



PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS LUNG CANCER HEALTH EQUITY SU2C CATALYST RESEARCH TEAM GRANT PROGRAM

ABOUT STAND UP TO CANCER

Stand Up To Cancer® (SU2C) raises funds to accelerate the pace of research to get new therapies to patients quickly and save lives now. SU2C, a division of the Entertainment Industry Foundation, a 501(c)(3) charitable organization, was established in 2008 by media and entertainment leaders who utilize these communities' resources to engage the public in supporting a new, collaborative model of cancer research, to increase awareness about cancer prevention, and to highlight progress being made in the fight against the disease. As of 2021, more than 1,950 scientists representing more than 210 institutions are involved in SU2C-funded research projects.

Under the direction of our Scientific Advisory Committee, led by Nobel laureate Phillip A. Sharp, Ph.D., SU2C operates rigorous competitive review processes to identify the best research proposals to recommend for funding, oversee grants administration, and ensure collaboration across research programs.

Current members of the SU2C Founders and Advisors Committee (FAC) include Katie Couric, Sherry Lansing, Kathleen Lobb, Lisa Paulsen, Rusty Robertson, Sue Schwartz, Pamela Oas Williams, and Ellen Ziffren. The late Laura Ziskin and the late Noreen Fraser are also co-founders. Sung Poblete, Ph.D., R.N., serves as SU2C's CEO, and Russell G. Chew, serves as SU2C's President. For more information, visit StandUpToCancer.org.

ABOUT BRISTOL MYERS SQUIBB

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.



For information about the Bristol Myers Squibb research and pipeline, please visit <https://www.bms.com/researchers-and-partners.html>. In addition to our internal discovery efforts, Bristol-Myers Squibb wishes to advance science by supporting novel, independent research that addresses unmet need surrounding our products and therapeutic areas. For more information on how to submit an application for use of BMS products for Independent Research or in conjunction with a SU2C Catalyst grant, please visit the [BMS ISR Portal](#).

SU2C CATALYST® MISSION STATEMENT

The SU2C Catalyst® is a new collaborative initiative intended to leverage all stages of the pharmaceutical, biotechnology, diagnostic, and devices industries (collectively referred to herein as "industry") to bring new treatments to patients as rapidly as possible. SU2C is at the intersection between a large and highly skilled scientific community consisting of its Scientific Advisory Committee, Dream Teams, Translational Research Teams, and Innovative Research Grant recipients, academic institutions, and industry. The SU2C Catalyst® establishes a mechanism through which industry and academic scientists in the cancer community will conduct SU2C collaborative research projects that will deliver significant benefits for patients and society, accelerating the development of new treatments and, where appropriate, combination therapies. The principles guiding SU2C collaborations with industry are designed to accelerate the pace of

groundbreaking translational research that provides new therapies to patients rapidly:

1. **Integrity:** Industry, academia, and SU2C will act with integrity at all times, putting patients at the center of everything we do.
2. **Independence:** SU2C and affiliated researchers will maintain independent strategies, activities, or information with unbiased scientific overview by its Executive Committee and associated Industry Steering Subcommittees.
3. **Transparency:** SU2C will be transparent, consistent, and fair when collaborating with industry.
4. **Accountability:** SU2C is accountable to many stakeholders and thus will not promote, endorse, or favor any particular product.

SU2C HEALTH EQUITY COMMITMENT STATEMENT

Stand Up To Cancer is committed to eliminating barriers of access to state of the art screening, diagnosis, and treatment for all cancer patients. In doing so, with mounting evidence for the need to develop precision medical prevention, treatment, and intervention solutions based on diverse patient populations, we are actively engaged in changing the health equity landscape by expanding diversity in the inclusion of historically underrepresented racial and ethnic minority populations into clinical trials that we fund. We are especially interested in supporting clinical trials and research studies that have developed successful strategies, measurable outcomes, and robust outreach plans to feasibly and effectively include these populations into these studies.

