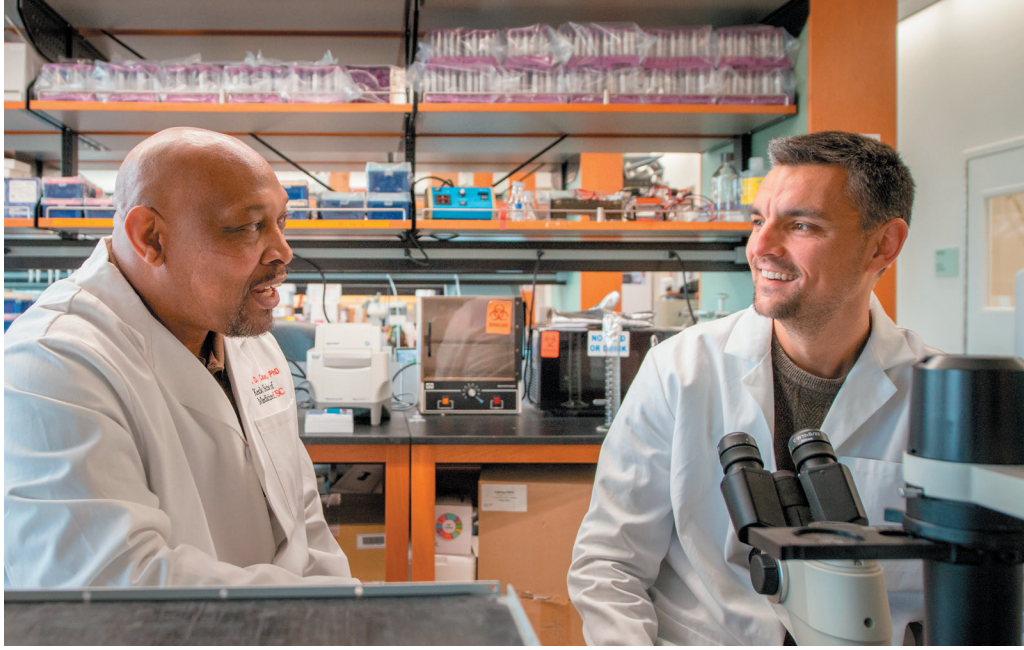

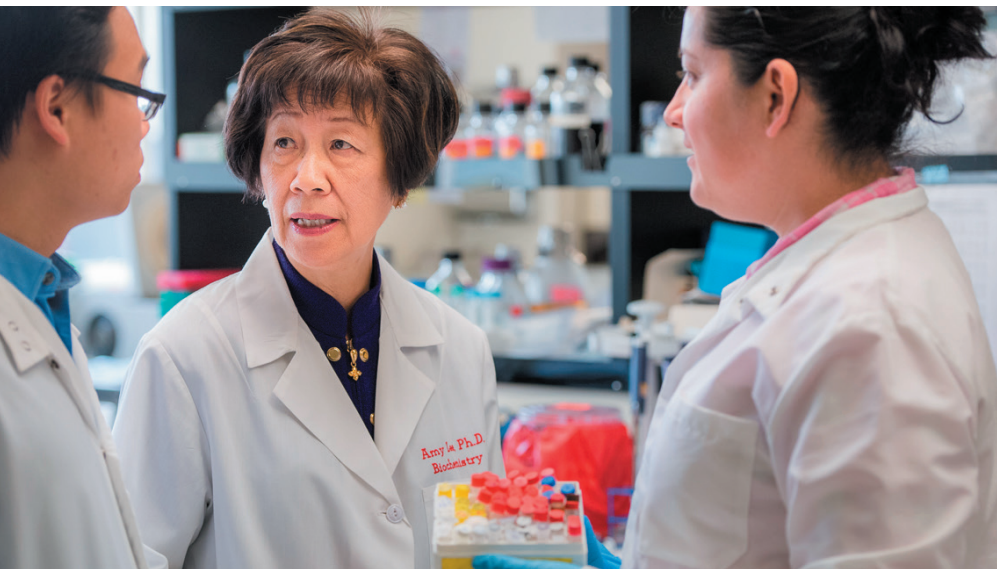

USC Norris
2020-2025 Strategic Plan

Shaping the Future of Cancer Science

NCI Designated Comprehensive Cancer Center

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Our Vision
To reduce the burden of cancer and cancer health disparities for all people.

Our Mission
To foster and integrate high impact research, education, community engagement, and personalized cancer

I. INTRODUCTION AND EXECUTIVE SUMMARY

As one of the first eight Comprehensive Cancer Centers to receive the NCI comprehensive designation in 1973, the USC Norris Comprehensive Cancer Center (USC Norris) at Keck Medicine of USC is an international leader in cancer research, education, and oncology care. A central priority for USC Norris is to serve the unique needs of our multicultural catchment area, Los Angeles County. The substantial diversity of our patients and community enables USC Norris to understand the heterogeneity of cancer and ensure that new forms of prevention, diagnosis, and therapy will reduce the cancer burden for *all people*, including historically underserved groups. With our strong community partnerships, USC Norris is ideally positioned to reduce disparities in specific cancers in Los Angeles County by fostering an even higher level of collaboration - from fundamental science to translational and clinical science to population science. Our cancer research training and education programs are part of the fabric of these efforts, creating a diverse pipeline for the next generation of exceptional cancer scientists and clinicians. Our Office of Community Outreach and Engagement (COE) is the vehicle by which we understand and serve the needs of the underserved communities in our catchment area.

In addition to our close alignment with the Keck School of Medicine and Keck Health System, USC Norris has a rich tradition of collaboration across multiple USC Schools, as well as with our close partner, Children's Hospital of Los Angeles (CHLA). We leverage the intellectual capital and technologies across USC's dynamic Centers and Institutes, including the Michelson Center for Convervgent Bioscience, the Lawrence J. Ellison Institute for Transformative Medicine, the Zilkha Neurogenetic Institute, and the Eli and Edythe Broad Center for Regenerative Medicine and Stem Cell Research. USC Norris members have appointments in six different schools, including the Viterbi School of Engineering, the School of Pharmacy, the Dana and David Dornsife College of Letters, Arts and Sciences, the Leonard Davis School of Gerontology, the Herman Ostrow School of Dentistry, and the Keck School of Medicine. These linkages enable us to solve complex problems in cancer medicine beyond what one Department, Center, or School could accomplish on its own.

Building upon this legacy, ***Shaping the Future of Cancer Science* (2020-2025)** will strengthen and accelerate USC Norris' impact with a sharp focus on five overarching strategic scientific priorities that constitute the pillars of our aspirations to reduce the burden of cancer in our catchment area and beyond. Importantly, each pillar addresses research across the cancercontinuum from cells to society and engages multiple USC Norris Research Programs.

