SU2C Catalyst® Research Grants

Genentech-Supported Projects

Program Guidelines and Application Instructions

ADMINISTERED BY

American Association for Cancer Research

FINDING CURES TOGETHER®

SCIENTIFIC PARTNER OF STAND UP TO CANCER

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PROGRAM GUIDELINES

ABOUT STAND UP TO CANCER
Stand Up To Cancer (SU2C) was created through an unprecedented collaboration uniting the major television networks, entertainment industry executives and celebrities, and prominent leaders in cancer research and patient advocacy. SU2C believes that the last thirty years have brought about a revolution in our understanding of the origins and causes of cancer. Today’s cancer scientists are now on the verge of translating these scientific discoveries into new, life-saving strategies to prevent, diagnose, or treat cancer. SU2C embarked on a series of projects to raise significant dollars to fund cancer research that will positively impact patient care and prevention. These projects included five internationally televised events, which aired on September 5, 2008, September 10, 2010, September 7, 2012, September 5, 2014, and most recently on September 9, 2016 on major networks and were viewed in more than 170 countries. The funds raised through this and other SU2C efforts are supporting translational cancer research Dream Teams, Translational Teams, and the SU2C Innovative Research Grants.

As the scientific partner in the SU2C initiative, the American Association for Cancer Research (AACR) provides scientific oversight and conducts expert peer review and grants administration for SU2C. The AACR is highly regarded as the scientific brain trust in all subfields of cancer research and for its peer review process that is fast, flexible, rigorous, and transparent.

ABOUT GENENTECH, A MEMBER OF THE ROCHE GROUP
Founded 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. Genentech has the largest biotech research center in the world and markets approximately 40 medicines, including 13 medicines for cancer. Genentech is testing new medicines with the hope of helping people with serious diseases live longer and better lives and are committed to developing personalized medicines and getting the right medicine to the right patient. The company, a member of the Roche Group, has headquarters in South San Francisco, California (www.gene.com).

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 of 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. As the Scientific Partner in the SU2C Catalyst, the AACR provides scientific oversight and conducts expert peer review and grants administration for SU2C.
The principles guiding SU2C collaborations with industry are designed to accelerate the pace of groundbreaking translational research that provides new therapies to patients rapidly:

- **Integrity**: Industry, academia, and SU2C will act with integrity at all times, putting patients at the center of everything we do.

- **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.

- **Transparency**: SU2C will be transparent, consistent, and fair when collaborating with industry.

- **Accountability**: SU2C is accountable to many stakeholders and thus will not promote, endorse, or favor any particular product.

**APPLICATION DEADLINE**

Proposals for SU2C Catalyst Research Grant: Genentech-Supported Projects must be submitted by **12:00 p.m. (noon) United States Eastern Time on Monday, October 22, 2018**. See page 13 for further Application Instructions.

In early December, selected finalists (Principal Investigator and Clinical Lead/Co-leader) will be invited to defend their proposal for an in-person Selection Meeting on January 26, 2019, in Santa Monica, California. More details will be provided to the finalists, but in-person attendance at the Selection Meeting is a prerequisite to become a recipient of this funding program.

**RESEARCH PROJECT CRITERIA**

The SU2C Catalyst takes a structured and prioritized approach to early-phase clinical studies and translational research in order to accelerate the time to get new treatments to patients and bring together all the key players in a collaborative and strategic manner. The SU2C Catalyst Research Grant: Genentech-Supported project should focus on clinical trials within the following thematic areas of research:

**Solid tumors**

- **Alectinib** or **entrectinib** combinations with other targeted therapies to address unmet medical needs in ALK+, RET+, ROS1+ and NTRK+ indications.

- Combinations with **ipatasertib** to explore mechanistic synergies with cancer immunotherapy, either by reversing potentially immunosuppressive effects in tumors exhibiting PTEN loss or PI3K pathway activation, or by promoting memory T cell responses by modulating Akt/mTor signaling.
Also of interest will be similar mechanism-based studies of other targeted agents (Genentech or external) in combination with atezolizumab either to extend efficacy or to address resistance.