PROGRAM MISSION STATEMENT

The Lung Cancer Health Equity SU2C Catalyst Research Team Grant Program endeavors to address the issue of low participation by racial and ethnic minority populations in cancer research and unequal access to cancer care despite the disproportionate burden of disease in those groups. Health disparities research has traditionally been fragmented, with research in the social sciences exploring socioeconomic and cultural barriers to access and the biological sciences studying genetic and environmental drivers of disease. A new collaborative approach that brings together investigators from the health services, health disparities, biological science and other fields, together with digital technology enablers, to design and implement a model of care that improves health equity among lung cancer patients. ***This Lung Cancer Health Equity SU2C Catalyst Program will focus on developing scalable solutions that address provider-level barriers by leveraging remote and virtual care technologies augmented with Artificial Intelligence (AI) in an innovative care delivery model, leveraging services and tools from Apricity Health.***

The Lung Cancer Health Equity SU2C Catalyst Team will benefit from SU2C's structure and oversight through which a multi-disciplinary team will come together with support to focus on a discrete set of aims. The biannual progress review practiced by SU2C ensures that milestones and deliverables are met and will keep the project focused on its goals. Moreover, the SU2C practice of integrating multidisciplinary experts on research teams, including lay patient advocates, leaders of advocacy organizations, community leaders, and non-clinical research experts, creates a sense of urgency among team members and results in more patient-centered clinical research. The Lung Cancer Health Equity SU2C Catalyst Program is supported by a transformational grant from Bristol Myers Squibb.

STATEMENT OF PROBLEM

The Lung Cancer Health Equity SU2C Catalyst Program represents an unprecedented opportunity to bring together the best scientific and clinical minds from diverse fields of research and care to develop technology-enabled approaches to address health equity. In addition to patient-level factors, there are provider-level contributors to barriers of access, such as knowledge gap and unconscious bias. These challenges are more acute in lung cancer, amplified by shortage of subspecialty trained oncology providers.

PROGRAM DESIGN AND OBJECTIVES

This Lung Cancer Health Equity SU2C Catalyst project will test the hypothesis that an effective solution to address these provider-level barriers to health equity should include a suite of technology-enabled AI-assisted services including:

1. AI decision support to augment the expertise of practicing oncology teams at points-of-care to ensure guideline-based best practice in real world care
2. Digital technology to monitor patients while at home in between clinic visits so the appropriate care can be extended to patients at the proper time without delay
3. On demand staff augmentation strategy to address the shortage of oncology expert care providers that contributes to coverage gaps in these communities
4. Incorporation of in-home supportive care, or under certain circumstances, home hospitalization for those with significant care distance barriers.

Apricity Health will provide these technology-enabled services to support and complement the care delivery strategies designed for specific local community needs, as proposed by the Lung Cancer Health Equity SU2C Catalyst Team.

This Lung Cancer Health Equity SU2C Catalyst Program will provide support for Phase 4 care delivery studies to examine and develop a scalable technology-enabled health equity solution. The ApricityRx™ for Oncology (or ApricityOncology) solution and associated CARE (Cancer Adverse even Rapid Evaluation)™ service will be provided (see description below) as the virtual front-door to guideline-based proactive care management for patients in medically underserved communities. The goal is to demonstrate how technology-enabled services, in conjunction with community engagement, can mitigate provider-level contributors to access barriers.

The proposed project should target patients with non-small cell lung cancer (NSCLC) eligible for immunotherapy combinations, with particular emphasis on people of color and minority patients in medically underserved communities. Apricity Health will provide the ApricityOncology solution and CARE service to enable (1) remote patient monitoring (RPM) to detect toxicity early; (2) 24/7 virtual triage and navigation by trained oncology nurses assisted by AI decision support to ensure timely and accurate response; and (3) guideline-based expert-curated recommendations for management of adverse events to ensure best practice. As an AI decision support platform, ApricityOncology enables coordinated and connected care by a diverse and distributed team. It facilitates data continuity and access to best practice recommendations at points of care. When extended to non-oncology care providers delivering at-home care, ApricityOncology additionally enables incorporation of more convenient patient-centric care for patients facing distance or other social determinants of health (SDOH) barriers to care.

ApricityOncology will capture and track the following data longitudinally:

- High-resolution patient reported outcomes (PRO) and electronic medical record (EMR) data on symptomatology and lab abnormalities
- Serial surveys of SDOH and Quality of Life (QOL)
- Time to onset, progression, and severity of toxicities (at diagnosis and resolution/progression)
- Time to intervention, from symptom report to triage and follow-up evaluation/workup
- Clinicians' adherence to best practice guidelines (practice pattern) as documented in EMR
- Shared decision making with patients as deviations from guidelines (due to SDOH)
- % high-grade vs low-grade toxicities at end of study
- % treatment discontinuity or interruption
- % utilization of acute care service (ED, hospitalization)

The Lung Cancer Health Equity SU2C Catalyst Team will (1) leverage and bring together community oncology practices in underserved communities, (2) implement ApricityOncology and associated CARE services to address

