Program Guide
Pediatric SU2C Catalyst®
supported by a grant from Bristol-Myers Squibb

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 (EIF), a 501(c)(3) charitable organization, was established in 2008 by film and media leaders who utilize the industry's resources to engage the public in supporting a new, collaborative model of cancer research, and to increase awareness about cancer prevention as well as progress being made in the fight against the disease. SU2C's innovative research portfolio includes its signature Dream Teams as well as Research Teams that address critical problems in patient care and deliver near-term patient benefit through investigation by small collaborative teams of expert investigators, including SU2C Catalyst® using funding and materials from the pharmaceutical, biotechnology, diagnostic, and medical devices industries to rapidly explore new uses of potential compounds for cancer prevention, detection, and treatment; and SU2C Convergence grants bringing together quantitative scientist and oncologists in integrated projects focused on cancer biology. The SU2C Scientific Advisory Committee led by Nobel Laureate Phillip A. Sharp, PhD, conduct rigorous, competitive reviews to identify the best research proposals to recommend for funding, and semi-annual rigorous scientific progress reviews of all active SU2C-funded research.

Current members of the SU2C Council of Founders and Advisors (CFA) include Katie Couric, Sherry Lansing, Lisa Paulsen, Rusty Robertson, Sue Schwartz, Pamela Oas Williams, Ellen Ziffren, and Kathleen Lobb. The late Laura Ziskin and the late Noreen Fraser are also co-founders. Sung Poblete, PhD, RN, has served as SU2C's president since 2011. For more information on Stand Up To Cancer, 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 more information about Bristol-Myers Squibb, please visit www.bms.com, or follow us on LinkedIn, Twitter, YouTube and Facebook.

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.

PEDIATRIC SU2C CATALYST® - RESEARCH PROJECT CRITERIA

The Pediatric SU2C Catalyst® endeavors to accelerate the development of treatments for pediatric cancers by decreasing the time between lead compound development and initiation of the pivotal clinical trial. The Pediatric SU2C Catalyst® will support preclinical research and early phase clinical trials to provide foundational data that will allow pediatric trials to progress in parallel with adult clinical trials. This cutting-edge program will have a strong focus on preclinical and early, rationally-designed clinical trials in order to identify medicines that are suitable for further clinical development in pediatric oncology. The Pediatric SU2C Catalyst is also welcoming combinations of therapies and devices from other sources and companies for refractory pediatric cancers.

APPLICATION DEADLINE

Proposals for the Pediatrics SU2C Catalyst® supported by Bristol-Myers Squibb must be submitted by **12:00 p.m. (noon) United States Eastern Time on April 9, 2018.** See the section "Applications" on page 8 for further instructions.

ELIGIBILITY CRITERIA

Definitions:

1. **Team Leader** (required): The Pediatric SU2C Catalyst Team Leader is the person responsible for the scientific and technical direction of the research project, contractual and financial obligations, and other organizational assurances/certifications. The Leader must ensure that the Team complies with the terms and conditions of the award and will be the primary contact person for SU2C. This researcher must be identified as having expertise in pre-clinical, clinical, or translational research. If the project is requesting funding for a clinical trial, then either the Leader or Co-Leader must be the Clinical Leader for the Team.

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 Pediatric SU2C Catalyst - Bristol-Myers Squibb Team activities supported by the grant.

3. **Team Co-Leader** (required): The Team Co-Leader has expertise in a different area than the Team Leader: pre-clinical, clinical, or translational research. If the project is requesting funding for a clinical trial, then either the Leader or Co-Leader must be the Clinical Leader for the Team.

4. **Team Principal**: The head Investigator at a specific institution or site. Either a Team Leader, Team Co-Leader, or a Team Principal must be identified at each institution requested to receive funding for this project.

5. **Investigator**: An Investigator is a senior researcher who leads a component/subcomponent/clinical trial and contributes substantively to the Catalyst Team research project.

6. **Young Investigator**: Junior faculty (i.e. independent investigators who have completed their training no more than 5 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 Team Leader, Team Co-leader, Team Principal, or Investigator) may be included as members of the Pediatric SU2C Catalyst Team.

7. **Industry scientist (clinical/research)**: An Industry Scientist is a clinician or researcher employed by the industry sponsor or collaborating company who contributes to the Pediatric SU2C Catalyst Team project. Industry scientists may not receive salary or research support from the SU2C award.