Strategic Goals

- Lead in reducing cancer disparities in our catchment area and the nation: fostered by our office, develop a Cancer Disparities Index to identify and monitor the cancer burden in our catchment area and identify key biological, genomic, environmental, lifestyle, and social contributors to cancer disparities; increase engagement of underserved individuals and populations in cancer disparities research; expand the portfolio of implementation science research to reduce cancer disparities; and broadly disseminate our tools and findings for a national impact on cancer disparities.
- Harness data science to advance multi-level cancer risk prediction for precision cancer prevention: leverage, augment, and integrate talent and resources to identify determinants of cancer risk and progression; integrate multi-level data for ethnically-tailored prediction of cancer risk and cancer outcomes utilizing deep learning approaches; and validate and translate multi-level cancer risk models for individualized cancer prevention.
- Transform laboratory discoveries of novel targets and pathways into new therapies for our patients: implement a systematic approach to identify and prioritize novel targets identified in USC Norris laboratories to advance for future development; create cross-functional teams of basic, translational and clinical scientists to advance new early stage clinical trials based upon USC Norris discoveries; and catalyze strategic industry partnerships to accelerate translational drug development and target discovery.
- Leverage fundamental science to pioneer development of multi-modal biomarkers to monitor cancer evolution: identify, prioritize, and develop new biomarker/monitoring capabilities based on clinically relevant questions in our catchment area; link basic and translational scientists with existing tissue/clinical archives to monitor and study mechanisms of cancer evolution with time and treatment; prioritize a subset of biomarker/monitoring assays for transition to clinical or commercial grade assays; and integrate novel assays, companion biomarkers and correlative basic science into investigator-initiated clinical trials.
- Establish a world-class comprehensive cancer immunotherapy program to increase availability of new therapies for our diverse catchment communities: construct a cGMP facility at USC Norris and recruit new leaders, investigators and technical/regulatory personnel; advance basic research in immunotherapy target and biomarker discovery for hematologic and solid malignancies; assess response and resistance to immunotherapy in diverse populations; and develop novel combination therapies to overcome resistance to immunotherapy.

To achieve these goals, we will also make significant investments to expand and leverage our infrastructure with a focus on the following objectives:

- Biobanking and Profiling: improve the process for consenting, biospecimen, and clinical data accession in our diverse patient populations; and conduct comprehensive multi-modal profiling

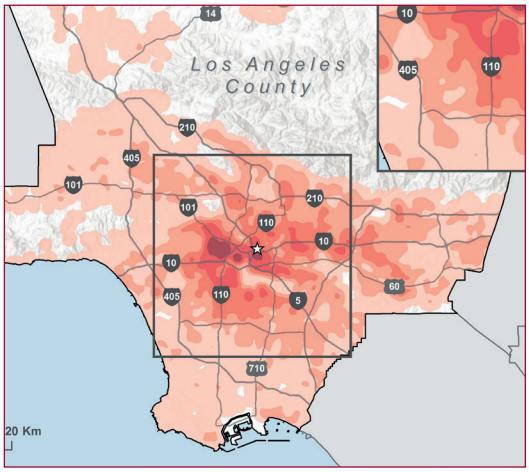
of specimens with linkage to curated patient data in a prospective project-driven manner.

- Data Science: create a modern Data Science Shared Resource with the expertise and computational tools needed to integrate and analyze data from the electronic health record, -omics platforms, and wearable devices; recruit and leverage talent in artificial intelligence for cancer risk prediction and clinical decision-making; and build a community of cancer-focused data scientists to train the next generation.
- Clinical Trials: develop and implement a comprehensive strategy to expand USC Norris clinical trials to address catchment area needs; increase access to and participation in clinical trials; implement strategies to overcome barriers to enrollment of diverse patient populations; and foster the translation of USC Norris discoveries into novel, early stage investigator-initiated trials.
- Cancer Research and Career Evolution: train the next generation of basic, population and clinical researchers; create a pipeline of integrated educational programs with an emphasis on underrepresented and socio-economically disadvantaged populations; develop innovative education programs for health care professionals and community cancer educators; and evaluate the success of these programs on trainees' career evolution in the cancer field.

Shaping the Future of Cancer Science (2020-2025) will enhance our ability to offer atients the most advanced cancer diagnostics and therapies across the cancer continuum from risk assessment and prevention to therapy and survivorship. In parallel, we will promote the health of individuals and diverse populations in our catchment area by disseminating our findings and providing culturally appropriate education and resources. Investment in our top talent and the latest technologies and informatics platforms will enable novel discoveries that will become the next cancer cures. By enhancing USC Norris' eminence and impact, we will further solidify USC Norris as a destination Cancer Center that serves patients across our region and nation and attracts a diverse pipeline of the best and brightest trainees who are the future of cancer science and care.

II. USC NORRIS STRATEGIC PRIORITIES

1. Lead in reducing cancer disparities



Our catchment area of Los Angeles County (LAC) includes a diverse population defined by race/ethnicity, as well as age, immigration status, acculturation, socioeconomic status, language, and access to health services. Cancer health disparities are highly prevalent in this region. For example, African Americans in LAC have a higher incidence and mortality of lung and prostate cancer, and higher mortality of breast cancer. Liver cancer is particularly burdensome for Asians and Latinos. Korean Americans and Latinas suffer higher rates of cervical cancer when compared to other population groups. Although California has made great progress reducing tobacco use, there are still some population groups with high rates of use (Vietnamese, American Indians, LGBTQ). Further, Latinos and African Americans are impacted by obesity and sedentary lifestyles.

Although we have made great strides in vaccinations against the Human Papillomavirus, many vulnerable populations in LAC still lag behind, and the vast majority of boys in these communities have rarely been vaccinated. Gastric cancer particularly impacts Korean Americans, followed by Hispanics. We have the largest Korean population outside of the Korean peninsula and a new USC Norris Koreatown Clinic enables us to study unique cancers in this group.

USC Norris is in a strong position to lead the nation in reducing cancer disparities. Currently, we achieve a close match between our USC Norris patient base and our LAC catchment area racial and ethnic characteristics. Moreover, roughly two-thirds of the patients enrolled in clinical trials at USC Norris are underrepresented minorities. Although we have a high percentage of Hispanics/Latinos, which are representative of the numbers in the population, our communities would benefit from increased engagement with African American and American Indian communities. To achieve the goals below, we will leverage longitudinal data collected over 46 years from the Cancer Surveillance Program (CSP) as well as expertise in spatial sciences/GIS mapping to monitor and assess progress in reducing disparities in our catchment area. Given our strengths in pediatric cancers, AYA, and adult cancers, we can examine disparities within a lifespan approach. Our overarching goal is to position USC Norris as the leading cancer center in identifying, understanding, and addressing cancer disparities with culturally and language-specific interventions and rigorous research. To realize our aspirations, we will pursue the following strategic goals and objectives for COE and cancer disparities research, in collaboration with the USC Norris Community Advisory Board:

- Develop a Cancer Disparities Index to identify and monitor the cancer burden and identify contributors to cancer disparities in our catchment area, by: developing a common definition for cancer health disparities and health inequality; refining assessment tools for defining disparities, especially measurement of social determinants of health; mining existing data resources and geospatial approaches to map "hot spots" for putative determinants of cancer disparities such as poverty, environmental exposures, behavioral risk factors, access to care, and excess cancer burden; and disseminating the Cancer Disparities Index (scorecard) to community leaders and policy makers.

