speak with the NCRA to share the unique way that CGC is bringing the collective patient perspective to research and show how patient advocates can be a part of team-based science. Ms. Ellis added that there may be an opportunity for NCRA to provide feedback on how NCI can effectively engage with patient advocates. Ms. Delgado Harris added that some patient advocates from CGC are working to develop a training for researchers about how to utilize advocate expertise.

Legislative Report

Ms. Holly Gibbons

Ms. Gibbons provided an overview of activities related to fiscal year (FY) 2025 appropriations, legislative issues to watch, and NCI's recent engagement and advocacy with Congress.

- Ms. Gibbons reminded the Council members that the FY24 appropriations were enacted halfway through the fiscal year in March, and Congress provided a base increase of $120 million for NCI. Additionally, FY23 was the last year of mandatory funding for the Cancer Moonshot^{SM} as authorized under the 21st Century Cures Act, so NCI's overall budget experienced a net $96 million decrease.
- Ms. Gibbons noted that there was a significant leadership transition in Congress. Representative Kay Granger of Texas is retiring and retired from her post as the Chair of the House Appropriations Committee ahead of the FY25 appropriations process. Representative Tom Cole of Oklahoma, who is the former chair and ranking member of the Labor, Health and Human Services (HHS), Education, and Related Agencies Subcommittee, is now the Chair of the House Appropriations Committee. Representative Cole has continually advocated for sustained investments in biomedical research and has emphasized the importance of these investments for national security.
- Ms. Gibbons shared details about the recently released House Labor-HHS appropriations bill for FY25, which was drafted by Republicans and addresses many of their priorities. The bill is written to a topline level that is below FY24 enacted levels. It proposes flat funding for NIH at $48 billion but an increase of $655 million to NCI's budget for a total of $7.875 billion. However, this planned increase is the result of a proposed plan to restructure the Institutes and Centers (ICs) within NIH. The proposal is expected to move out of the subcommittee on June 27 along party lines.
- Ms. Gibbons showed photos of the May 23 hearing on the President's FY25 NIH Budget Request with the Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies. The NIH Director, Dr. Monica Bertagnolli, and five IC directors attended, including Dr. Kimryn Rathmell from NCI.

- Ms. Gibbons shared the Congressional calendar and highlighted some specific dates for the appropriations process. She noted that it is unlikely that the FY25 appropriations will be enacted before the end of the fiscal year, so there will likely be a continuing resolution. As a note, the lame duck session of Congress begins November 12 and runs through January 3, 2025, when the new Congress is sworn in. In 2020 and 2022, appropriations bills were enacted during the lame duck session, but it is unclear what will happen this year.
- Ms. Gibbons shared photos of NCI's recent engagements with Congress. In May, the director of the NCI Center to Reduce Cancer Health Disparities, Dr. Sonya Springfield, spoke at a Congressional briefing hosted by the American Association for Cancer Research (AACR) to highlight the release of the AACR Cancer Disparities Progress Report. Also in May, NCI hosted Congressional staff for a visit focused on childhood cancer research. The staff met with Dr. Rathmell, extramural program leaders, NCI Pediatric Oncology Branch leadership, and two patients. Dr. Rathmell also met with several members of congress, including Representatives Rosa DeLauro, Roger Aderholt, and Joe Morelle, and Senator Tammy Baldwin.
- Ms. Gibbons highlighted several legislative proposals that are pending ongoing congressional committee activity focused on telehealth extensions, drug shortages, improving the clinical trial process for researchers and participants, the role of artificial intelligence in biomedical research and other sectors, and potentially restructuring NIH.
- Regarding the potential legislation to restructure NIH, Ms. Gibbons said that in May, Senator Bill Cassidy released a white paper proposing policy changes to modernize NIH, such as prioritizing research, balancing the portfolio, sustaining the United States' competitive advantage in biomedical research, and streamlining the peer review process. On June 14, Representative Cathy McMorris Rodger released a framework for reforming NIH, including a proposal to consolidate NIH ICs from 27 to 15. Notably, NCI, the National Institute of Mental Health, and National Institute on Aging would not be consolidated. The recently released House Labor-HHS appropriations bill reflects this proposed framework, but this issue will likely be discussed and negotiated as part of the appropriations process.
- Ms. Gibbons noted a bipartisan effort to explore opportunities to expand the 21st Century Cures Act, which originally authorized funds for the Cancer Moonshot, the *All of Us* Research program, and the Brain Research Through Advancing Neurotechnologies® (BRAIN) Initiative. Representatives Diana DeGette and Larry Bucshon released a request for information about potential policies that could be included in the 21st Century Cures 2.0 Act as way to continue moving the biomedical research and regulatory sectors forward.
- Ms. Gibbons acknowledged Congressional engagement and outreach efforts led by AACR, Association of American Cancer Institutes, and the American Society of Clinical Oncology (ASCO). Dr. Rathmell also met and had discussions with patient advocates at the ASCO annual meeting in June.