8. **Collaborator**: Investigators who not employed by a participating company and are unfunded in this project budget yet make valuable contributions to the Pediatric SU2C Catalyst Team research project

9. **Project Manager** (required): Manages all administrative aspects of project and coordinates all sites associated with the grant. Serves as the lead administrative contact for SU2C.

10. **Budget and Contract contact** (required per institution): For each participating institution/clinical trial site, provide at least two officials responsible for grant agreements.

11. **Other (Scientific/Technical)**: Any person providing scientific or technical support such as Lab managers and technicians

12. **Other (Administrative)**: Any person providing administrative support such as Program Managers, Administrative assistants

13. **Patient Advocate** (required): Patient Advocates will bring the perspectives of those affected by cancer (e.g., patients, survivors, caregivers) to the work of the Catalyst Team. They will enable the Team scientists to see their research through the eyes of the target population and integrate these perspectives into the direction of the Team research. Patient Advocates represent the best interests of patients and do not represent the specific agenda of any advocacy organization.

14. **Public Information Officer** (PIO, required per institution): The PIO is the communications coordinator or spokesperson for the institution.

The Team Leader, Team Co-Leader, and Team Principals must have acquired a doctoral or medical degree, and must be independent investigators affiliated with an academic, medical, or research institution. Applications are encouraged from the scientific community, including current and former SU2C grantees as well as non-SU2C affiliated scientists. Individuals on the FDA Debarment List may not apply.

All team members and/or their institutions must be willing and able to sign non-disclosure agreements to gain access to certain compounds available for use in the Pediatric SU2C Catalyst.

Research must be carried out within the United States and/or Canada. There are no citizenship or residency status restrictions.

Employees or subcontractors of for-profit industry are not eligible to apply, but their participation as unfunded Collaborators or Industry Scientists is encouraged.

Members of the Pediatric SU2C Catalyst Executive Committee are not eligible for funding as part of the Pediatric SU2C Catalyst. Members of the Pediatric SU2C Catalyst-Bristol-Myers Squibb Steering Subcommittee are not eligible for a Pediatric SU2C Catalyst - Bristol-Myers Squibb Research Grant but may apply for other SU2C Catalyst funding opportunities.

Candidates with questions about the eligibility requirements are encouraged to contact SU2C at proposals@su2c.org prior to submitting a proposal.

EVALUATION OF PROPOSALS

The Pediatric SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee will review the proposals for the Pediatric SU2C Catalyst. The Steering Subcommittee Chair will be drawn from academia. Excluding the Chair, an equal number of Committee members will be drawn from academia and Bristol-Myers Squibb. The Pediatric SU2C Catalyst Executive Committee will consider the Pediatric SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee recommendations for funding and make the final selection of Pediatric SU2C Catalyst grantees.

The Pediatric SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee will consider the following criteria when evaluating the proposals:

- The proposal must be a non-duplicative, non-detrimental research project.
- Scientific merit of the proposed research project and the pre-clinical or clinical nature of the research
- Significance of the proposed research
- Novelty of the hypothesis or methodology
- Degree to which the studies have a positive therapeutic impact on the detection or treatment of cancer
- Team leadership qualities (Team Leader, Team Co-Leader, and Team Principals): Willingness to collaborate, demonstrated ability to bring together and lead a team of experts to a successful conclusion, expertise in the field, and commitment to pediatric cancer research with a clear emphasis on near-term clinical application
- Willingness of the Team members to collaborate, their research credentials, and their unique contributions to the Pediatric SU2C Catalyst research project
- A clear commitment towards data sharing by the Pediatric 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 research project will achieve its stated goals given the budget requested, institutional environments, and other resources available
- Likelihood that patient enrollment to clinical trials will be completed within the timeframe of the grant
- Whether adequate institutional and/or financial support exists to sustain the research project
- The cost effectiveness of the budget

CONFIDENTIALITY OF APPLICATION REVIEW

For the purposes of the Pediatric SU2C Catalyst - Bristol-Myers Squibb 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

Contracts. A Grant Agreement will be executed between SU2C and the Team Leader's institution (the Lead Institution). An agreement will also need to be executed between the Lead Institution and Bristol-Myers Squibb prior to start of the research project. 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 institutions of other Pediatric SU2C Catalyst - Bristol-Myers Squibb Team members and collaborators, and assurances that these contractual agreements have been executed will be required prior to funding. Administration of the grant funds by the Lead Institution must meet appropriate benchmarks to ensure an accelerated pace of cancer research.