- Increase engagement of underserved individuals and populations in cancer disparities research, by: creating a *Catchment Area Planning Committee on Cancer Disparities* to advise on COE and catchment area activities and inform priorities for catchment-relevant research; increasing the proportion of COE activities focused on African American and American Indian communities; conducting research to better understand systemic, cultural, and personal barriers (including financial toxicity) to clinical trials participation; engaging our partners in community needs assessments (every three years) to better understand needs in the community and to help address the cancer burden; engaging impacted communities (including survivors) in community-based participatory research, interventions, and outreach to further reduce disparities; and utilizing the Cancer Disparities Index to monitor our progress.

- Catalyze expansion of the portfolio of research on catchment area priorities to reduce cancer disparities, by: increasing interactions with USC Norris investigators in basic, clinical, and population science to maintain a sharp focus on catchment area needs; expanding expertise in the biology of cancer disparities and in implementation science; targeting primary prevention interventions (e.g., diet, exercise, smoking cessation, and HPV vaccination) to areas where risk factors are most prevalent; targeting secondary prevention interventions (e.g., skin, cervical, breast, prostate, and colorectal cancer screening) to areas and populations with elevated risk; and targeting tertiary prevention interventions to improve cancer outcomes and reduce recurrence risk in vulnerable populations, using an implementation science approach.
- Broadly disseminate our tools and findings for a national impact on cancer disparities, by: sponsoring a cancer health disparities symposium (every 1 to 2 years); creating and disseminating mini-reports and policy briefs targeted to different audiences (e.g., community members, scientists, and policy makers); developing and disseminating cancer-related vignettes (3 minutes of storytelling) with positive messaging about cancer survivors engaging in early screening, risk reduction, and/or participation in clinical trials in collaboration with the USC School of Cinematic Arts, the USC Annenberg School of Communication and Journalism, and the Keck School of Medicine Marketing Department; and maintaining a leadership presence in national initiatives, such as the AACR Minorities in Cancer Research Council and the ASPO Cancer Health Disparities Working Group.

Timeline and Target Goals

Year 1

- Launch the Catchment Area Strategic Planning Committee on Cancer Disparities
- Enhance the COE and cancer disparities material on the USC Norris website
- Complete and disseminate 2 mini-reports on priority cancers in the catchment area and related risk factors
- Initiate regular presence at program meetings and retreats to foster catchment-relevant research by USC Norris investigators
- Work with the cancer center to foster submission of at least 1 new major NCI grant focused on addressing cancer disparities in our catchment area
- Launch a transdisciplinary gastric cancer initiative, focused on reducing rates of gastric cancer in high-risk Asian communities
- Launch a cancer control initiative in collaboration with tribal communities to address cancer disparities in American Indians
- Recruit a national leader in implementation science

Year 2-3

- Recruit a new faculty member with expertise in the biology of cancer disparities
- Complete work on the Disparities Index and publish in a peer-reviewed journal
- Deliver the first Cancer Health Disparities Symposium
- Develop and disseminate patient, caregiver, advocate vignettes via multiple mechanisms, in

collabortion with the Annenberg School for Communication and Journalism, and the Center for Health Journalism in collaborative research on cancer disparities

- Foster submission of at least 3 new multi-investigator cancer health disparities grants
- Complete and disseminate 3 additional mini-reports on priority cancers and related risk factors

Year 4-5

- Increase engagement and participation in clinical trials among African Americans and other underrepresented groups by 20%
- Attract 3 to 5 new cancer health disparities grants based on the development work in Years 1 to 3
- Complete and disseminate 3 new additional mini reports on priority cancers and related risk factors
- Publish at least 10 scientific articles on cancer disparities by Year 5

2. Advance multi-level cancer risk assessment for personalized cancer prevention

USC Norris has a rich tradition of high impact cancer epidemiology and genomics investigations that have advanced our understanding of cancer etiology and progression. As we look to the future, there is a tremendous opportunity to extend beyond traditional risk factors and germline genomic sequencing to harness and integrate advances in exposure biology, geospatial coding, immunology, virology, and the microbiome to assess and monitor cancer risk. Leveraging technologies such as wireless monitoring devices, we will collect and incorporate naturalistic data on nutrition, physical activity, and environmental exposures, and improve understanding of cultural and behavioral factors that increase cancer risk and influence cancer outcomes. Enabled by data science, and considering biological, environmental, and social determinants, we will utilize artificial intelligence and deep learning approaches to validate the first comprehensive, multi-level cancer risk prediction models. This work will enable us to target cancer prevention and screening efforts to address specific cancer burdens in our catchment area, particularly among racially/ethnically diverse and/or under-studied populations who suffer cancer health disparities. These advances will also guide policy to reduce cancer determinants in the catchment area, for example, policy efforts to reduce teen vaping and environmental carcinogen exposures.

Several unique resources at USC Norris will enable our success in these efforts. Among the key resources are the NCI U19 Multiethnic Cohort Study, which is the only multiethnic cohort in the U.S. designed to address cancer risk factors, and the NCI Los Angeles Cancer Surveillance Program (CSP). The CSP is the most diverse cancer registry in the world, with an exceptional track record of guiding studies focused on cancer risk assessment among minority populations. Further, the CSP affords the opportunity to detect changing cancer patterns and act early to identify novel cancer risk factors in order to avoid new cancer 'epidemics' in our catchment area. Leveraging talent across all five USC Norris research programs, and our highly diverse catchment area, we are uniquely positioned to drive innovation in multi-level cancer risk assessment for

all populations. These efforts will elevate further USC Norris' ability to lead in cancer risk assessment and prevention. To achieve these goals, we will pursue the following objectives and strategies:

- Leverage, augment, and integrate talent and resources to identify putative determinants of cancer risk and disparities, by: establishing a *Cancer Risk Assessment Advisory Committee* composed of experts on genetic and cancer epidemiology, spatial science, cancer registry, environmental toxicants assessment, lifestyle, social and individual factors, and novel tools to assess them (e.g. EMA, interactive smart apps, citizen science sensors); strengthening expertise in nutrition science and energy balance, including metabolic diseases microbiome, and physical activity; and identifying the independent and synergistic interactions of biology, environment, lifestyle, and social determinants of health on disparities in our catchment area.
- Develop new approaches to integrate multi-level data for ethnically-tailored prediction of cancer risk and cancer outcomes, by: creating a new Population Research Shared Resource to provide catchment area-level data and geospatial analysis of cancer determinants; implementing a uniform approach and tools to collect patient-reported risk factors and outcomes in the clinics; developing a "USC Norris app" for real-time assessment of key lifestyle factors and environmental factors, and to facilitate patient follow-up; establishing new cohorts to examine the role of these determinants across the age lifespan and the cancer continuum; and collaborating with the expanded Data Science Shared Resource to apply deep learning approaches to these multi-level data to model cancer risk and recurrence.
- Validate and translate multi-level risk models in the clinic to promote individualized cancer prevention, by: building risk prediction models using machine learning approaches, and estimating sensitivity and specificity for predicting incidence/mortality outcomes for selected catchment area cancer burdens; evaluating the impact of targeting prevention strategies (e.g., tobacco cessation, diet/exercise) based on risk level; developing and testing novel models for cancer risk communication in multi-ethnic populations; creating longitudinal cohorts of individuals with certain cancer indicators (e.g. elevated PSA; genomic risk) to determine whether risk models can identify those who may require imaging or surveillance vs. biopsy; and determining patients' risk for post-treatment cancer recurrence and monitoring with longitudinal liquid biopsy assays to examine differences in cancer evolution.