Discussion

- In response to a comment from Ms. Ellis, Ms. Gibbons said that the FY25 budget will not be passed before the end of FY24 and there will likely be at least one continuing resolution that funds the government until after the election in November. There may be additional continuing resolutions that carry into the lame duck session.

- Mr. Chakoian commented on the Congressional proposal to restructure NIH from Representative Cathy McMorris Rodgers. Ms. Gibbons noted that this proposal is not a bipartisan proposal. The plan would consolidate the ICs at NIH was also included in the FY25 appropriations proposal that was just released.

National Standards for Cancer Survivorship Care

Dr. Michelle Mollica

Dr. Mollica shared an overview of the process to develop the National Standards for Cancer Survivorship Care and the next steps for implementation.

- Dr. Mollica shared that NCI recognizes that an individual is considered a cancer survivor from the time of diagnosis through the balance of life. In the United States, there are over 18 million cancer survivors both with and after a cancer diagnosis. Dr. Mollica also noted that cancer survivorship care is complex.
- Dr. Mollica highlighted current cancer survivorship care guidelines. There are guidelines from the National Comprehensive Cancer Network®, the Children's Oncology Group, and LIVESTRONG. There is also the Quality of Survivorship Care Framework, which was developed in collaboration with several NCI staff, and the Commission on Cancer (CoC) accreditation, which has a specific cancer survivorship standard that was updated in 2019. The current CoC focuses on survivorship care programs and requires a survivorship care coordinator at each CoC accredited site as well as at least three programs or services for survivors.
- Despite these guidelines, Dr. Mollica noted that survivorship care in the United States is variable and suboptimal. These guidelines are not systematically implemented among providers or health care systems and delivery of survivorship care varies based on both the location and resources of a health system. The lack of consistent survivorship care leads to survivors with unmet needs, poor health outcomes, and lack of quality care.
- Dr. Mollica explained that the development of the National Standards for Cancer Survivorship Care was conducted as part of the Cancer Moonshot and the President's Cancer Cabinet, which created a Supporting Patients and Caregivers Task Force. The Survivorship Working Group is within this taskforce and worked on developing the survivorship standards. This working group includes members from across government agencies, such as the Centers for Disease Control and Prevention, the US Department of Veterans Affairs (VA), and the Centers for Medicare & Medicaid Services. These are standards rather than guidelines; guidelines are recommendations for health care providers to give optimal care to a specific patient. Standards are recommendations for health systems that apply to the patients they serve.
- Dr. Mollica highlighted the three focus areas for these national standards: (1) health system policy, which are the principles and procedures guiding an organization's capacity and structure to provide survivorship care; (2) health system processes, which are an organization's capacity to deliver survivorship care through its embedded practices and procedures, and (3) health system evaluation and assessment, which is the ability to measure the impact of survivorship care within an organization.

- Dr. Mollica shared the process for developing the National Standards for Cancer Survivorship Care involved conducting a landscape review of information on survivorship care (e.g., guidelines, frameworks), identifying possible indicators for the three focus areas, holding subject matter expert consensus meeting, and developing the standards based on the inputs. Subject matter experts included research advocates and representatives from a variety of fields, including social work, oncology, and primary care.
- Dr. Mollica showed the 10 indicators for each focus area (health system policy, health system processes, and health system evaluation and assessment) of the newly developed national standards for cancer survivorship, which are detailed on this website.
- Dr. Mollica said that the working group is currently in the process of pilot testing the standards for feasibility and working on future dissemination and evaluation efforts. The VA is piloting testing these standards through its VA Comprehensive Survivorship Program, and NCI recently published an administrative supplement notice for currently funded grants focused on assessing and enhancing survivorship care. The working group is developing a toolkit with guidance for support health care systems that are implementing these standards. The working group is also focused on advancing research and policy for survivorship care.
- Dr. Mollica highlighted some efforts by the NCI Office of Cancer Survivorship (OCS) to recognize National Cancer Survivors Month in June. These efforts include a director's webinar featuring a panel of cancer survivors and advocates, new cancer survivor stories on the OCS website, and webpages highlighting research areas, including the development of the national standard for survivorship.

