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Progress and potential: the Cancer Moonshot

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In 2016, US Congress passed the 21st Century Cures Act, which provided funding to the National Cancer Institute for the Beau Biden Cancer Moonshot (hereafter, "Moonshot"). Funding for the initiative began in 2017 and is intended to continue annually for 7 years. Now that we are just beyond that halfway point, the time seems right to assess the progress of this visionary effort. Already, it is clear the Moonshot is meeting its three broad goals of accelerating scientific discovery in cancer, fostering greater collaboration, and increasing the sharing of data to improve cancer prevention, diagnosis, treatment, and care by implementing the recommendations of its advisory Blue Ribbon Panel.

In shaping the Moonshot, leaders explicitly sought to prioritize those areas of basic, clinical, and population science research that could most rapidly improve patient care (Table 1). In all, the Moonshot supports more than 240 new projects, fostering progress across a broad range of research topics. In pursuit of the goal of accelerating cancer progress for patients, there are four essential features of all parts of the Moonshot: a strong commitment to collaborative research, an embrace of open access publications, a robust policy of complete data sharing, and an intense focus on the elimination of cancer health disparities. In this report, we present overarching reflections on these common thematic elements of the Moonshot and then provide specific highlights of a few of the advances enabled by this investment. We cannot cover all programs supported by the Moonshot in this Commentary, but for those who are interested, additional information is available on the NCI website at https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative.

Overarching themes

Collaboration: An instrument of success

A fundamental premise of the Moonshot is that collaboration and partnership are critical to accelerating translational research. Productive collaboration in medical research is not merely a matter of will or incentives. NCI has a long history of developing effective networks and supporting meaningful coordination and cooperation across networks. We have found that networks can more rapidly capitalize on opportunities from new discoveries and can conduct research that would not be possible by individual teams.

Drawing on this experience, many—although not all—Moonshot programs are designed as networks to leverage the strengths and expertise of all investigators and partners involved. These networks communicate, collaborate, and share data and resources to form a research

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community that is greater than the sum of its parts. Among the networks established under the Moonshot are public-private partnerships, such as the PartnershipforAcceleratingCancerTherapies (PACT) and the NCIFormulary. In addition, new patient engagement programs developed through the Moonshot are exploring new ways for patients and their loved ones to work in partnership with cancer researchers.

Open access publication

The architects of the Moonshot understood that progress in cancer research requires quick dissemination of data and findings. To ensure that results of Moonshot studies are promptly and broadly accessible, NCI requires that all Moonshot-supported publications be made publicly available immediately. NCI worked with journals that did not yet offer an option for authors to have their papers immediately and freely available to provide this option to authors of Moonshot-supported papers. This marks the first time a federal agency has set such a requirement for its grantees. To date, more than 1,000 papers have been published reporting on Moonshot-supported research.

Rapid sharing of research data

NCI also requires broad and immediate sharing of underlying primary data from Moonshot publications. Moonshot coordinating centers build data storage, sharing, and analysis platforms to harmonize and disseminate data to the wider scientific community. The transformational Moonshot data-sharing policy has become the model for other innovative projects at NCI, such as NCI's Serological Sciences Network, and for other projects across the National Institutes of Health.

An important effort to support this goal of data sharing has been our development of the NCI Cancer Research Data Commons (CRDC), a virtual data science infrastructure that leverages the power of cloud computing to connect cancer research data with analytical tools. The CRDC is just one component of the broader Cancer Data Ecosystem being developed through the Moonshot but is already a robust central resource. Through the CRDC, researchers can access a variety of data repositories—created through the Moonshot and otherwise—that include genomic, proteomic, imaging, clinical trial, and even canine data as well as advanced analytical tools.

Two infrastructure pieces in development will drive the interoperability and accessibility of data within the CRDC. The CenterforCancerDataHarmonization is developing resources, such as a standard data model (CRDC-H) to harmonize data across the CRDC repositories. The CancerDataAggregator (CDA) will act like a search engine to help researchers to query complex data across CRDC's varied repositories. Using CRDC-H, the CDA will aggregate different kinds of data into a harmonized dataset to allow for easier integrative analysis.