**Hematologic malignancies**

- Novel treatment combination strategies with polatuzumab (including basket/umbrella concepts) in CD79b expressing B-Cell malignancies with high unmet need.

- Applicability of BCL-2 inhibition (venetoclax) in combination with novel/targeted therapies in high unmet need populations of acute myeloid leukemia (AML) or multiple myeloma (MM), including biological subgroups.

- Evaluation of minimum residual disease (MRD) as endpoint across histologies (including MRD guided treatment strategies).

- Refined exploration of diffuse large B-cell lymphoma (DLBCL) biology based on genomic alterations, gene expression, and protein profiles, in the context of molecular subtypes (e.g. including elucidation of mechanisms of response and acquired resistance to existing agents including anti-CD20 antibodies, venetoclax, polatuzumab, R-CHOP, etc.).

Clinical trials can utilize molecules listed alone or in combination with other compounds, biologics, diagnostics, or devices intended as therapeutic interventions, and/or methods for biomarker identification.

Clinical trials with correlative research will be prioritized. If a product is proposed for use that is marketed or is under development by another company, SU2C will facilitate any necessary meetings to help secure the necessary agreements between the parties. Multi-investigator, multi-institutional projects are required. The project must be designed to accelerate the application of therapeutic agents or methods to the clinic (i.e., lead to patient involvement within the timeframe of the grant) and deliver near-term patient benefit through investigation by a collaborative SU2C Catalyst Genentech Team of expert investigators. The ideas should be based on perceived opportunities for success as well as high-priority areas with a critical need for rapid progress beyond current medical care. An emphasis on early phase, signal-finding clinical trials is encouraged. **Clinical trials must be planned so that the final patient is enrolled by the end of the grant term.** Note: If not provided with the original application, finalists invited to defend their proposal will have to provide a clinical trial protocol (in draft or final form) ahead of the Selection Meeting (see page 18 for more details).

**ELIGIBILITY CRITERIA**

**Definitions:**

- **Principal Investigator (Team Leader)** is employed at the Lead Institution and is the primary person responsible for the scientific and technical direction of the proposed research project, contractual and financial obligations, and other organizational assurances/certifications. The
Principal Investigator must ensure that the SU2C Catalyst Genentech Team complies with the terms and conditions of the award, and will be the primary contact person for AACR’s Scientific Review and Grants Administration (SRGA) Office. The Principal Investigator can be the Clinical Lead.

- **Lead Institution** is the organization at which the Principal Investigator is employed, and it will be legally and financially responsible for the conduct of SU2C Catalyst Genentech Team activities supported by the grant.

- **Clinical Lead** (Co-leader) is overseeing all phases and sites of the clinical trial(s). If the Principal Investigator is not the Clinical Lead, a Clinical Lead must be identified.

- **Investigators** are funded senior investigators who contribute substantively to the SU2C Catalyst research project and may be included as members of the SU2C Catalyst Genentech Team. Multi-investigator, multi-institutional projects are required.

- **Project Manager** is managing all administrative aspects of project and serves as contact for SU2C/AACR and all sites associated with the grant. They will be asked to fulfill important administrative responsibilities; e.g. facilitate communication within Team members, keep track of different reporting requirements, arrange collaborative Team meetings, etc. Each Team should include at least 1 Project Manager.

- **Advocates** will bring the perspectives of those affected by cancer (e.g., patients, survivors, caregivers) to the work of the SU2C Catalyst Genentech Team. They will enable the scientists to see their research through the eyes of the target audience and integrate these perspectives into the direction of the SU2C Catalyst research. Advocate members do not represent the viewpoints or issues of any advocacy organization or their individual personal issues. Each Team should include at least 2 Advocates.

- **Young Investigators** are 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., Principal Investigator, Clinical Lead or Investigator) may be included as members of the SU2C Catalyst Genentech Team. Although Young Investigators are not eligible to serve as a Principal Investigator, Clinical Lead or Investigators, their participation in Team research projects is encouraged.

- **Collaborators** are unfunded investigators who make valuable contributions to the SU2C Catalyst research project.