Discussion

- Mr. Jones said that a major issue for cancer survivorship care is the transition from cancer care to primary care. The national standards should include developing a survivorship care plan that survivors can keep and share with their primary care doctors or any specialist. There should also be resources and support to help survivors cope with their experience. Dr. Mollica noted that transitioning from cancer care to primary care is an indicator in the health system processes focus area of the survivorship standards. NCI also released a request for applications about system-level interventions to ensure that primary care providers are informed on how to provide care for cancer survivors.
- Ms. Santiago shared that even though she has a cancer survivorship plan, that plan was never reviewed by her primary care doctor. Hopefully, the National Standards for Cancer Survivorship Care will put the responsibility to share survivorship plans on the health care system rather than on the survivor.
- In response to Ms. Santiago's suggestion to provide incentives or reimbursements for the VA to implement and act on these standards, Dr. Mollica clarified that the VA Comprehensive Survivorship Program is in its very early stages and is starting very small. There may be opportunities for incentives as these efforts expand and include primary care systems.
- Ms. Jacqueline Smith noted the issue of community health care or primary care providers who are not prepared to help cancer patients who are experiencing adverse events related to their treatment through a clinical trial, such as immunotherapies. Dr. Mollica said that the working group is developing resources for health systems that can be tailored to a variety of providers,

including those from smaller community health centers. The working group is discussing how the standards will apply to patients who are being treated with immunotherapies as well as newer, targeted therapies.

- Mr. Robert Riter commented that interest among health care systems to provide cancer survivorship plans has not been consistent over the years and asked how advocates can ensure that survivorship plans are an embedded part of the cancer treatment culture. Dr. Mollica noted that providers often only focus on the cancer survivorship plan rather than the process of care, which includes communicating with survivors and not having the burden of finding the proper care fall on the survivor.
- Mr. Chakoian noted that cancer survivorship should go beyond traditional health care and focus on aspects like diet, exercise, financial support, and workplace accommodations. Dr. Mollica said that even though implementing the standards is in the pilot phase, there are efforts to work with nonprofit organizations that are already providing this type of supportive care and ensure survivors have better access to these resources.
- Ms. Ellis shared her experience of having information missing from her cancer survivorship plan, which resulted in her having to go through the time and expense of receiving a diagnostic test to share that information with her primary care provider. These cancer survivorship plans should be comprehensive.
- Regarding the VA Comprehensive Survivorship Program, Dr. Brittany McKelvey highlighted that the VA population is not reflective of the general population. Therefore, lessons learned from this pilot may not be generalizable to the larger patient population. Dr. Mollica said that there are plans to expand this pilot work to other sites, including community health care systems. NCI is funding supplements and grants to support these efforts.

Director's Update

Dr. Kimryn Rathmell

Dr. Rathmell provided updates on recent accomplishments by NCI investigators, discussions from major cancer meetings, and newly appointed leaders and working groups at NCI. She also discussed NCI's budget and highlighted recent research and program activities.

- Dr. Rathmell recognized and thanked the NCRA members whose term on the council is ending Mr. Biru, Ms. Santiago, Ms. Smith, Mr. Kevin Stemberger, and Dr. Willmarth. While new members will join the council soon, NCI is updating its advisory board orientation process, which will include an in-person orientation.
- Dr. Rathmell acknowledged NCI intramural investigators who were recently elected to the National Academy of Sciences, the American Society for Clinical Investigation, and the Association of American Physicians.
- Dr. Rathmell attended the AACR and ASCO annual meetings. NCI investigators received major awards at these meetings. Steven Rosenberg, MD, PhD, received the AACR Award for Lifetime Achievement in Cancer Research for his pioneering work on immunotherapy treatments for cancer. Satish Gopal, MD, MPH, who is the director of the NCI Center for Global Health, received the ASCO Humanitarian Award.
- Dr. Rathmell shared that the major topic of discussion at the AACR meeting was to ensure cancer

research is more multidisciplinary and collaborative, emulating a major goal of the National Cancer Plan to engage every person. At ASCO, the discussions focused on accelerating the clinical research process and working to get treatments to patients faster.