Building infrastructure of this kind is necessary to apply today's data science and computing power to cancer research needs now and in the future. Importantly, it is already clear that the research community is eager for these resources: over 70,000 users access components of the CRDC each month, and in 2020 alone, users of the cloud-based data infrastructure performed nearly 70 million compute hours.

Health disparities

Reducing cancer health disparities has long been an area of focus for the NCI and was embraced as a crucial cross-cutting theme in developing the Moonshot's scientific initiatives. Opportunities to better understand or address health disparities were articulated in the development of each Moonshot initiative and each funded project. This includes building more diverse cancer models for use in research, engaging with underrepresented and hard-to-reach patients, expanding use of proven strategies for cancer prevention and early detection among underserved populations, and rapidly disseminating and implementing new advances.

Many of the Moonshot research consortia (e.g., Human Tumor Atlas Network, Immuno-Oncology Translational Network, and others described below) have recognized the need for more diversity in samples and models. They are working to generate better pre-clinical models and improve sample collection from more diverse patient bases. Underserved populations experience worse treatment-related side effects, so there is also an interest in advancing symptom management research to reduce disparities through attention to patient-reported outcomes related to social determinants of health.

Examples of progress

Highlights of selected Moonshot initiatives are described below. This list is by no means comprehensive but provides insight into the variety of ways that Moonshot efforts are having an impact. Additional information is available from NCI.

Community resource programs

Several Moonshot efforts are focused on creating resources for the larger cancer research community, with the notion that these shared resources will be used to rapidly accelerate progress for patients. The NCI has a long history of developing research resources for the community, such as the Cancer Genome Atlas, and knows the power that such resources can provide to the research community. These efforts follow in that spirit of making high-quality data available to diverse groups of scientists:

The HumanTumorAtlasNetwork (HTAN) is constructing publicly available sets of three-dimensional atlases of the cellular, morphological, and molecular features of human cancers as they evolve from precancerous lesions to advanced disease. HTAN investigators are developing innovative technologies and resources to build detailed, dynamic atlases that enable computational models to predict how cancers develop and respond to treatment in different populations.

One group of HTAN investigators has developed a toolbox of approaches for profiling the molecular characteristics of fresh and frozen tumor samples to chart the complex tumor ecosystem (Slyper et al., 2020). HTAN investigators have also generated an Omic and Multidimensional Spatial tumor atlas of an evolving metastatic breast cancer. This atlas shows comprehensive features of tumor organization that can inform cancer biology and therapeutic response, including strategies to counter resistance mechanisms when they arise.

Several HTAN centers have developed and applied a highly multiplexed immunofluorescence technology that shows single-cell data in the context of the original spatial arrangement of the tissue to allow analysis of interactions between different cell types, such as within the immune microenvironment (Rashid et al., 2019).

The highly productive HTAN research teams have plans to release over 50 terabytes of data in the coming months in a coordinated publication and data release. This includes single-cell and bulk sequencing, proteomics, and imaging data from several hundred tumor samples of eight tumor types, ranging from pre-cancer samples to metastatic lesions. The atlases, underlying data, and metadata will be available through the HTAN data portal (https://data.humantumoratlas.org/) to the broader research community for analysis and integration with their own data and research.

The Patient-DerivedXenograftsResearchNetwork (PDXNet) is a coordinated research effort to develop large collections of PDX models that are standardized and reliable and reflect the diversity of clinical tumors. PDXNet investigators have engaged in collaborative research projects to show that PDX tumor models retain the genetic characteristics of the primary human tumor (Woo et al., 2021) and that PDX drug responses and sequencing results are reproducible across diverse experimental protocols, establishing the potential for multisite pre-clinical studies to translate into clinical trials (Evrard et al., 2020). PDXNet researchers have developed hundreds of new PDX models that are being expanded by the Patient-Derived Models Repository (PDMR), https://pdmr.cancer.gov/, and made available to the research community through PDXFinder https://www.pdxfinder.org. Already, the PDMR has distributed more than 1,000 fragments or cultures of patient-derived models to academic and industry researchers.

PDX Development and Trial Centers (PDTCs) have tested dozens of novel combination therapies on these models, and many of these treatments are now being evaluated in clinical trials. Minority-focused PDTCs are establishing PDXs from African American, Hispanic/Latino American, and Asian American patients to increase the diversity of the PDXNet repository. These models are being used by the cancer research community to study cancer disparities and understand why minority populations sometimes respond differently to certain cancer therapies.