The Principal Investigator, Clinical Lead, Investigators, Project Manager, and Advocates are collectively referred to as **Catalyst Key Personnel**. The Principal Investigator, Clinical Lead and Investigators must have acquired a doctoral or medical degree, and must be independent investigators affiliated with an academic, medical, or research institution.
Catalyst Team Composition

Key Personnel:

| Principal Investigator | Clinical Lead* | Investigator(s) | Project Manager | Advocates (2) |

*If the Principal Investigator is not the Clinical Lead, a Clinical Lead must be identified

Additional Members:

- Young Investigators
- Collaborators

Applications are encouraged from the scientific community, including current and former SU2C grantees and non-SU2C affiliated scientists. Individuals on the FDA Debarment List may not apply.

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

Employees or subcontractors of for-profit industry are only eligible to apply as unfunded Collaborators.

Scientists from governmental agencies are eligible to apply, but no SU2C funds may be used, including salaries and supplies.

Members of the SU2C Catalyst Executive Committee are not eligible for funding as part of the SU2C Catalyst. Members of the SU2C Catalyst Genentech Steering Subcommittee are not eligible for an SU2C Catalyst Research Grant: Genentech-Supported Projects but may apply for other SU2C Catalyst funding opportunities.

Candidates with questions about the eligibility requirements are encouraged to contact the AACR’s SRGA Office at su2c@aacr.org prior to submitting the proposal.

EVALUATION OF PROPOSALS

The SU2C Catalyst Genentech Steering Subcommittee will review the proposals for the SU2C Catalyst Research Grants: Genentech Supported Projects. The Subcommittee consists of highly accomplished world class scientists, physician-scientists, and clinicians. The Steering Subcommittee Chair will be drawn from academia. Excluding the Chair, an equal number of Committee members will be drawn from academia and Genentech. All Steering Subcommittee members have relevant scientific expertise, and Genentech members are high-level individuals at Genentech with decision-making authority. The SU2C Catalyst Executive Committee will consider the SU2C Catalyst Genentech Steering Subcommittee recommendations for funding and make the final selection of SU2C Catalyst Genentech grantees.
The SU2C Catalyst Genentech Steering Subcommittee will consider the following criteria when evaluating the proposals:

- The proposal must be a non-duplicative research project;
- Scientific merit of the proposed research project and the clinical or translational nature of the research, i.e., plan for translating the work from the laboratory to the clinic to deliver near-term patient benefit (lead to patient involvement within the timeframe of the grant);
- Significance of the proposed research, i.e., whether it addresses a critical need for rapid progress beyond current medical care for cancer;
- Novelty of the hypothesis or methodology;
- Degree to which the studies will have a positive therapeutic impact on the detection or treatment of cancer;
- Principal Investigator’s leadership qualities, 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 translational cancer research with a clear emphasis on near-term clinical application;
- Willingness of the Key Personnel to collaborate, their research credentials, and their unique contributions to the SU2C Catalyst research project;
- Degree of collaboration among the SU2C Catalyst Genentech Team members;
- A clear commitment by the SU2C Catalyst Genentech Team that all data resulting from their work will be available to the scientific community at large at the earliest opportunity;
- Likelihood 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; and
- Whether adequate institutional and/or financial support exists to sustain the research project.

CONFIDENTIALITY OF THE APPLICATION REVIEW*

For purposes of the SU2C Catalyst Research Grants: Genentech-Supported Projects funding opportunity, “Confidential Information” shall mean any 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. By way of example, “Confidential Information” may include without limitation descriptions of proprietary assays, unpublished data, algorithms or analytical models. Notwithstanding the foregoing, however, “Confidential Information” shall not include ideas or information about a Genentech or Roche marketed or investigational pharmaceutical or diagnostic product, or about the class of products to which a Genentech or Roche product belongs. Further 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
the Recipient; (b) becomes available to the Recipient 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 the Recipient
immediately prior to the time of disclosure as shown by the Recipient’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 the Recipient who did not have access to the Confidential Information.