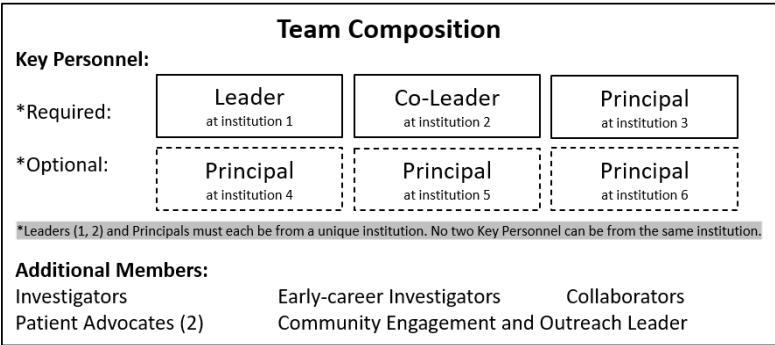
care gaps, and (3) optimize workflow and capture data to establish a new paradigm of technology-enabled oncology care for the underserved.

Apricity Health will provide additional information regarding ApricityRx™ for Oncology and associated CARE service included in this Lung Cancer Health Equity SU2C Catalyst Program. All applicants are strongly encouraged to engage Apricity Health directly during the proposal development process to ensure responsiveness. Contact SU2C at proposals@su2c.org to learn more and to be connected with Apricity.

TEAM COMPOSITION AND MEMBER ELIGIBILITY CRITERIA

To achieve the objectives of this project, the Lung Cancer Health Equity SU2C Catalyst Team must include clinical and evaluation expertise, including senior and early-career investigators. The Team will consist of a Team Leader, a Team Co-Leader, no more than four additional Team Principals, a Project Manager, and at least one Patient Advocate, **with a minimum of three participating institutions**. Racial and ethnic diversity among SU2C Catalyst Team personnel is strongly encouraged.

Research Team Composition Overview



Definitions

- 1. Team Leader (TL) (required):** The Team Leader is the person responsible for the scientific and technical direction of the proposed research project, contractual and financial obligations, and other organizational assurances/certifications. The TL must ensure that the Team complies with the terms and conditions of the award, and will be the primary contact person for SU2C science staff.
- 2. Lead Institution** is the organization at which the Team Leader is employed, and it will be legally and financially responsible for the conduct of Research Team activities supported by the grant.
- 3. Team Co-leader (TC) (required):** A Team Co-leader is designated by the Team Leader to assist in directing the scientific and technical work of the Team. A Co-leader serves as an alternate contact person for SU2C science staff.
- 4. Team Principal (TP) (required):** Team Principal(s) is a senior investigator(s) who will lead a component(s)/subproject(s) of the Team research project.
- 5. Project Manager (required):** The Team Project Manager (PM) is the administrative leader of the Team and the key administrative contact for the Team with SU2C. The PM is responsible for the coordination of all team efforts to consistently maintain a high level of functionality, collaboration, and communication. The PM coordinates the Patient Advocates and the scientific reporting, and, where appropriate, assists the Team in developing a plan for clinical trial accrual, diversity, and tracking.
- 6. Community Outreach and Engagement Leader (required):** These leaders represent the perspective of the community that is expected to benefit from widespread use of newly developed treatments. These individuals may be affiliated with your institution, a specific organization or the broader community and enable the Team to better understand existing local barriers to clinical trial participation. Where appropriate, Community Outreach and Engagement Leaders may work with the Team in developing a

plan for clinical trial recruitment and retention. If you need assistance with the identification of qualified Community Outreach and Engagement Leaders for your application, you may contact Advocacy@su2c.org.