Translational research to improve patient care

Many parts of the Moonshot are taking findings from basic cancer research and seeking to translate these cutting-edge concepts into better therapies for patients.

One exciting effort is the Partnership for Accelerating Cancer Therapies (PACT), a public-private research collaboration that includes the NCI and the National Institutes of Health, the Foundation for National Institutes of Health, the US FDA, and 12 pharmaceutical companies. The goal of PACT is to identify and develop robust, standardized biomarkers and related clinical data and to support the selection and testing of promising immunotherapies for the treatment of cancer, with the goal of bringing effective therapy to more patients. Pharmaceutical companies have contributed $60 million to the effort.

PACT works in collaboration with the CancerImmuneMonitoringandAnalysisCenter-CancerImmunologicDataCommons (CIMAC-CIDC), which is focusing on discovery and validation of immunology biomarkers to improve outcomes for patients who receive immunotherapy. This network has already developed standardized and harmonized assays across multiple sites. Together, CIMAC and PACT are supporting immunology biomarker assays for 41 trials from NCI national clinical trial networks and pharmaceutical companies. The assays are now being used to characterize responses in patients treated on these clinical trials. In addition, several publications on the standard operating procedures of harmonized assays have been shared with the research community to disseminate the knowledge gained by this important public-private partnership.

A different kind of effort is exemplified by the FusionOncoproteinsinChildhoodCancer (FusOnC2), a collaborative research network that is investigating the biology of fusion oncoproteins in childhood cancers to inform the development of targeted treatments for cancers that are at high risk for treatment failure or that don't currently have effective targeted therapies. The network brings together researchers with expertise in structural biology, proteomics, genomics, medicinal chemistry, pharmacology, and cancer biology, along with patient advocates from two major foundations dedicated to childhood cancer research.

Already, the network's researchers have developed new models to study these rare cancers and have made advances in understanding how each oncogenic fusion affects the protein's function and localization in the cell. For example, one team has defined the molecular basis for the cancer-specific targeting properties of the fusion protein that drives synovial sarcoma, a rare but highly aggressive childhood cancer (McBride et al., 2020).

In an example of inter-network collaboration enabled by the Moonshot, the FusOnC2 network is collaborating with the PediatricImmunotherapyDiscoveryandDevelopmentNetwork (PI-DDN), sharing a pediatric core and participating in joint working groups. The latter network is advancing preclinical immunotherapy research for children and adolescents with cancer by developing new cancer models, identifying possible targets, and testing combination treatments.

Many of the preclinical studies carried out within the PI-DDN are revealing disease mechanisms that can be rapidly translated into clinical benefit. For example, PI-DDN researchers have discovered a way to optimize the design of an FDA-approved immunotherapy to enhance activity against low-antigen-density tumors (Majzner et al., 2020). Another PI-DDN group discovered an alternative splicing event in B cell acute lymphoblastic leukemia (B-ALL) that plays a role in the relapse of about 30% of children and adults with B-ALL being treated with CAR T cells (Asnani et al., 2020). PI-DDN researchers are also developing and testing combinatorial CAR-T cell immunotherapy approaches for several high-risk subtypes of childhood leukemias, including acute myeloid leukemia (Vadakekolathu et al., 2020). Thus, the understanding of disease mechanism that has been afforded by the Moonshot is rapidly translating into clinical benefit.

Translational research in immunotherapy is also a focus of the Immuno-OncologyTranslationalNetwork (IOTN), which aims to better understand how tumors evade the immune system, identify new targets for therapies, develop improved immunotherapy and immunoprevention approaches, and find ways to mitigate the side effects of immunotherapies. The IOTN Cellular Immunotherapy Data Resource (CIDR) supports a data registry for collecting long-term outcomes of patients receiving cellular immunotherapies. Consonant with the Moonshot principle of data sharing, CIDR makes the data available to IOTN members and the broader research community. The IOTN Data Management and Resource-Sharing Center provides multidisciplinary analytic expertise to support numerous collaborative research activities across the network. It also facilities community outreach and education as well as cross-consortia interactions.