*For additional information, please see the Non-Disclosure Agreement attached as an Appendix at the end of these Guidelines (page 21).*

**GRANT TERMS**

**Contracts.** A Grant Agreement will be executed between the AACR and the Principal Investigator’s Institution (the Lead Institution). In addition, the Lead Institution will also need to directly enter into an agreement with Genentech for supply of the study drug(s), which include terms relating to intellectual property arising out of the study. 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 any necessary subcontracts with Institutions of other SU2C Catalyst Genentech 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. The Lead contract must be executed within ninety (90) days of receipt of the Lead Contract template by the Lead Institution. All subcontracts are required to be executed within ninety (90) days of receipt of the executed Lead Contract. Failure to comply to these deadlines may result in the rescinding of the award.

**Commencement.** The Principal Investigator must agree to commence the SU2C Catalyst research project described in the proposal on or about the time the first grant payment is received by the Lead Institution. If the Principal Investigator is unable to commence the SU2C Catalyst research project at that time, the AACR’s SRGA Office should be immediately notified. The AACR retains the right to terminate the grant if the research project is not commenced in a timely manner.

**Budget.** The available funds are expected to fund several projects. The final grant amount may vary depending on the number of projects selected. Applicants may apply for total support of up to $3 million over a 3-year term. A detailed budget for the overall project will be required. Separate budgets for expenses related to the research components conducted by the Principal Investigator, Clinical Lead and Investigators will also be required. Budget expenses must be justified. Teams are asked to allocate funding to the three years according to realistic expectations (e.g. the budget for the first year should be smaller than other years to account for time required for start up of the projects, regulatory approvals, etc.). All funding is contingent upon Milestones and Deliverables being appropriately selected, satisfactorily pursued and achieved, as determined by the AACR, the SU2C Catalyst Genentech Steering Subcommittee, and the SU2C Catalyst Executive Committee.
**Use of Funds.** The grant funds may be used for direct research expenses attributable to the proposed research, which may include:

- A percentage of the salary expenses (limited to 20 percent of the total budget) of Senior Investigators (including the Principal Investigator and Clinical Lead);
- Salary expenses for Project Manager;
- A percentage of salary expenses of the Young Investigators on the SU2C Catalyst Genentech Team;
- Salary expenses for research assistants or technicians;
- Supplies and other laboratory or clinical expenses;
- Travel expenses relevant to the SU2C Catalyst research project for the Principal Investigator and Key Personnel to attend Investigator meetings with the SU2C Catalyst Genentech Steering Subcommittee or Progress Review Team at an Investigator’s institution or the annual SU2C Scientific Summit; and
- Expenses related to publication page charges up to $1000 (one-time).

Salary benefits, equipment, tuition and professional membership dues are not allowable expenses. 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 SU2C Catalyst research project that are incurred by these individuals. Registration costs for scientific conferences are not allowable expenses.

Payments and other transfers of value to health care professionals (e.g., SU2C Catalyst Genentech Team members, data monitoring committee members, consultants, etc.) must comply with applicable laws, including but not limited to the Physician Payment Sunshine Act, also known as section 6002 of the Affordable Care Act (ACA) of 2010, state gift laws, and regulatory requirements, as reasonably required by the funders.

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. Indirect costs must be included in the total budget. For example, for a $1 million grant the indirect costs may not exceed $250,000 and the total budget may not exceed $1 million.

**Payments.** The Principal Investigator and 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. Quarterly installment payments will initiate within 3 months after the Grant Agreement has been signed and no earlier than the start date agreed upon by the Principal Investigator and AACR’s SRGA Office. Assurances that all contractual agreements have been negotiated and signed, as well as organizational assurances/certifications, will be required prior to receiving payments. The Principal Investigator and the Lead Institution acknowledge and accept that subsequent funding is contingent upon the timely submission of progress and financial reports that are reviewed and found to
be satisfactory by the AACR, SU2C, SU2C Catalyst Genentech Steering Subcommittee, and SU2C Catalyst Executive Committee.