Timeline and Target Goals

Year 1

- Establish a Population Research Shared Resource and Cancer Risk Assessment Advisory Committee
- Design and deploy a USC Norris app for patient follow-up with built-in capability to track key risk factors (i.e. diet, physical activity, exposures)
- Design and deploy novel methods to measure the changing characteristics of specific communities over time and cancer determinants across the lifespan
- Develop a Cancer Disparities Index, working with COE

Year 2 to 3

- Recruit a new faculty member with expertise in translating observational research to interventional trials

- Form multidisciplinary teams of investigators and data scientists to integrate data and develop predictive models
- Implement a pilot demonstration project for data integration and risk model validation for secondary and tertiary prevention for a specific organ site, using a competitive internal grant mechanism
- Deploy new secure patient databases for priority cancers and foster access among USC Norris members

Year 4 to 5

- Obtain at least 3 NCI P/U grants to support creation of new cohorts and to translate multi-level cancer risk modeling into targeted interventions for risk reduction, with emphasis on diverse populations in our catchment area
- Based on the pilot demonstration project, scale the multi-level cancer risk assessment program to additional organ sites
- Deploy new interventional studies targeting cancer risk factors in areas of high risk factor prevalence and/or among susceptible populations (i.e. minorities with higher cancer burden, AYA)
- Deploy new interventional studies among cancer survivors targeting cancer outcome determinants identified through data collected via USC Norris app, new patient databases, and risk modeling efforts

3. Transform laboratory discoveries of novel targets and pathways into new therapies for our patients

Single Molecule Super Resolution Imaging

The importance of conducting research with the intent of generating early stage cancer drug candidates at USC Norris cannot be overstated. Despite development of new molecular targeted therapies and immunotherapies in recent years, survival rates for many cancer patients remain low. Innate and acquired therapeutic resistance are common features of cancer evolution and progression which need to be identified and characterized in order to develop approaches to overcome these by modulating specific cellular and molecular mechanisms of resistance. Basic and translational research that leads to a better understanding of molecular mechanisms involved in cancer development and progression will allow discovery of novel targets and pathways by USC Norris investigators. By leveraging high-throughput screening, medicinal chemistry, and drug metabolism/pharmacokinetics, we will identify and prioritize the most promising targets/pathways and drug candidates for testing in early preclinical and clinical models. To achieve this goal, we have launched a systematic and transparent process for making go/no-go decisions in an attrition-based pipeline. Such a concerted effort will address a critical unmet need in oncology and lead to more effective and less toxic therapies.

With our expertise at USC Norris and our collaborations with USC's Medicine, Engineering, Science, and Humanities (MESH) Academy, the USC Michelson Center for Convergent Bioscience, and the Bridge Institute, we will be very competitive to expand strategic partnerships with biotech and pharmaceutical industry partners to develop high quality, small molecule

drugs and other biologicals together. Our goal is to foster strategic industry partnerships and commercialization of USC Norris' discoveries, making USC a destination for early and first-in-human trials. Through our scientific and clinical expertise, we are ableto develop a drug from the bench to the clinic all the way to registration trials. To lead in this area, we will pursue the following goals and objectives:

- Implement a systematic and transparent approach to identify and prioritize novel targets identified in basic science laboratories to advance for future development, by: establishing a Targets to Therapies Steering Committee to: (a) offer consultation for USC Norris investigators and their teams regarding the process of target validation; (b) provide a rigorous review of targets/drugs in the pipeline and recommendations on go/no-go decisions based on a clear set of endpoints at each stage in the validation process; and (c) based on a transparent rating system, make recommendations to the USC Norris Executive Committee regarding investment in advancing specific targets/drugs to preclinical development and/or beyond.
- Create cross-functional teams of basic and translational/clinical scientists to advance early stage clinical trials with companion biomarkers, based upon discoveries by USC Norris investigators, by: creating a "developing" CCSG shared resource for preclinical drug development to enable testing of new drugs and combinations in preclinical models; creating a new transparent process for interdisciplinary teams to compete for funding to advance promising targets; enhancing infrastructure for real time molecular monitoring with liquid biopsies and extensive molecular characterization to examine intermediate cellular and molecular endpoints; and refining the clinical trials research infrastructure as described in section III below.
- Catalyze strategic industry partnerships to accelerate early drug development and biomarker discovery, by: leveraging and marketing unique strengths in genomics, pre-clinical models, and drug development; continuing to work with MESH Academy to identify and advance potential public-private partnerships; deepening the functional working relationship with the USC Stevens Center for Innovation to promote greater efficiencies and ensure that we capture new inventions and intellectual knowledge from USC Norris investigators; and promoting bi-directional exchange with industry partners to promote innovation, including leveraging USC Norris' unique resources and population diversity that would be of interest to industry.

Timeline & Target Goals

Year 1:

- Establish the Targets to Therapies Steering Committee, finalize the go/no-go process for target validation and lead compound development, and communicate the availability of this resource to the scientific community
- Utilize the Targets to Therapies Steering Committee to review and prioritize targets to select for investment in further development
- Expand infrastructure for collecting biospecimens within clinical trials as intermediate endpoints of target effects and/or to monitor cancer evolution
- Release an RFA for investigators or teams to compete for funds to advance novel targets into preclinical models and/or lead compounds/combinations into early phase clinical trials
- Recruit a senior basic scientist with expertise in epigenomics

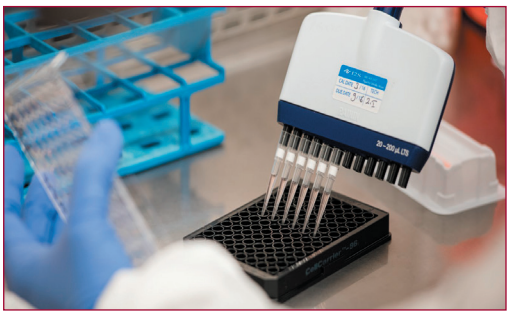
Years 2 to 3:

- Produce lead candidates for 1 to 2 targets
- Recruit a faculty member with expertise in molecular therapeutics and/or precision oncology to expand expertise in these areas
- Attract 4 to 6 new strategic industry partnerships for drug development
- Submit 2 to 3 new grant applications
- Move 1 to 2 lead compounds into first-in-human trials

Years 4 to 5:

- Advance 3 to 5 novel targets or drug combinations into early phase clinical trials

4. Pioneer new multi-modal biomarkers to monitor cancer evolution and predict outcomes



Liquid Biopsy: monitoring cancer with a blood test

Building upon our historical strengths in genomics, epigenomics, and the tumor microenvironment, USC Norris is poised to pioneer multi-modal cancer biomarkers to advance oncology research and precision care delivery. These efforts will leverage the resources of the Department of Translational Genomics, the ORIEN initiative, and our first-in-the-nation NCI-designated Liquid Biopsy Shared Resource. We will profile specimens using the most up-to-date advances, including: single cell genomics, liquid biopsies, and spatial transcriptomics. This work will be applied to one of the most diverse patient populations in the U.S., with the goal to enable treatment stratification, close monitoring for recurrence among cancer survivors, and development and commercialization of new predictive and prognostic tools. To lead in knowledge of cancer evolution and apply this knowledge to the diagnosis and treatment of USC Norris cancer patients, we will pursue the following objectives:

- **Identify, prioritize, and develop existing and new biomarker/monitoring capabilities based on clinically relevant questions in our catchment area, by:** cataloging existing biomarker capabilities and needs (assay technologies, emerging markers, CLIA assays, commercial grade); and creating a Biomarker/Monitoring Steering Committee to guide our investments based on emerging biomarker capabilities and patient populations.

- **Link basic and translational scientists with existing tissue/clinical archives to monitor and study mechanisms of cancer evolution with time and treatment, by:** leveraging informatics to link with existing USC Norris tissue repositories including working with ORIEN leadership to expand investigators' use of this resource by basic, translational/clinical and population scientists; developing mechanisms to collect longitudinal biomarker/monitoring assays in our multiethnic catchment groups and linking those assays to longitudinal clinical data; and integrating and validating multiple biomarker/monitoring assays (tissue, synthetic, digital) to generate multi-parametric assays to validate datasets for future research.

- **Prioritize a subset of biomarker/monitoring assays for transition to clinical or commercial grade assays, by:** establishing a quarterly commercialization meeting to assess candidates and

recommend next steps for advancement to clinical/commercial status; launching a "virtual conference room" with key industry partners to advertise emerging capabilities and specific assays for further co-development; and providing internal support for a Biomarker Incubator Program.

- **Integrate novel assays and correlative basic science into investigator-initiated clinical trials, by:** fostering greater alignment between transdisciplinary disease research affinity groups and clinical disease groups to identify opportunities for integrating emerging biomarkers into USC Norris investigator-initiated clinical trials; proposing translational correlative components for existing multi-center clinical trial cohorts and advancing the necessary infrastructure (storage, informatics, statistics) to scale new assays to large validation cohorts.

Timeline & Target Goals

Year 1:

- Build an internal molecular data resource from USC Norris/LA County Hospital patients that can be leveraged for research and precision patient care
- Establish the Biomarkers and Monitoring Steering Committee to prioritize advancement of the most promising biomarkers for validation and inclusion in clinical trials

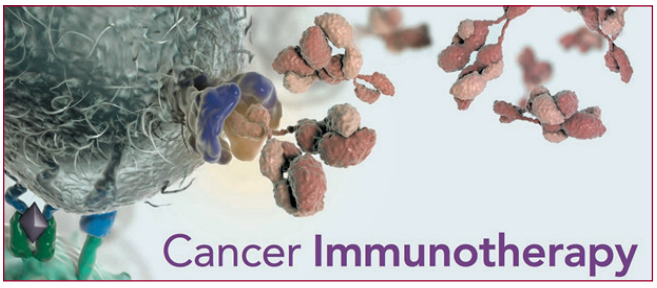
Years 2 to 3:

- Catalog all existing repositories and link these databases to the molecular data resources
- Develop integrated multi-parametric biomarker profiles to apply repeatedly over time to select multi-ethnic subpopulations at LAC/CHLA
- Launch at least 3 investigator-initiated studies advancing promising biomarker assays in clinical trial cohorts

Years 4 to 5:

- Advance at least 2 promising new biomarker assays toward a commercial grade test in partnership with industry
- Increase the number of strategic industry partnerships for biomarker development by 20%

5. Establish a world-class comprehensive cancer immunotherapy program



Immunotherapy is revolutionizing the approach to cancer treatment. The development of antibody-based therapies, cancer vaccines, and cellular therapies already represents an area of major investment by leading academic cancer centers and pharmaceutical companies. USC Norris is poised to develop a comprehensive cancer immunotherapy program leveraging existing research programs, infrastructure, and investigators. With additional strategic investments, our portfolio of pre-clinical work and early phase clinical trials will bring novel cancer immunotherapies and combinations to the diverse patient populations within our catchment area – a population

that has not had full access to this therapeutic revolution. Moreover, because genetic and environmental diversity is associated with many biological differences, it is critical to study immunotherapy response or resistance across the broad USC Norris catchment area to identify approaches that are most efficacious for a given population.

USC Norris has strong pre-clinical programs in cell therapeutics and tissue engineering and robust capacity to conduct clinical trials. However, progress in cancer cell therapy at USC Norris is critically dependent on the development of a new FDA-compliant cGMP core facility for cell- and tissue-engineered product development and human testing. With the planned cGMP facility, our investigators will be able to address critical gaps in immunotherapy development and delivery. For example, despite the remarkable results of genetically modified chimeric antigen receptor (CAR) T cells in the setting of lymphoid malignancies, CAR-T cell therapy has had limited efficacy for solid tumors. Thus, the development of T cell receptor (TCR)-T cell therapies targeting solid cancers are urgently needed. To achieve this goal, we will pursue the following strategic goals and objectives:

- Increase access to novel cellular therapies for the diverse patient population in our catchment area, by: constructing a cGMP facility at USC Norris, including vector production capabilities to support pre-clinical studies and clinical development and recruiting key leadership, investigators, and a multidisciplinary team of experts including technical and regulatory personnel to accelerate discovery, translation and bench-to-bedside GMP development of cell therapies to treat high-priority cancers.
- Advance basic research in immunotherapy target and biomarker discovery for hematologic and solid malignancies, and assess response and resistance in diverse populations, by: investing in research and pathology laboratory technology platforms for single-cell sequencing, biomarker studies, mutation-derived neoantigen discovery, and TCR profiling; providing seed funding for companion biomarker studies to be conducted as part of cancer immunotherapy clinical trials; and developing a cancer immunotherapy biorepository to support collection and storage of critical samples from patients treated on associated clinical trials.
- Develop novel combination therapies designed to overcome resistance to immunotherapy, by: studying epigenetic and metabolic reprogramming to enhance cell-based immunotherapies (e.g. CAR-T and TCR-T); deploying gene-editing approaches to improve immune cell function, persistence, and resistance to immune suppression in the tumor microenvironment (e.g. CRISPR technology); exploring nanotechnology approaches to reprogram the tumor microenvironment and enhance antitumor immunity; and expanding HPV/cervical cancer/gynecologic oncology/immune-oncology clinical trials in the minority populations in our catchment area.