7. **Patient Advocates** (required): Patient Advocates bring the perspectives of those affected by cancer (e.g., patients, survivors, caregivers) to the work of Team. They enable the Team scientists to see their research through the eyes of the target audience and integrate these perspectives into the direction of the Team research. Patient Advocate members do not represent the viewpoints or issues of any advocacy organization or their individual personal issues. Where appropriate, Patient Advocates also work with the Team in developing a plan for clinical trial accrual, diversity, and tracking, including measures to ensure recruitment and retention of diverse participants. If you need assistance with the identification of qualified Patient Advocates for your application, you may contact Advocacy@su2c.org.
8. **Investigators**: Senior investigators, other than the TL, TC, and TPs, who are employed at the TL, TC, or TP institutions and contribute substantively to the Team research project, may be included as members of the Team.
9. **Early-Career Investigators**: Junior faculty (i.e. independent investigators who have completed their training no more than seven years prior to the start of the grant term), postdoctoral fellows, clinical research fellows, or any other researchers-in-training who are working under the direction of a scientific mentor (i.e., a TL, TC, TP, or Investigator) may be included as members of the Team.
10. **Collaborator**: An Investigator who is not employed by a participating institution and is unfunded in this project budget yet makes valuable contributions to the Team.
11. **Budget and Contract contact** (required per institution): For each participating institution/clinical trial site, provide at least two officials responsible for grant agreements.
12. **Other (Scientific/Technical)**: Any person providing scientific or technical support, such as Lab managers and technicians
13. **Other (Administrative)**: Any person providing administrative support such as Administrative assistants
14. **Public Information Officer (PIO)** (required per institution): The PIO is the communications coordinator or spokesperson for the institution.

Team Member Eligibility Requirements

1. The TL, TC, and TPs must have acquired a doctoral or medical degree and must be independent investigators affiliated with an academic, medical, or research institution. Individuals on the FDA Debarment List may not apply.
2. Applications are encouraged from the scientific community, including current and former SU2C grantees as well as non-SU2C affiliated scientists.
3. Research must be carried out within the United States. There are no citizenship or residency status restrictions for team members.
4. The TL and TC are expected to each dedicate at least 20 percent (or 40 percent combined) of their time and effort to the Team research project.
5. TPs must each dedicate at least 10 percent of their time and effort to the Team research project.
6. No Team will have more than one Key Personnel (TL, TC, or TP) from any given institution at the time of their initial appointment on the Team. No more than two Key Personnel may be from affiliated institutions. It is expected that additional Investigators from the TL, TC or TP institutions may be involved in the Team research project in some other capacity, and there is no limit to the number of Investigators from each of these institutions that may contribute to the Team project.
7. Employees or subcontractors of for-profit industry are not eligible to serve as a TL, TC, or TP; however, their participation as unfunded Collaborators is encouraged, where appropriate, to foster the development of novel strategies.
8. Early-Career Investigators are not eligible to serve as a Team Leader, Co-leader, or Principal; however, their participation in the Team research projects is highly encouraged.
9. Members of the SU2C Catalyst Executive Committee are not eligible for funding as part of the Lung

Cancer Health Equity SU2C Catalyst. Members of the Lung Cancer Health Equity SU2C Catalyst – Bristol Myers Squibb Steering Subcommittee are not eligible for a Lung Cancer Health Equity SU2C Catalyst grant resulting from this Request for Applications but may apply for other SU2C Catalyst funding opportunities that are not reviewed by the Lung Cancer Health Equity SU2C Catalyst – Bristol Myers Squibb Steering Subcommittee.

APPLICATION DEADLINE

The deadline to submit the full application is Tuesday, November 16, 2021, at 11:59pm midnight Pacific Daylight Time at StandUpToCancer.org/BMSCatalystGrant. APPLICANTS ARE STRONGLY ENCOURAGED TO CONTACT SU2C AT proposal@su2c.org PRIOR TO SUBMITTING AN APPLICATION TO OBTAIN ADDITIONAL INFORMATION REGARDING APRICITY HEALTH RESOURCES AND TO ENGAGE APRICITY HEALTH THROUGHOUT THE PROPOSAL DEVELOPMENT PROCESS.

The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a virtual selection meeting to be held on Friday, January 21, 2022. The selected team will be notified in February 2022 with anticipated project start dates in May 2022. See the section “Application Instructions” on page 12 for further information.

EVALUATION OF PROPOSALS

The Lung Cancer Health Equity SU2C Catalyst – Bristol Myers Squibb Steering Subcommittee will review the proposals for the Lung Cancer Health Equity SU2C Catalyst. The Steering Subcommittee Chair and Committee members will be drawn from academia. Bristol Myers Squibb will recommend one non-voting member to serve on the Committee. The SU2C Catalyst Executive Committee will consider the Lung Cancer Health Equity SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee recommendations for funding and make the final selection of Lung Cancer Health Equity SU2C Catalyst grantees.