**Patient Accrual.** The Principal Investigator and the Lead Institution will assist SU2C in efforts to quickly accrue patients to clinical trials funded by the grant. All SU2C Catalyst Genentech 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.** The semi-annual Progress Reports are a tool to ensure that the Principal Investigator and Team are meeting the pre-defined Milestones and Deliverables, and are on track to achieve the ambitious goals that this grant requires. Progress reports are to be submitted twice a year (typically June and December) and are intended to highlight the accomplishments of that specific reporting period. Progress Reports will be reviewed by the AACR, SU2C, Genentech, and a Progress Review Team established by the SU2C Catalyst Genentech Steering Subcommittee and approved by the SU2C Catalyst Executive Committee. More frequent reports, including clinical trial updates, may be requested by the SU2C Catalyst Committees and/or Progress Review Team. Once a clinical trial is open, Catalyst Teams will be asked to submit a Monthly Clinical Trial Report.

Information will be requested regarding payments and other transfers of value to health care professionals for purposes of compliance with reporting requirements under applicable laws (including but not limited to the Physician Payment Sunshine Act and state gift laws) and regulatory requirements, as reasonably required by the funders.

AACR may withhold release of any future Grant Funds until the reports have been filed and approved by AACR, SU2C, SU2C Catalyst Genentech Steering Subcommittee, and SU2C Catalyst Executive Committee. All funding is contingent upon Milestones and Deliverables being satisfactorily pursued and achieved, as determined by the AACR, SU2C, SU2C Catalyst Genentech Steering Subcommittee, and SU2C Catalyst Executive Committee. If the accomplishments have not met the standards of the 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 Principal Investigator. Failure to address deficiencies, meet grant requirements, or achieve the pre-defined Milestones and Deliverables may result in discontinuation of the grant.

SU2C Catalyst Genentech Teams must meet three times a year, either in person, by teleconference, or videoconference, to review progress and, if necessary, adjust research plans. These meetings will include all key personnel involved in the project as well as staff from the AACR’s SRGA Office as necessary. In addition, the Principal Investigator and Key Personnel are required to meet with the Progress Review Team and all other Team members at least once a year, following the submission of Progress Reports, to thoroughly discuss the Teams’ progress. One meeting will take place during the annual SU2C Scientific Summit held in late January; a second meeting will take place during the summer if necessary. These events will provide opportunities for Principal Investigators and other Key Personnel to engage in integrated team collaboration. Principal Investigators and other Key Personnel may also be asked to meet individually with the Progress Review Team.
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 progress and financial report
will be provided by the AACR’s SRGA Office prior to the report due date.

The AACR may provide copies of interim and 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 AACR or SU2C newsletter, on the
AACR or SU2C websites, or in other similar manners.

Publications and Acknowledgment of Support. During the term of the Grant or afterwards, any
publications resulting from research funded in whole or in part by the Grant must be cited as follows:
“Research supported by a Stand Up To Cancer– Genentech Catalyst Research Team (Grant Number:
SU2C-AACR-CTXX-XX). Stand Up To Cancer is a division of the Entertainment Industry Foundation.
Research grants are administered by the American Association for Cancer Research, the Scientific
Partner of SU2C.” In addition, whether during the term of the Grant or afterwards, the 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 all scientific publications and grant-related written material must
be forwarded to the Grants Office after acceptance but before publication. Embargoed material will be
held in confidence by AACR until published.

Insurance. Insurance shall be maintained by the Principal Investigator and SU2C Catalyst Genentech
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 the AACR, SU2C, or Genentech and shall provide appropriate waivers of subrogation against
the AACR, SU2C, Genentech, and its directors, committee members, employees, affiliates and agents.

Notification of Changes. It is the responsibility of the Principal Investigator to notify the AACR’s SRGA
Office immediately of any changes in the composition of the SU2C Catalyst Team, and changes in the
position or institution of any of the SU2C Catalyst Genentech Team members. The AACR may not accept
proposals to change the research project from that described in the application, and may terminate the
grant.

Organizational Assurances. It is the responsibility of the Principal Investigator and their Institution to
ensure that organizational assurances/certifications from all SU2C Catalyst Genentech Team Member
Institutions are obtained.