Timeline & Target Goals

Year 1:

- Establish an Oversight Committee to provide cGMP facility governance with approval authority over project selection, prioritization, budgets, and program development
- Recruit a faculty leader to serve as Scientific Director of the cGMP facility to provide oversight of unit organization, staffing for operations and regulatory oversight, SOP development, and collaboration with investigators/users

- Establish working groups, teams, and virtual infrastructures by forming collaborations and MOUs with existing USC and CHLA entities, including a Cancer Immunotherapy Biomarker Discovery Group

Years 2 to 3:

- Open new cGMP facility at USC Norris
- Design new studies and perform pre-clinical and IND-enabling studies with the goal of developing at least 2 new cell-based immune-oncology products for human testing within 12 to 24 months of unit opening
- Organize an immuno-oncology focused clinical research support team dedicated to enabling combinatorial studies including procurement of samples required for biomarker studies
- Open 1 to 2 new investigator-initiated cell therapy clinical trials and 1 to 2 new immune-oncology clinical trials annually in partnership with industry
- Publish at least 5 pre-clinical studies in the scientific literature demonstrating collaboration among USC Norris Research Program investigators
- Submit 1 to 2 new research grant applications
- Initiate immuno-oncology specific biorepository sample acquisition
- Initiate scientific research to evaluate the impact of germline mutations on response and resistance to immuno-oncology therapies

Years 3 to 5:

- Recruit additional immuno-oncology research faculty and additional staff as the program grows
- Open 1 to 2 new innovative, biomarker-driven clinical trials annually
- Submit at least 1 new multi-PI collaborative immunotherapy grant application (e.g., P01, SPORE)
- Establish at least 2 additional new industry partnerships for immuno-oncology clinical trials annually, and present at least 5 clinical trials in progress at scientific meetings
- Publish 5 to 10 high impact papers in the field of immuno-oncology

III. ENABLING INFRASTRUCTURE FOR STRATEGIC PRIORITIES

To achieve these goals, we will make significant investments to expand and leverage our infrastructure in biobanking, data science, clinical trials, and training/education

1. Biobanking and Profiling Infrastructure

Currently, there is a dearth of information relative to the epidemiological (risk), molecular, immunological, metabolic, and cellular context of cancer in diverse populations. At USC Norris, our mission and diverse catchment area align to uniquely position our investigators to spearhead

"Connecting the dots between diverse cancer patients and the best treatments."

the deep molecular and clinical profiling of cancers necessary to accelerate our understanding of cancer heterogeneity and develop new forms of prevention and treatment that will benefit all patients. Specifically, we will bank and profile specimens using the most up-to-date advances including single cell genomics, liquid biopsies for screening and residual disease, and imaging mass cytometry and spatial transcriptomics to capture hundreds of tumor-tumor microenvironment interactions. We will also leverage our Residual Tissue Repository which houses a unique collection of tumor blocks from > 90,000 Los Angeles County cancer patients beyond those seeking care at USC hospitals. Our goal is to capture not just "snap shots" of molecular and risk factor profiles, but also to foster analysis of longitudinal multi-modality profiling data that is highly integrated and searchable across the USC Norris enterprise. To achieve this vision, we propose two overarching goals with the following objectives:

- Improve the process for consenting, biospecimen, and clinical data accession and collection of biospecimens from diverse patient populations, by: developing a multi-culturally sensitive universal consent process that addresses the unique backgrounds and needs of individuals in our diverse patient population; mapping existing resources for tumor and other biospecimens that are annotated for histological features and clinical outcomes, including the ORIEN project; integrating biospecimens from catchment area participants from epidemiological studies for access to pre-diagnostic samples; implementing a uniform process to collect patient reported risk factors and outcomes; leveraging the Data Science Shared Resource (below) to create an integrated data management system for easy identification of available specimens and related data; and refining the standardized system to ensure a transparent process for prioritizing access to specimens for USC Norris members.
- Conduct comprehensive multi-modal profiling of specimens with linkage to curated patient data in a prospective, project-driven manner, by: cataloging existing liquid, radiometric, and digital biomarker capabilities and needs (assay technologies, emerging markers, CLIA assays, commercial grade); supporting an integrated system for tumor banking and collection of longitudinal patient clinical and follow-up data in a project-driven manner at USC Norris, LA County Hospital, and CHLA; building molecular profiling data resources within the new Data Science Shared Resource; integrating multiple biomarker/monitoring assays (tissue, synthetic, digital) with one another and with existing tissue-based assays to generate multi-parametric assays and datasets; and expanding molecular tumor boards to focus needs around key clinical questions and informative markers.

Timeline and Target Goals:

Year 1:

- Complete cataloging of current biospecimen resources and biomarker capabilities across campus

- Establish a universal consent form and process and complete a pilot in selected clinics
- Initiate a pilot for prospective longitudinal biospecimen, clinical, and lifestyle data collection based on a competitive review process
- Create, communicate, and implement a new process for prioritizing access to specimens and enabling chargebacks for USC Norris members
- Communicate the availability of ORIEN specimen data with necessary education of investigators

Years 2 to 3:

- Launch the universal consent process enterprise wide
- Fully integrate specimens from epidemiologic studies into the biobank
- Complete annotation for the Residual Tissue Repository to increase access to investigators
- Roll out the enterprise-wide biobanking data management system

Years 4 to 5:

- Complete the development of an internal molecular data resource from USC Norris patients that can be leveraged for research and precision patient care
- Scale prospective longitudinal data collection for selected catchment area burdens

2. Data Science Infrastructure

A modern academic cancer center includes scientists conducting research and clinicians delivering precision patient care. Common to these efforts is a reliance on data science, a multi-faceted approach that incorporates study design, data processing, analytics, and infrastructure systems to extract meaningful and impactful insights from "big data". The sources of such data include our patients, individuals sampled from the population, or experiments using animal models, tissues, or cells. For such samples, data are acquired using a variety of tools and methodologies such as questionnaires to measure patient-reported outcomes, wireless monitoring devices (e.g., exposure or geographic activity assessment), information from electronic health records, imaging data, state of the art sequencing techniques from blood, liquid biopsies, and tumor specimens for identification of germline variants, RNA and DNA profiles, and assays of the tumor microenvironment (e.g., immune infiltration). Whatever the data source or analysis requirements, we must leverage specific expertise from data science disciplines including research informatics, bioinformatics, and biostatistics to leverage and integrate data and provide high quality analytic insights. Underlying this data flow is an infrastructure including high performance computing and storage, programs for version control, and scripting tools for analysis, visualization, and reproducibility.