- Dr. Rathmell announced the formation of the NCI Center for External Affairs, which will include NCI's Office of Communications and Public Liaison, the Office of Government and Congressional Relations, and the Office of Advocacy Relations (OAR). The hope is that bringing these offices together under this center will make them each more effective and cohesive.
- Dr. Rathmell shared some additions to NCI leadership. Warren Kibbe, PhD, will become the Deputy Director for Data Science on June 30. His focus will be on strategies for artificial intelligence (AI) initiatives, data harmonization, common data elements, coding algorithms, and digital transformation. Shaalan Beg, MD, MBA, will join NCI as a Senior Advisor for Clinical Research and will focus on strategies to accelerate and democratize clinical research. NCI also recently announced the formation of Cancer Equity Leaders, which is composed of cancer center and medical school leaders who are committed to transforming the future of cancer health equity.
- Dr. Rathmell recently attended NCI's first Black in Cancer Conference—a grassroots effort to build a community of Black cancer leaders in all sectors of the field.
- Dr. Rathmell noted that the Center to Reduce Cancer Health Disparities (CRCHD) will change its name to the Center for Cancer Health Equity (CCHE).
- Dr. Rathmell highlighted the cuts to NCI's FY24 budget due to loss of funding for the Cancer Moonshot, which was funded by the 21st Century Cures Act. Despite the need for more funding to continue supporting and growing NCI's research portfolio, the budget is expected to remain flat.
- Dr. Rathmell explained the current grant funding paylines for FY24. Once the FY24 budget was finalized, the paylines for R01 grants for established new investigators and R21 exploratory grants was set to the 10th percentile. The final payline for R01 grants for early-stage investigators was set to the 17th percentile. Over the years, NCI has prioritized supporting early-stage investigators by steadily increasing their payline.
- Dr. Rathmell highlighted the National Cancer Plan and reminded the NCRA members of its eight goals that are divided into two groups. The health-centric goals include preventing cancer, detecting cancer early, developing effective therapies, and delivering optimal care. The empowering goals include maximizing data utility, eliminating inequalities, optimizing the workforce, and engaging every person. Discovery science is the fuel behind each of these goals.
- Dr. Rathmell shared several recent, notable publications from NCI-funded researchers. These publications focused on determining the percentage of cancer patients who participate in clinical trials, identifying high-risk prostate cancers with a urine test, studying how childhood cancer survivors may age faster, and testing biomaterials that could enhance cancer vaccines. There are also studies using AI to more precisely match cancer drugs with patients and predict responses to immunotherapy.
- Dr. Rathmell explained NCI's efforts to accelerate clinical trials and broader populations so that treatments can reach patients faster. NCI is testing decentralized clinical trial designs, piloting a Virtual Clinical Trials Office, continuing the Clinical Trials Innovation Unit, and running the NCI

MATCH successor trials.

- Dr. Rathmell highlighted research at NCI that is set to transform clinical research, such as multi-cancer detection (MCD) tests, developing a test for self-screening for human papillomavirus (HPV), and collaborating with global partners to develop better diagnostic tests and an effective one-dose vaccine for HPV. With respect to MCDs, Dr. Rathmell noted the Vanguard study is expected to launch in early 2025.
- Dr. Rathmell noted another important effort from NCI to improve clinical trials and ensure they are reaching communities where patients are. The NCI Board of Scientific Advisor's Ad Hoc Working Group to Enhance Community Cancer Research and Quality Care is composed of experts from across the government, cancer centers, and professional societies. The goal of the working group is to find capacity in our health care systems to do clinical research and identify any gaps that can impact broad-reaching clinical trials.
- Dr. Rathmell expressed a commitment to hear from the community. Dr. Rathmell has made open calls for input through social media and attended in-person meetings to meet with advocates and trainees. In July, NCI's first annual scientific priorities retreat will bring together NCI leaders and board chairs from the Institute's six boards. This meeting will focus on areas where NCI needs to make investments. Additionally, NCI is hosting a community conversation as part of the Cancer Cabinet within the Cancer Moonshot. The topic of the conversation will be how to promote access to clinical trials research in rural and other medically underserved communities.
- Dr. Rathmell asked the Council members for their input on several topics, including how to engage the advocacy community in clinical study innovation, how the NCI Designated Cancer Center Community Outreach and Engagement Program can continue or improve connecting with local communities, and specific issues NCI should address.