For research involving human subjects, the appropriate SU2C Catalyst Genentech 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 accredited university or medical school Institutional Review Board (IRB) constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services (HHS) and approved by HHS, or by the Association for the Accreditation of Human Research Protection Programs (in the absence of an HHS-approved university or medical school IRB).

b. The Principal Investigator and SU2C Catalyst Genentech 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 the AACR 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 certification should be documented by submitting a copy of the institutional letter of approval, which identifies the Principal Investigator or Key Personnel responsible for the relevant project component, SU2C Catalyst research project title, the AACR as the funding agency and date of approval, and is signed by the IRB Chair or equivalent responsible institutional official. Prior IRB certification for another project cannot be substituted, but can be officially amended to include the proposed project. Funds will NOT be released unless and until proof of all IRB certifications is received by the AACR.

c. The Principal Investigator, Clinical Lead, Investigator(s), 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.

d. The Principal Investigator and SU2C Catalyst Genentech 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 Genentech 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 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 Principal Investigator or Key Personnel responsible for the project, the SU2C Catalyst research project title, the AACR as the funding agency, 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**

The AACR requires applicants to submit an online application. Completed online applications should be submitted by **12:00 p.m. (noon) United States Eastern Time on Monday, October 22, 2018** using the proposalCENTRAL website at https://proposalcentral.altum.com. An e-mail will be sent to confirm your online submission.

The materials to be submitted, in the order listed and using the templates provided, are:
I. Signature Pages, with contact information and the original signatures of the Principal Investigator, Key Personnel, and Institutional Signing Officials. *Signatures must be in blue in and submitted in color*

II. Lay Abstract

III. Research Project Proposal

IV. Catalyst Budget

V. Budget Justification

VI. Biographical Information of Principal Investigator, Clinical Lead and Investigators (no template provided; provide NIH biosketch: https://grants.nih.gov/grants/forms/biosketch.htm)

VII. Letters from Collaborators (no template provided)

VIII. Organizational Assurances (no template provided)

IX. Project Milestones

X. Appendices:
   a. Investigator Initiated Study (IIS) Proposal Synopsis Form (REQUIRED)
   b. Additional Appendices, if applicable (see below, page 18)

GETTING STARTED IN proposalCENTRAL

If you are a new user of proposalCENTRAL, follow the “REGISTER” link and complete the registration process. After you register, complete your Professional Profile (green tab, second from the left) before starting an application.

If you are already registered with proposalCENTRAL, access the site and log in with your Username and Password. If you have forgotten your password, click on the “Forgot your password?” link. Supply your User ID or e-mail address in the space provided; your password will be sent to you by e-mail.

To start an application, select the “Grant Opportunities” tab (gray tab furthest to the right). A list of applications will be displayed. Find the “SU2C Catalyst Research Grant: Genentech-Supported Projects” and click the “Apply Now” link (second to last column) to create your application.

To access your application, select the “Manage Proposals” tab (blue tab first on the left). Below the “Manage Proposals” tab are several links; select the “In Progress” link. A list of all applications for which you have applied through proposalCENTRAL will appear. Find the program titled, “SU2C Catalyst Research Grant: Genentech Supported Projects”. Then in the “Edit” column (second column from the left), select the “Edit” link to access your application.

Complete all fields in the application and all templates that are provided. Upload all requested documents in portable document format (PDF). See the proposalCENTRAL FAQ section, https://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp, for more information.

If you have any difficulties registering, logging in, or creating your application, contact proposalCENTRAL Customer Support immediately:

      Phone: 1-800-875-2562 or (703) 964-5840       E-mail: pcsupport@altum.com
APPLICATION PROCEDURE

The following information is required to submit a complete application. Numbers correspond to the application sections found on the left side of the proposalCENTRAL website.

1. **TITLE PAGE.** Enter contact information directly into proposalCENTRAL system. The title it limited to no more than 75 characters in length (including spaces). Do not use abbreviations. A project title must be entered and saved before additional sections may be accessed.

2. **DOWNLOAD TEMPLATES & INSTRUCTIONS.** The Program Guidelines and all templates can be downloaded from this page. You must download the following documents: Signature Pages Template, Lay Abstract Template, Research Project Proposal Template, Budget Template, Budget Justification Template, Project Milestones Template, and the Investigator Initiated Study (IIS) New Proposal Application Form Template (Appendix I).

   - Click the ‘Download’ link to save templates to your computer.
   - Complete the templates and convert to PDF format. You do not need to be connected to the internet or proposalCENTRAL while working on the templates.
   - Upload the completed template files to your online application in the section for attaching files.