USC Norris is now well positioned to leverage and integrate our rich clinical and research data resources, state-of-the-art health information technologies, world-class basic science and

clinical faculty, and a thriving healthcare system. Our aspirational goal is to provide a full-service big data infrastructure to accelerate discovery science on cancer etiology and translate this knowledge to improve oncology care. This endeavor will have a significant impact on the scientific community by facilitating higher quality science that will ultimately aid in reducing the cancer burden in our catchment area. To realize this ambitious goal, the USC NCCC will create a new Data Science Shared Resource to organize and oversee these various components, facilitate efficient implementation, and ensure the availability of these resources to all cancer center members. Our specific goals and objectives include:

- Create a modern Data Science Shared Resource with the expertise and computational tools needed to integrate and analyze multi-modal data, by: restructuring the USC Norris Biostatistics Core to include state-of-the-art study design and analysis for clinical trials, epidemiologic investigations, and experimental studies, including the analysis of -omic data from emerging technologies; hiring a USC Norris Cancer Research Informatics Officer (CRIO) to restructure and integrate clinical research informatics technologies and workflows and hire additional staff as needed to support integration of data from the cancer registry, electronic health record, -omics platforms, etc.; and develop an easily searchable cancer data repository that integrates germline genetic data, tumor profiling data, and clinical data.
- Leverage talent in artificial intelligence for cancer risk prediction and clinical decision-making, by: catalyzing teams of scientists (including data scientists) and clinicians to design 1 to 2 unique, high-impact cancer research projects that leverage genomic, immunologic, radiologic, and other big data to develop prediction models for cancer etiology, improved diagnoses, and patient stratification for treatment; evaluating the clinical utility of biologic variation for precision diagnostics and therapies in rigorous investigations and providing solutions for clinical decision support; facilitating access to data by faculty, staff, and trainees via web-based and smartphone-enabled applications; and by instituting a comprehensive concierge service that provides the necessary education, training, and support.
- Build a community of cancer-focused data scientists who will train the next generation of leaders, by: partnering with the Keck School of Medicine to provide support and sponsorship for cancer members to participate in local and national data science training programs; offering 1 to 2 competitive stipends for USC Norris members to participate in USC's LA Best Program; and sponsoring "happy scientist" seminars, NIH R grant series workshops/ bootcamps, and community groups to support mentorship and networking.

Timeline and Target Goals

Year 1:

- Recruit and onboard the new CRIO
- Recruit and onboard a new Director of the USC Norris Data Science Shared Resource and an additional faculty member with expertise in AI/machine learning
- Create a Cancer Data Science working group that engages data scientists across USC's campus to create a community and provide advice and evaluation of success
- Complete a needs assessment, including common infrastructure and service needs
- Restructure the biostatistics core and the current informatics infrastructure to create a

full-service Data Science Shared Resource including mechanisms for marketing, access, prioritization, and tracking of usage

- Incorporate data science training into the USC Norris Cancer Research Career Enhancement initiative

Years 2 to 3:

- Complete additional staff hires for the Data Science Shared Resource and related infrastructure as needed for investigator support
- Complete a one-year assessment of the new Data Science Shared Resource including a member survey and analysis of scientific impact, productivity, usage, and finances
- Incorporate data science cores into the submission of 1 to 2 major NCI P or U grants
- Publish 2-3 peer reviewed articles on novel methodologies and prediction models

Years 4 to 5:

- Receive at least 1 new major NCI P or U grant that includes a data science core
- Receive at least 2 new R grants that incorporate novel data science applications
- Publish 4 to 6 peer reviewed articles on novel methodologies and prediction models
- Increase Data Science Shared Resource usage by at least 25%

3. Clinical Trials Infrastructure

Clinical trials represent a critical and indispensable bridge to translate discoveries from the bench to the patient. They are at the center of every NCI-designated comprehensive cancer center's mission. It is through high-quality, rigorous, and compliant clinical trials that the cancer care community verifies the validity of pre-clinical discoveries and their impact on cancer patients' life expectancies and quality of life. Furthermore, clinical trials can tackle broad and diverse areas of research related to cancer care ranging from prevention to diagnosis to novel therapies and to palliative care.

Through our partnerships with the Los Angeles County-USC Medical Center, CHLA, and a growing network of oncology satellite offices, USC Norris has an unparalleled opportunity to conduct clinical trials that account for the biologic and social diversity in the U.S. population. Currently, roughly two-thirds of patients enrolled are from underrepresented ethnic and racial groups. With these opportunities in mind, it is critical to refine existing processes or establish new ones to ensure that investments in clinical trials are made in a strategic way that is responsive to the catchment area needs and supportive of the scientific goals of the cancer center programs. Furthermore, maintaining a competitive edge in this arena requires that we foster an environment and provide the tools necessary for active translation of basic discoveries into clinical trials that benefit patients and advance cancer care. To that end, we propose the following goals and objectives:

- Increase the percentage of patients who are enrolled in therapeutic clinical trials, by: broadening our clinical trials protocols to include surgical interventions, radiomics, digital health, and predictive analytics; leveraging data science and AI to identify potential clinical trials candidates, including EMR flags and apps for investigators; aligning clinical care teams with clinical trials efforts with support for clinical trials navigation and clinical care pathways that incorporate clinical trials; improving operational efficiencies such as reducing activation times, expanding OnCore implementation, and improving staff retention; and enhancing disease team and investigator engagement, including training and recognition for accrual performance.
- In alignment with the Targets to Therapies priority (above), foster the translation of USC discoveries into novel early stage investigator initiated trials (IITs), by: creating Disease Affinity Research Groups to foster engagement between basic scientists and clinician scientists to identify novel targets to advance; enhancing support for investigators to develop novel protocols (e.g., database, registry, protocol writing); expanding infrastructure for multi-modal biospecimen collection in support of correlative science to identify biomarkers of on- and off-target effects; creating a training pathway for fellows and junior faculty to become clinical trialists; creating a Preclinical Core to generate preclinical data to compete for NCI-CTEP sponsored trials; and advancing new strategic commercial partnerships in collaboration with MESH and the Stevens Center.
- Develop and implement a comprehensive strategy to expand USC Norris clinical trials to address catchment area needs, by: prioritizing through disease teams and PRMS the clinical trials that address priority cancers that disproportionately affect catchment populations; and working with COE to ensure that geographic expansion of clinical trials within and outside our catchment area is strategically aligned with the USC Norris Strategic Plan and includes ongoing financial support for operations and regulatory oversight.