One IOTN research team has developed models that integrate patients' clinical information and the molecular characteristics of their tumors to predict whether patients with advanced melanoma will develop resistance to immunotherapy (Liu et al., 2019). Another IOTN preclinical study engineered the TGF-β receptor to enhance natural killer cells as an immunotherapy to fight neuroblastoma (Burga et al., 2019). This novel approach could be translated into the clinic to overcome TGF-β-mediated immune evasion in cancer patients (Phillips et al., 2020).

Translational research is also the focus of the DrugResistanceandSensitivityNetwork (DRSN), which is developing new experimental models, investigating mechanisms of drug resistance in cancer, and designing new approaches to exploit the sensitivity of cancer cells to specific treatments. This consortium includes teams of cancer biologists, computational scientists, and clinicians who are performing bench-to-bedside translational studies of cancer drug resistance and sensitivity. Through collaborations with other research teams and Moonshot networks, the DRSN researchers have used a variety of high-throughput methods to identify drug sensitivities and effective drug combinations in a variety of cancer types. In addition to these new discoveries, the network is building a collection of resources that can be used by the wider cancer research community to examine mechanisms of drug resistance.

In one DRSN study, a research group has generated a large, functional genomic dataset of acute myeloid leukemia, which has revealed mutations and gene signatures that predict patient drug responses (Tyner et al., 2018). Another DRSN team identified an adaptive feedback mechanism that drives resistance to KRAS inhibitors in cancer. This study highlights the potential importance of vertical inhibition strategies to target the RAS-MAPK pathway (Ryan et al., 2020).

Health care delivery research

The Moonshot has a strong focus on the delivery of cancer care, as well as cancer screening and prevention. As healthcare systems work under increasingly dynamic and resource-constrained conditions, evidence-based strategies and interventions are essential to ensure that research investments maximize healthcare value, improve public health, and increase health equity.

The AcceleratingColorectalCancerScreeningandFollow-UpthroughImplementationScience (ACCSIS) initiative is working to build an evidence base on multilevel interventions to increase rates of colorectal cancer screening, follow-up, and referral to care. ACCSIS research projects focus on underserved groups, including racial and ethnic minority populations, low-income populations, and people living in rural or difficult-to-reach areas. Many of these programs take advantage of fecal tests, which can be done at home to increase participation rates. They also include provider education and patient navigation systems that help patients overcome the barriers of cost, fear, and misinformation surrounding disease diagnosis and treatment.

In a parallel program to ACCSIS, the DisseminationofaColorectalCancerScreeningProgramAcrossAmericanIndianCommunitiesintheSouthernPlainsandSouthwestUnitedStates consortium was established to address the need for improved evidence-based colorectal cancer screening interventions in AI communities. Through this program, screening interventions are being implemented in health clinics serving more than two dozen American Indian tribes in both rural and urban populations.

Quitting smoking after cancer diagnosis improves the patient's prognosis, reduces complications and side effects of treatment, and lowers the risk of recurrence. Through the CancerCenterCessationInitiative (C3I), over 50 NCI-designated cancer centers are building and implementing sustainable tobacco cessation treatment programs for cancer patients, guided by a central coordinating center. One C3I study provides data for a paradigm shift from a frequently used specialist referral model to a point-of-care treatment model for tobacco use assessment and cessation treatment (Ramsey et al., 2020). The rapidly growing evidence base from C3I studies can be quickly deployed across a broad range of care settings to ensure that people with cancer have access to optimal interventions to cease tobacco use and see improved outcomes.

ImprovingtheManagementofsymPtomsduringandfollowingCancerTreatment (IMPACT) is a consortium seeking to reduce the considerable symptom burden experienced by people with cancer. The IMPACT centers are evaluating the adoption of integrated electronic systems for monitoring and managing patient-reported symptoms in routine cancer care. One IMPACT center has developed a clinical trial to evaluate a guideline-informed, enhanced electronic health record-facilitated cancer symptom control care model (Finney Rutten et al., 2020). This trial also seeks to identify disparities in the adoption and implementation of the intervention among elderly and rural-dwelling patients with cancer, groups with disproportionately more cancer symptoms and worse outcomes. The study is testing validated approaches to detect and effectively manage symptoms including sleep disturbance, pain, anxiety, depression, fatigue, and functional decline.