Discussion

- Ms. Ellis remarked that treating cancer is highly profitable and creates competition between hospitals and health systems. Dr. Rathmell said that a session at the White House Clinical Trials Forum focused on moving to develop a model where some cancer patients have two oncologists, one at a health care center close to their home and one at an academic center. This model should focus on maximizing the relationship between these two centers and understanding what incentives are needed. Ms. Ellis and Dr. Rathmell noted the potential of interstate telehealth to support cancer patients.
- Ms. Smith shared two examples of community engagement proposed or developed by the External Advisory Committee for the Moffitt Cancer Center. First, the committee suggested creating satellite centers throughout the state to reach more patients; many patients are driving several hours to receive treatment or participate in clinical trials, which can be a barrier for them. These satellite centers should have oncologists who specialize in cancers that are prevalent in the region, partnerships with community-based organizations, and staff that speak languages of the area (e.g., Spanish). Second, the committee developed Moffitt's mobile skin cancer screening initiative, called Mole Patrol, which would visit baseball spring training sites, conduct screenings, and promote skin cancer awareness. By investing in the community, cancer centers can bring health care to people instead of expecting people to come to the cancer center.

- Ms. Santiago suggested that NCI's research efforts should focus on early screening and detection, modifiable risk factors, biomarker testing and precision medicine, and palliative care.
  Ms. Santiago also suggested that NCI could partner with the *All of Us* Research Program to promote more people sharing their data and making the program more impactful. Dr. Rathmell said that she would work with NCI and OAR staff to arrange speakers from NCI who are leading detection, biomarker, and palliative care research to speak with the NCRA. She will also invite someone from *All of Us* to speak to the NCRA.
- Mr. Jones said that as a member of several IRBs, he noticed that the clinical trial process was developed for testing chemotherapy treatments and does not translate to immunotherapy or targeted therapy trials. For example, the maximum tolerated dose criteria in phase 1 only applies to chemotherapies and not immunotherapies or target therapies. NCI should consider reworking the clinical trial process based on what drug is being tested.
- Mr. Jones also said that the field should move away from using the term "subjects" in clinical trials and instead say "participants." While scientists view cancer clinical trials as scientific discovery, patients consider these trials as treatment, potentially the best available treatment or their last possible treatment. Ms. Ellis said that since the Human Subjects Protections include the word "subject," then this language will move into patient-facing materials. However, there should be efforts to update to more patient-centric language.
- Dr. Buenger asked whether NCI was involved in international, multi-institution trials to study childhood and rare cancers. Ms. Ellis said that the childhood cancer research community is a model of collaboration in running clinical trials. The identification of more cancer subtypes will make clinical trials smaller and more targeted with their treatments and patient populations. Global efforts and cooperation are needed to support registration for these childhood and rare cancer trials. Dr. Rathmell agreed that the pediatric groups have led the way in studying rare cancers, and the field should apply the best practices from pediatric cancer research to adult cancer research. Leadership from NCI and the European Organisation for Research And Treatment (EORTC) have discussed ways to share resources and make progress toward understanding and treating rare tumors. There may be ways to find commonalities between rare cancers, such as common mutations causing a similar response to a drug.
- Mr. Jones said that the FDA allows people as young as 12 to participate in adult clinical trials, but this is very rarely done. NCI could find opportunities to lower the age criteria for clinical trials and include younger participants, especially for these rare cancer trials. Dr. Buenger said that the European Medicines Agency allows younger participants in clinical trials based on their body weight, and the FDA has guidance for including children in trials. Ms. Ellis said that a potential clinical trial criterion could be that if there are no safety signals in the first five participants, then pediatric participants can be enrolled. Mr. Jones noted that obtaining consent is more difficult for pediatric participants, especially if they have guardians or divorced parents. Dr. Rathmell said that she would investigate options for some level of flexibility around the age of clinical trial participants. One discussion point at the White House Clinical Trials Forum was about managing levels of risk tolerance. The NCRA or another group of advocates could be involved in discussions about the acceptable levels of risk in a clinical trial and instances where risk may be warranted.

Closing Remarks and Board Administration

Ms. Annie Ellis

Mr. Jones made a motion to approve the minutes of the 90th NCRA meeting. The motion passed unanimously.

Ms. Ellis and Ms. Williams thanked Council members for their time, attention, and feedback and thanked OAR staff. They also acknowledged the NCRA members concluding their terms of service at this meeting and thanked them for their contributions.

The next NCRA meeting will be held on September 18, 2024.

The meeting was adjourned at 3:17 p.m. ET.