Budget. The available funds are expected to support up to four projects. The final grant amount may vary depending on the nature and number of projects selected. Applicants may apply for total support of $1-3 million over a 4-year term.

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, which 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 Young Investigators on the Pediatric SU2C Catalyst - Bristol-Myers Squibb Team;
- Salary and benefits expenses for research assistants or technicians;
- Equipment, supplies, and other laboratory or clinical expenses;
- Travel expenses relevant to the SU2C Catalyst research project, including travel to the institutions of the Principal Investigator and Key Personnel and travel to meetings with the Steering Subcommittee, as well as to the annual SU2C Scientific Summit; and
- Patient care costs, both inpatient and outpatient;
- 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 $20,000/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.
- Other Expense must be thoroughly justified;
- Consortium/contractual direct costs;

The funds may not be used for the salary or benefits of any Collaborators from a government institution or for-profit industry, or for any research expenses related to the Pediatric SU2C Catalyst research 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.

Patient Accrual. SU2C will assist the Team Leader and the Lead Institution in efforts to quickly accrue patients to clinical trials funded by the grant. All Pediatric SU2C Catalyst -Bristol-Myers Squibb team Institutions are expected to support and participate in SU2C directed initiatives to accelerate patient enrollment in relevant clinical trials, which may include messaging about clinical trials in general.

Reporting Requirements.

1. **Progress Reports**: Progress reports are to be submitted twice a year (June 15th and December 15th) and are intended to highlight the accomplishments of that specific reporting period. Progress Reports will be reviewed by SU2C, Bristol-Myers Squibb, and a Review Team established by the Pediatric SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee and approved by the Pediatric SU2C Catalyst Executive Committee. SU2C may use, after a 30-day embargo period, all or portions of the report that do not violate intellectual property (IP) or confidentiality agreements, for public dissemination, such as within an SU2C newsletter, on the SU2C website, or in other similar manners.

2. **Clinical Trial Reports**: Clinical trial reports are to be submitted monthly upon initiation of clinical trials supported by the Pediatric SU2C Catalyst.

3. **Financial Reports**: Teams are required to provide a report of the budget and expenditures for the Lead Institution and the other institutions funded by the Pediatric SU2C Catalyst - Bristol-Myers Squibb twice a year (June 15th and December 15th). A meeting to discuss the team finances will be scheduled after submission of the report and in advance of the subsequent review meeting. Information may be required regarding payments and other transfers of value to health care professionals in compliance with reporting requirements under applicable laws, including the Physician Payment Sunshine Act.

4. **Team Meetings**: Pediatric SU2C Catalyst - Bristol-Myers Squibb Teams must meet three times per year to review progress and, if necessary, adjust research plans, either in person, by teleconference, or videoconference. These meetings will include all key personnel involved in the project as well as staff from the SU2C Scientific Team.

5. **Review Meetings**: Twice per year Review Meetings will be held with the Review Team for oversight and guidance by experts in the field following submission of the Progress and Financial Reports. The Team Leader and Team Co-Leader will be required to participate in these meetings along with other key personnel as requested. One meeting will take place during the annual SU2C Scientific Summit held in late January, and the second meeting will take place during the summer.

6. **Manuscripts and Presentations**: Any public presentations of unpublished research or manuscripts resulting from research funded in whole or in part by the grant must be submitted to Bristol-Myers Squibb and SU2C 30 days prior to submission for publication review and comment.

7. **Final Report**: A final written progress and financial report shall be submitted no later than sixty (60) days after the ending date of the grant term. Instructions on completion of a satisfactory final report will be provided by the SU2C Science Office prior to the end of term. SU2C will provide copies of final progress reports to the industry collaborator that has provided financial support for the grant prior to public disclosure, and also may use, after a 30-day embargo period, all or portions of the report that do not violate intellectual property (IP) or confidentiality agreements for public dissemination, such as within an SU2C newsletter, on the SU2C website, or in other similar manners.