The Lung Cancer Health Equity SU2C Catalyst – Bristol Myers Squibb Steering Subcommittee will consider the following criteria when evaluating the proposals:

- A responsive application should propose a Phase 4 real-world care delivery project focused on lung cancer.
- The proposal must be non-duplicative, non-detrimental.
- Scientific merit of the proposed care delivery project
- Significance of potential impact on the underserved patient populations
- Degree to which the studies can lead to a scalable health equity model in cancer care
- Team leadership qualities (Team Leader, Team Co-Leader, and Team Principals): Willingness to collaborate, demonstrated ability to bring together and lead a team of both researchers and clinicians
- Commitment to diversity, equity, and inclusion: How the project partnership is designed to prioritize different voices and power-sharing with the prioritized communities, the extent to which project leadership is representative of the populations of focus in the grant, the extent to which the proposal captures and effectively disaggregates data in order to determine precise impact (i.e., by race/ethnicity), potential for sustainability in the health equity environment, demographics of the institutions’ and project leadership, engagement of experienced and young investigators in the project, track record of collaboration and impact between academic and community partners, and how this project will leverage the learnings
- Involvement of patient advocates and/or community members in study design and implementation
- Willingness of the team leaders and members to collaborate with Apricity Health and other industry partners and incorporate digital technologies in innovative care delivery model
- A clear commitment towards data sharing by the Lung Cancer Health Equity SU2C Catalyst Team: All data resulting from their work will be available to the scientific community at large at the earliest opportunity, as allowed under patient privacy and other applicable laws.

- Likelihood of feasibility that the care delivery project will achieve its stated goals given the budget requested, institutional environments, and other resources available
- Likelihood that patient enrollment to clinical studies will be completed within the timeframe of the grant
- Whether the studies are designed to capitalize upon the unique populations and environments, specialized expertise, new concepts and perspectives, innovative methodologies, and/or emerging technologies that are available as a result of the multi-institutional collaboration
- Whether the studies are designed to capitalize upon Apricity Health’s technology-enabled CARE services, and other emerging technologies that are available as a result of the multi-institutional collaboration
- Plan for broad dissemination, impact, and sustainability of the models created
- Likelihood of proposed model being sustainable and replicable in targeted populations, based both on scientific merit and engagement with decision makers throughout the project
- Whether adequate institutional and/or financial support exists to sustain the care delivery project
- The cost effectiveness of the budget
- Plan for mentoring and integrating Early-Career Investigators and minority team members

CONFIDENTIALITY OF APPLICATION REVIEW

For the purposes of the Lung Cancer Health Equity SU2C Catalyst Research Grants funding opportunity, “Confidential Information” shall mean information, data, technical and non-technical materials, research concepts and design descriptions, and products or know-how relating to the research, software, developments, inventions and designs of any Applicant or Grantee identified as confidential upon disclosure. Notwithstanding the foregoing, no such information, data, materials, concepts, descriptions, products or know-how shall be deemed Confidential Information if it: (a) at the time of disclosure or thereafter becomes generally available to the public other than as a result of disclosure by Bristol Myers Squibb; (b) becomes available to Bristol Myers Squibb on a non-confidential basis from a source (other than the Applicant) that is entitled to disclose it; (c) was known to or in the possession of Bristol Myers Squibb immediately prior to the time of disclosure as shown by Bristol Myers Squibb’s records and files at such time or as may otherwise be shown; or (d) is subsequently independently developed by the employees or agents of Bristol Myers Squibb who did not have access to the Confidential Information.

GRANT TERMS

Changes to application. Applicants are not allowed to change the project nor the Team members proposed in the application. If changes are necessary, prior written approval from SU2C is required.

Contracts. A Grant Agreement will be executed between SU2C and the Team Leader’s Institution, referred to as the Lead Institution. A data sharing agreement and a service agreement will also need to be executed between the Lead Institution and each participating clinical site and Apricity Health prior to start of the care delivery project. THE MAJOR TERMS OF THE AGREEMENTS WITH APRICITY HEALTH ARE SUMMARIZED IN EXHIBIT A.

The Lead Institution must serve as the administrator of the grant funds and hold responsibility for the disbursement of the funds, management of the budget, and provision of progress reports. It is expected that the Lead Institution will enter into subcontracts with the institutions of the Team Co-leader and Principals, and assurances that these contractual agreements have been executed will be required for continuation of funding. All contracts with industry are encouraged to use the model contract language for clinical trials of potential new cancer treatments that has been made available by the CEO Roundtable on Cancer in partnership with the NCI to comply with the requirement of the SU2C founders to expedite the negotiation process. Please visit <http://transformingtrials.cancer.gov/initiatives/ctwg/standardization/highlights-start> for further details.