Timeline and Target Goals

Year 1:

- Open at least 2 trials beyond therapeutics, such as radiomics, liquid biopsies, digital health, and predictive analytics
- Form a working group to develop an executive strategy to attract select industry partnerships, working with MESH; consider funding model for staff support based on success
- Incorporate EMR flags (with bilateral feeds between Cerner and OnCore) and evaluate the impact on accrual in a pilot study (extends to Year 2)
- Develop strategies for enhanced alignment of multidisciplinary care teams with clinical trials efforts, including addition of 1 new navigator in designated clinics and 1 new protocol writer as a pilot demonstration project
- Design and roll out dashboards to provide feedback on accrual to internal clinicians and mechanism for feedback for external referring physicians, with appropriate recognition
- Hire joint CTO/CISO position to enhance harmonization with Keck School of Medicine
- Provide clinical trials information on the USC Norris website
- Complete assessment of clinical trials biomarker laboratory

- Complete a concept proposal for the Preclinical Development Core
- Enhance and maintain engagement of multi-disciplinary disease teams, including active role in protocol review and selection
- Complete evaluation of informatics needs under the leadership of the new CRIO

Years 2 to 3:

- Achieve sustainable improvements in activation times (45 days for phase I and high priority trials, 90 days for others)
- Increase the percentage of patients enrolled in therapeutic interventional trials to 18-20%.
- Expand the proportion of trials that are investigator-initiated by 20%
- Continue to aggressively close low accruing trials, increasing the proportion of trials hitting at least 75% of accrual targets by 25%
- Develop a clinical trials app for investigators
- In collaboration with the health system, roll out a new clinical trials marketing strategy and test impact on trial referrals
- Continue to expand support staff for investigators based on accrual performance: additional navigator and protocol writer
- Launch Preclinical Core as a developing NCI CCSG Shared Resource
- Expand OnCore implementation with reduced reliance on CAFÉ software

Years 4 to 5:

- Increase percentage of cancer patients enrolled in therapeutic interventional trials to 22%
- Increase the number of external trial referrals by 20%
- Increase the number of strategic industry partnerships by 15% above the Year 3 increases
- Attract 3 to 5 new NCI-CTEP sponsored clinical trials
- Maintain or improve activation times (above)
- Evaluate the performance and return on investment of the Preclinical Core and expand as needed

4. Train tomorrow's leaders in cancer research

The landscape of cancer research has dramatically changed over the last 50 years. With the advent of molecular biology in the 1960s, major discoveries in cancer genetics led to the identification, production, and clinical use of new cancer cell specific agents. This is recognized as the Molecular Biology revolution. In the late 1990s, the Human Genome sequencing project and its offspring, the Cancer Genome Atlas, led to a second revolution, the Genomic Revolution, which allows a precise approach to cancer prevention, treatment, and

diagnosis through the building and analysis of Big Data. As we approach the 2020s, it is clear that complex health problems like cancer will require a much broader trans-disciplinary and synergistic approach where not only clinicians, cancer biologists, chemists, mathematicians, physicists, and population scientists, but also economists, ecologists, climatologists, and members of other disciplines will join forces. This third revolution is known as the Convergence Revolution. It is therefore essential that as we educate and train the next generation of cancer researchers and cancer health professionals, we make sure they will be well prepared to cross disciplines and to productively function in a synergistic and convergent environment. The USC Norris program in cancer research education and training has a major priority to train the next generation of leaders from diverse ethnic and socio-economic backgrounds, who will have disciplinary depth as well as fluency in a range of related fields. To achieve this overarching objective, we have identified the four following goals:

- Train the next generation of researchers in the conduct of Convergent Science, by: developing a new course entitled, "Advancing Cancer Center Education in Synergistic Science" (ACCESS) program; providing curricula that engages scientists from various disciplines to teach novel conceptual models and translational frameworks to understand, prevent, and treat cancer. The ACCESS program will bring together faculty from multiple schools and colleges at USC (KSOM, Pharmacy, Viterbi, Marshall, Rosier, Annenberg, Dornsife College of Letters, Art and Sciences) and students enlisted in a variety of undergraduate and graduate programs with a common desire to bring innovative transdisciplinary approaches to eliminate the burden of cancer on human health.

- Create a pipeline of integrated educational programs with emphasis on underrepresented and socio-economically disadvantaged populations, by: expanding cancer education for students in elementary through high school, focusing on schools that reach underrepresented minority populations; developing and delivering an individualized mentored **"Bridges to Success"** program that integrates across existing education programs to help transition high school, undergraduate, and graduate students through the pipeline into graduate, post-doctoral, and medical school programs in the oncology field; and foster the career evolution of junior faculty through the K to R individualized grant mentoring program for successful careers in academic oncology.

- Develop innovative education programs for health care professionals and community cancer educators, by: working with the Office of COE to expand current programs to include education in emerging data in cancer etiology and prevention, clinical trials, and precision oncology; and providing materials to empower health care professionals and community educators in our catchment area with the ability to deliver state of the art community and patient education to help reduce the burden of cancer.

- Evaluate the success of these programs on trainees' career evolution in the cancer field, by: developing Cancer Research Education and Training Evaluation" (CREATE), a centralized trainee data base designed at USC Norris; soliciting standard feedback from all trainees and providing this to USC Norris faculty and educators for continuous program improvement; maintaining annual contact with trainees to monitor their placement and achievements at every step of their career development and including these data in CREATE; and disseminate data summaries to the USC Norris and scientific communities.

Timeline & Target Goals

Year 1:

- Pilot the "Convergence: the Third Revolution in Medicine and its Impact on Cancer Research" class and evaluate its success through students and faculty written and oral evaluation
- Expand the K to R club to support 10 junior faculty members
- In collaboration with COE, hold a second symposium for community educators focused on "New Approaches to Addressing and Monitoring Cancer Prevention"
- In collaboration with USC-Keck Hospital and Norris Cancer Hospital, plan and organize the first annual Cancer Education Day for Health Care Professionals at USC Norris
- Obtain funding through intramural or extramural mechanisms to expand the elementary school cancer education program to 7 schools with students from Grade 3 to 5
- Design and implement the CREATE data base with information on graduate and post graduate trainees at USC Norris over the last 5 years
- Create a Training Grant Steering Committee with the PIs of all training grants at USC-NCCC with the mandate to develop strategies to increase the number of institutional training grants at USC Norris and to implement mechanisms to promote the exchange of innovative and cross-disciplinary training methodologies

Years 2 to 3:

- Expand the "Convergence in Cancer Research" course to the Pre-Med and other undergraduate programs at USC
- In collaboration with USC and CHLA training programs for URMs and through the "Bridges to Success" program, identify and individually mentor students at all levels of training motivated to a career in cancer research to help them successfully move from one training program to the next
- Develop clinical trials training workshops and a career development track for junior clinical investigators
- In collaboration with the COE program, maintain an annual workshop for community educators
- Fill the USC NCCC training database with information on trainees who entered non-undergraduate and non-graduate programs (SORF, C-SEPP etc.). Complete an annual update on all trainees
- In collaboration with Keck Medicine and the Norris Cancer Hospital, conduct an annual USC Norris education day for health care professionals
- Submit URM-focused T32 cancer education training grants on convergent science and cancer disparities

Years 4 to 5:

- Submit an institutional T32 grant for the training of physician investigators in adult oncology and malignant hematology, with a focus on URMs
- Evaluate accomplishments through the analysis of the CREATE data base and the feedback from past trainees

STEERING COMMITTEE AND WORK GROUP APPENDIX

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