SU2C may withhold release of any future Grant Funds until the reports have been filed and approved by SU2C, the Pediatric SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee, and the Pediatric SU2C Catalyst

Executive Committee. All funding is contingent upon Milestones and Deliverables being satisfactorily pursued and achieved, as determined by SU2C, the Pediatric SU2C Catalyst - Bristol-Myers Squibb Steering Subcommittee, and the Pediatric SU2C Catalyst Executive Committee. If the accomplishments have not met the standards of the Pediatric SU2C Catalyst Committees, the Committee will provide detailed information on specific areas of deficiency and its recommendations. All deficiencies will need to be addressed by the Team Leader. Failure to address deficiencies, meet grant requirements, or achieve the pre-defined Milestones and Deliverables may result in discontinuation of the grant.

Publications, Presentations, and Acknowledgment of Support. Any publications resulting from research funded in whole or in part by the grant must be cited as follows: "Research supported by a Pediatric Stand Up To Cancer Catalyst Research Grant, Grant Number SU2C-PCTXX-XX." In addition, whether during the term of the grant or afterwards, the Team Leader and other Pediatric SU2C Catalyst - Bristol-Myers Squibb Team members shall include this citation on any publicity or communications (external or internal) resulting from the grant, including but not limited to press releases, media reports, interviews, conference talks, and poster presentations of data. Copies of such publications must be forwarded to SU2C.

Insurance. Insurance shall be maintained by the Team Leader and Pediatric SU2C Catalyst -Bristol-Myers Squibb 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 or Bristol-Myers Squibb and shall provide appropriate waivers of subrogation against SU2C, Bristol-Myers Squibb, and its directors, committee members, employees, affiliates and agents.

Notification of Changes. It is the responsibility of the Team Leader to notify SU2C immediately of any changes in the composition of the Pediatric SU2C Catalyst - Bristol-Myers Squibb Team, and changes in the position or institution of any of the Pediatric SU2C Catalyst - Bristol-Myers Squibb Team members. Team Leaders may request changes to the project, clinical trial protocol, and/or budget through a written amendment request.

Organizational Assurances. It is the responsibility of the Team Leader and his/her Institution to ensure that organizational assurances/certifications from all Pediatric SU2C Catalyst - Bristol-Myers Squibb Team member institutions are obtained.

For research involving human subjects, the appropriate SU2C Catalyst Bristol-Myers Squibb Team member(s) and U.S. Institution(s) shall certify that:

a. 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).

b. The Team Leader and Pediatric SU2C Catalyst - Bristol-Myers Squibb Team members 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.

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 Pediatric 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 and 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 Institutional 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 Leader or Team member responsible for the project, the Pediatric SU2C Catalyst research project title, Stand Up To Cancer as the funding agency, and the date of approval.

APPLICATIONS

The application includes both (1) a text application template and (2) spreadsheet templates for completion and submission. 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 Pediatric 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 3 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
  - Advocate Role
- 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 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 throrough 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)
- Budget (should not exceed 3 million dollars total): See sections "Budget" and "Use of Funds" on p. 5 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. 2 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 fixe (5) pages per individual)
- Letters of Support
    - Letters from Leadership at each Institution involved in the Team
    - Letters from other Company(ies) collaborating with the Team
- 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.
        - References: List references, studies, and sources that support the study design.
        - Targeted Patient Population: Specify age, gender, and other demographic information for the trial population.
        - Specify the dose, schedule, duration, and any pre-medications, etc.
        - Participating Countries
        - Sample Size Calculation
        - Sample Size Justification: The sample size must reference the primary endpoint.
        - List any correlative studies.
        - Key Inclusion Criteria: List the inclusion criteria necessary to support the trial design and drug safety requirements.
        - Key Exclusion Criteria: List the exclusion criteria necessary to support the trial design and drug safety requirements.
        - Secondary Endpoint
        - Data Handling and Record Keeping

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. If the project includes a clinical trial, then either the Team Leader or the Team Co-Leader must be identified as the Clinical

Lead. Teams must include a Project Manager and an Advocate. Projects should be planned for four years, with any proposed trials completing accrual by the end of the grant period. For projects involving both pre-clinical research and a clinical trial, the timeline and budget must be planned considering a go/no-go decision at 18-24 months. The scale of a project should not exceed 3 million dollars total. Letters of Support from leadership at each institution and company involved with the Team are required. 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/CatalystApplication. 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.

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