Commencement. The project will commence upon execution of the contract agreement with the lead institution. SU2C retains the right to terminate the grant if the project is not commenced in a timely manner.

Budget. Lung Cancer Health Equity SU2C Catalyst Teams may apply for total support up to \$1 million over a 3-year term, including indirect costs up to 25 percent, in addition to technology-enabled care services by Apricity Health that will be provided (not included in Catalyst Team budget) to support patient care as summarized in FAQ. Contact proposal@su2c.org to be connected with Apricity Health to learn more.

The templates provided with the grant application should be used to complete a detailed budget. SU2C strongly advises a limited first year budget as past Teams over-allocated funds in the timeframe. All funding is contingent upon milestones and objectives being appropriately selected and satisfactorily pursued and achieved, as determined by SU2C and the Steering Subcommittee.

Use of Funds. Regulatory requirements must be in place before funding is disbursed. Grant funds may be used for direct research expenses attributable to the proposed research, that may include:

- A percentage of the salary and benefits expenses (limited to 20 percent of the total budget) of senior investigators
- A percentage of salary and benefits expenses of the Early-Career Investigators on the Team
- Salary and benefits expenses for research assistants or technicians
- Equipment, supplies, and other laboratory or clinical expenses
- Travel expenses relevant to the Lung Cancer Health Equity SU2C Catalyst Team research project, including travel to the institutions of the Team Leaders/Principals and travel to meetings with the Review Team, as well as to the annual SU2C Scientific Summit
- Patient care costs, if any, for both inpatient and outpatient care, excluding cost duplicative of in-kind service already provided for
- Costs associated with infrastructure and supplies needed to advertise, to recruit and retain participants, and to track participation. The SU2C web page will include a page for each project.
- Expenses (limited to a total of \$10,000/year) related to publication page charges and/or the presentation of research data at scientific meetings or through other means that will contribute to the dissemination of the scientific knowledge derived from the proposed research
- Consortium/contractual direct costs
- Other Expense must be thoroughly justified.

The funds may not be used for salary or benefits of any Collaborators from a government institution/agency or a for-profit industry, or for any research expenses related to the Team project that are incurred by these individuals. Tuition and professional membership dues are not allowable expenses.

Any indirect costs charged by the institutions will correspond with what is typically negotiated for industry support at each institution but will not exceed 25 percent of the total budget.

Payments. The payment schedule between the Lead Institution and SU2C will be delineated in the contract agreement after awarding of the grant.

Reporting Requirements. Progress reports, submitted on July 15 and January 15, shall highlight the accomplishments of that specific time period bearing in mind the pre-defined Milestones and Deliverables of the Team. Progress Reports will be reviewed by SU2C and a Review Team drawn from the Selection Committee.

SU2C may withhold release of any or cancel future Grant Funds until the reports have been filed and approved. Failure to address deficiencies, meet grant requirements, or achieve the pre-defined Milestones and Deliverables may result in discontinuation of the grant.

Teams must meet three times a year, either in person, by teleconference, or by videoconference, to review

progress and, if necessary, adjust research plans. Two of the required meetings can be fulfilled prior to the semi-annual reviews, where Team Leaders meet with the Review Team and all other Team members, following the submission of Progress Reports, to thoroughly discuss the Teams' progress. The review meeting schedule will be an appendix to the Team contract.

A final written progress and financial report shall be submitted no later than sixty (60) days after the ending date of the grant term. The reporting materials must include all project components.

SU2C will share copies of interim and final progress reports and may provide these materials, at their discretion, to other funders that have provided financial support for the grant and also may use all or portions of the report for public dissemination, such as within SU2C newsletters or websites, or in other similar manners.

Publications, Presentations, and Acknowledgment of Support. Any publications resulting from research funded in whole or in part by the grant must cite SU2C as funders in the acknowledgment. The contract between SU2C and the Lead Institution will contain exact wording. Copies of such publications shall be forwarded to SU2C after acceptance but before publication.

Intellectual Property. SU2C must be notified of any discovery that is protectable under applicable law (e.g. patentable), that is discovered in the course of the research funded through this grant. SU2C shall have no responsibility or interest in the protection of, commercialization or licensing of intellectual property resulting from the Team. The Team Leader and the Lead Institution shall notify SU2C of the granting of each patent or other legal protection and of all commercial exploitation of any Invention.