The Participant Engagement and Cancer Genome Sequencing (PE-CGS) Research Network is the newest patient engagement-focused Moonshot initiative. PE-CGS uses direct participant engagement approaches to advance the understanding of rare cancers, highly lethal cancers, cancers with an early age of onset, cancers with high disparities, and cancers that are prevalent in understudied populations. One of the PE-CGS centers is engaging American Indians of Southwestern Tribal Nations as participants in cancer research. The

team uses comprehensive cancer genome sequencing approaches to address important knowledge gaps in the genomic characterization of tumors. Count Me In is a related effort that was underway prior to the Moonshot (https://joincountmein.org/), but with Moonshot support, its efforts have expanded to engage adult and pediatric participants with osteosarcoma and leiomyosarcoma—both of which are exceedingly rare and difficult to treat. Using novel web-based approaches to find patients, this approach allows the patient to drive research by then joining the study to generate a shared database of clinical, genomic, molecular, and patient-reported data. These efforts, along with other Moonshot-supported patient engagement networks, lay the foundation for further development of a system of direct patient participation in cancer research.

The way forward

As these examples of progress across the Moonshot research initiatives illustrate, this massive undertaking has already borne scientific fruit and laid critical foundations for future advances and potential. We have been gratified by the progress already made by the Moonshot research teams, and we are confident that these will engender further discovery and innovation.

Still, there remain gaps and hurdles that we are continuing to address. We have identified gaps in technology development, such as data visualization tools, advanced imaging capabilities to facilitate early detection screening approaches, and cell-based therapy manufacturing technologies to accelerate the accessibility of cancer immunotherapies to patients. Some efforts, such as addressing the recommendation for retrospective analysis of biospecimens, have taken longer to implement than originally anticipated. But NCI has established the Molecular Profiling to Predict Response to Treatment (MP2PRT) initiative, which is currently positioned to undertake this recommendation in the coming years.

Despite these limitations, the early groundswell of enthusiasm for the potential of the Moonshot to transform cancer research and translate rapidly to tangible improvements for people with cancer, combined with the significant infusion of new funding and effective stewardship from NCI, has enabled the cancer research community to develop key resources that will fuel further progress.

Importantly, though, cancer is not merely a challenge of resources, where some combination of investment and time could guarantee successful prevention strategies and cures across disease types and populations. We cannot predict from where the next breakthrough that revolutionizes cancer medicine will come. The impact of curiosity-driven discoveries can be unpredictable, and the progress of investigator-initiated research may not adhere to desired preset timelines and goals. As we navigate past the midpoint of planned funding for the Moonshot, we at NCI are examining which projects initiated in this period should be sustained and leveraged in the post-Moonshot years, and how to do so without jeopardizing the mainstay of our cancer research portfolio: supporting investigator-initiated research, the engine of discovery. We will engage with our external advisors to identify strategies and priorities for successful transitions of these activities when planned Moonshot funding ends after fiscal year 2023. And we will ensure that the results of these diverse programs are

leveraged for broad dissemination, application, and adoption to maximize their benefits—to cancer research—and to people everywhere with cancer.

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Table 1.

Overview of the Cancer Moonshot

The Cancer Moonshot^{SM} at a Glance							
3 goals	• accelerate scientific discovery in cancer • foster greater collaboration • improve the sharing of data						
4 cross-cutting features	• enhanced data sharing • addressing cancer health disparities • open access publications • collaboration and networks						
12 priority areas	• establish a network for direct patient engagement • create an adult immunotherapy network • create a pediatric immunotherapy discovery and development network • develop ways to overcome cancer's resistance to therapy • build a national cancer data ecosystem • intensify research on the major drivers of childhood cancers • minimize cancer treatment's debilitating side effects • prevention and early detection of hereditary cancers • expand use of proven cancer prevention and early detection strategies • retrospective analysis of patient data and biospecimens • generation of human tumor atlases • develop new enabling cancer technologies						
Funding for NCI from 21st Century Cures Act	FY 2017 $300M	FY 2018 $300M	FY 2019 $400M	FY 2020 $195M	FY 2021 $195M	FY 2022 $194M	FY 2023 $216M
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