Insurance. Insurance shall be maintained by the Team Members and Institutions for professional liability and comprehensive general liability insurance, on an "occurrence" basis, against claims for "personal injury" liability, including bodily injury, death, or property damage liability. Such insurance shall be primary and noncontributory with any other insurance carried by SU2C and shall provide appropriate waivers of subrogation against SU2C, and its directors, committee members, employees, affiliates, and agents.

Notification of Changes. The Team Leader is responsible for notifying SU2C immediately of any changes in the composition of the Team and changes in the position or institution of any of the Team Members. SU2C may not accept proposals to change the research project from that described in the application and may terminate the grant.

Organizational Assurances. The Team Leader and Lead Institution are responsible for ensuring that organizational assurances/certifications from all Team Member Institutions are obtained.

For research involving human subjects, the appropriate Team Member(s) and U.S. Institution(s) shall certify that:

- a. Prior to the initiation of human research, the proposed research project has been reviewed and approved in writing by an Institutional Review Board ("IRB") constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services ("HHS") and registered with HHS.
- b. The Team Member(s) shall secure a legally acceptable informed consent from all human subjects taking part in any research funded in whole or in part by SU2C in accordance with and to the extent required by current regulations promulgated by the United States Department of Health and Human Services and approved by HHS. IRB approval for human subjects research should be submitted to SU2C, and funds for human subjects research will NOT be released unless and until proof of all IRB certifications is received by SU2C. Prior IRB approval for another project cannot be substituted but can be officially amended to include the proposed project.
- c. IRB certification should be documented by submitting a copy of the institutional letter of approval, which identifies the Team Leader or Team member responsible for the relevant project component, the

Lung Cancer Health Equity SU2C Catalyst research project title, Stand Up To Cancer as the funding agency, and date of approval.

- d. The Team Leader/Team member, or their institution, shall submit and hold the Investigational New Drug (IND) Application and/or Investigational Device Exemption (IDE) for studies that are not deemed exempt. All participating institutions are responsible for data management, safety reporting, and quality assurance processes associated with the research.
- e. The Team Leader, Team members, and their institutions are required to promptly report serious and other adverse events associated with the use of the study product(s) to the IRB, FDA, SU2C, and Bristol Myers Squibb according to all applicable regulations and requirements.

For research involving animals, the Institution(s) shall ensure compliance with applicable chapters of the Public Health Service Animal Welfare Policy, the NIH Manual for Grants and Contracts, and any and all requirements of the Institution concerning animal welfare. Certification by the Institution Animal Care and Use Committee (IACUC) or equivalent shall be documented by submitting a copy of the institutional letter of approval, which identifies the Team Member(s) responsible for the project, the Team research project title, SU2C as the funding agencies, and the date of approval, and is signed by the IACUC Chair or equivalent Institution official. Prior IACUC certification for another project cannot be substituted, but can be officially amended to include the proposed project.

APPLICATION INSTRUCTIONS

APPLICATIONS: Applications must be submitted before 11:59pm midnight Pacific Daylight Time on **Tuesday, November 16, 2021**, to StandUpToCancer.org/BMSCatalystGrant. The application includes both (1) a text application template and (2) spreadsheet templates for completion and submission and are available for download at the submission site. Instructions are available in the templates.

The application includes the following sections:

Application Template

- Title Page
- Signatures Pages: Signature pages must be submitted for every Institution requesting Lung Cancer Health Equity SU2C Catalyst funds through this grant application. The Team Leader, Team Co-Leader, every Team Principal, and Patient Advocate(s) must be included in the Signature Pages.
- Lay Abstract (limited to 1/2 page)
- Scientific Abstract (limited to 1/2 page)
- Research Proposal (limited to 10 pages; include the following information)
 - Background and Rationale
 - Specific Aims
 - Research Design and Methods
 - Statistical Plan
 - Projected Timeline and Milestones
 - Significance and Therapeutic Impact
 - Collaboration/Team Members
 - Data Sharing Plan
 - Patient Advocate Role
 - Demonstrated experience in proven success in relevant patient populations
 - Recruitment and Retention Plan
- Facilities (limited to 1 page per Institution)
- References (no page limit).
- Other Support

- Budget Justification: Limited to three (3) pages per institution. Detailed justification of the separate budget requests for expenses related to the research components/subprojects conducted by the Team leader, Team Co-Leader, and Team Principals is required for all items of the equipment costing over \$1,000, and the need for personnel, supplies, and other items. Provide the names of individuals whose salaries will be supported by the grant funds and justify the amount of support requested. If requesting “Other Expenses,” a thorough list of these expenses along with the justification is required.

Appendix

- Milestones and Deliverables Timeline (Tab A in Spreadsheet Templates)
- Requested funding and required regulatory approvals per Specific Aim (Tab B in Spreadsheet Templates) and Clinical Trials (Tab B.1 in Spreadsheet Templates)
- Budget (should not exceed 1.0 million USD): See sections “Budget” and “Use of Funds” on p. 8-10 for additional information.
 - Total Budget per Year (Tab C1 in Spreadsheet Templates)
 - Budget per Institution (Tab C2 in Spreadsheet Templates; complete for every institution)
 - Total Budget per Institution (Tab C3 in Spreadsheet Templates)
- Personnel Tracker (Tab D in Spreadsheet Templates): See section “Eligibility Criteria” on p. 4-6 for additional information.
- CVs for Team Leadership (Team Leader, Team Co-Leader, Team Principals; NIH Biosketch preferred but not required; no template is provided; do not exceed five (5) pages per individuals)
- Letters of Support
 - Letters from Leadership at each Institution involved in the Team
 - Letters from other Company(ies) collaborating with the Team
 - Letter(s) from the Chief Diversity Officer (or equivalent) at the Lead Institution as well as each Institution involved in patient recruitment or care for Team clinical trials
- Clinical Trial Protocol (if a clinical trial is proposed)
 - The Clinical Trial Protocol must include the following in no particular order (CTEP guidance may be followed https://ctep.cancer.gov/protocoldevelopment/templates_applications.htm):
 - Study Rationale: Provide a brief description of the medical question and the rationale of how this trial addresses the question. Provide a rationale for the dose schedule outlined for all treatment arms. Reference any non-labeled indication.
 - Primary Objective: Provide the main goal of the study and the study population. Provide a detailed definition that is directly linked to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section.
 - Primary Endpoint
 - Hypothesis
 - Study Assessments: Specify type and frequency of safety, efficacy, and outcome measures. Also indicate the method(s) used to assess measures.
 - Secondary Objective
 - Data and Statistical Plan: Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The range of sophistication will depend on a number of factors, including the size and complexity of the study. Indicate how incidence of the cancer(s) in the relevant patient population(s) will be reflected in the analysis of the sample data.
 - References: List references, studies, and sources that support the study design.
 - Targeted Patient Population: Specify age, gender, diversity, and other demographic information for the trial population.
 - Recruitment and Retention Plan : Specify approach to accrue representative patient population to the trial. Provide patient recruitment and retention plan addressing

methods to ensure appropriate representation of historically underrepresented racial and ethnic minority populations.

- Specify the dose, schedule, duration, and any pre-medications, etc.
- Sample Size Calculation
- Sample Size Justification: The sample size must reference the primary endpoint.
- List any correlative studies.
- Key Inclusion and Exclusion Criteria: List all inclusion and exclusion criteria necessary to support the trial design and drug safety requirements.
- Secondary Endpoint
- Data Handling and Record Keeping including a formal Data Use Agreement

Other Application Information

The spreadsheet templates include: (1) Milestones and Deliverables Timeline, (2) Requested funding and required regulatory approvals per Specific Aim, (3) Budget per year and per Institution, and (4) Personnel Tracker. Collaborative groups of researchers from diverse institutions are preferred; all applications must include inter-institutional collaborations. Curriculum vitae (NIH Biosketch preferred but not required) with a recent (five year) publication list as well as current funding should be included for Team Leadership (Team Leader, Team Co-Leader, and Team Principals). Teams are required to have a Team Leader and a Team Co-Leader. Teams must include a Project Manager and at least two Patient Advocates as well as a Community Outreach and Engagement Leader. Projects should be planned for three years, with any proposed trials completing accrual by the end of the grant period. The proposed budget should not exceed 1 million US dollars total. If a clinical trial is proposed, then a clinical trial protocol or a compelling justification for delaying the protocol development will be required.

Application Submission

The application submission site is available at StandUpToCancer.org/BMSCatalystGrant. An email will be sent to confirm receipt of your online submission.

Changes to the Application

Following the submission of an application, the Team Leader should notify SU2C in writing of (1) any changes of address, email, or phone number for any Team member, (2) any changes in institution for any Team member, or (3) withdrawal of the application for any reason.

Notification

The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a videoconference selection meeting to be held Friday, January 21, 2022. The selected team will be notified in February 2022 with anticipated project start dates in May 2022.

INQUIRIES

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to the SU2C Science Office at:

Phone: 832-684-6462

Email: proposals@su2c.org