   See Section 8 below for instructions on how to complete and upload the templates.

3. **ENABLE OTHER USERS TO ACCESS THIS PROPOSAL.** Optional.

4. **APPLICANT/PRINCIPAL INVESTIGATOR.** Enter contact information directly into proposalCENTRAL system. Indicate the percent effort on this project.

5. **INSTITUTION & CONTACTS.** Enter information regarding the Lead Institution (Principal Investigator’s Institution) and signing official directly into proposalCENTRAL system.

6. **KEY PERSONNEL AND COLLABORATORS.** Enter directly into proposalCENTRAL system. See page 6 for Key Personnel definition. Collaborators are unfunded investigators who make valuable contributions to the SU2C Catalyst research project.

7. **ORGANIZATIONAL ASSURANCES.** The assurances/certifications are made and verified by the signature of the Institutional official signing the application. The AACR does not require the supporting letters with your application. However, if awarded, IRB and/or IACUC approval (if applicable) must be submitted in writing to the AACR’s SRGA Office.

8. **UPLOAD ATTACHMENTS.** Prepare and upload the following documents into your application in portable document format (PDF). Details are provided below.

   **IMPORTANT:** Please clearly identify any information in the application that is confidential in nature (see “Confidentiality of Application Review”, page 8). It is the responsibility of the applicant to clearly indicate if information that is being disclosed in the application is confidential.

   I. **Signature Pages and Contact Information**
   
   Complete all information on the form. *All signatures must be in blue ink and submitted in color electronically.*
Lead Institutional and other Key Personnel Institutions Certification. The Lead Institution is the organization at which the Principal Investigator is employed, and it will be legally and financially responsible for the conduct of activities supported by the grant. In signing the application, the Authorized Lead Institution or Key Personnel Institution Representative certifies that the Institution will comply with all applicable policies, assurances, and/or certifications referenced in the application. The Institution is responsible for the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application. The signer further certifies that the Institution will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or SU2C Catalyst Genentech Team activities resulting from this application. The Lead Institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

NOTE: It is recommended that the collaborating Institutions be provided with the program guidelines as soon as possible. Certification of the SU2C Catalyst application by each of the Key Personnel Institutions (i.e., signatures from the Institutions' Representatives) will be required at grant submission.

II. Lay Abstract of Research Proposal. This abstract, limited to 3,000 characters (including spaces), should provide a clear, concise overview of the proposed research. Include language suitable for a non-scientific audience. Describe relevance of the proposed work to the goals of Stand Up To Cancer. A scientific abstract must be included within the research project proposal.

III. Research Project Proposal. Applicants must adhere to the following formatting guidelines in completing this section.

- Must use 12 point Times New Roman for the text, and no smaller than 9-point type for figures, legends, and tables.
- Single-spaced text is acceptable, and space between paragraphs is recommended.
- The page margins must be no less than 0.75 inches on each side.
- Pages must be numbered consecutively; in the Proposal Narrative, do not use section designations such as "3A" or "3B."

Present the required information, using the template, in this order:

A. Contents page. Complete the Table of Contents by indicating the appropriate page numbers for each section; do not exceed one page.

B. Title of Research Project. The title should not exceed 75 characters in length (including spaces). Do not use abbreviations unless absolutely necessary.

C. Scientific Abstract. Limited to 3,000 characters (including spaces). Should provide a clear, concise description of the proposed work, including the background, objective, hypothesis and its supporting rationale; specific aims of the study; study design; and clinical impact and significance of the proposed work.
D. **Proposal Narrative.** Limited to three (3) pages, including figures and tables. References and appendices do not count against this page limit. Describe the proposed research project, including:

1. **Background and Rationale.**

2. **Specific Aims.** State the hypotheses being addressed and the corresponding objectives.

3. **Research Design and Methods.** State the type of experimental design (observational or interventional; crossover etc.); clinical dosage/dosage form, route, and dose regimen; collateral biomarkers, PK, etc.

4. **Statistical plan.** Include justification for clinical sample size and primary hypothesis testing.

5. **Projected Timeline and Milestones.** Provide a sequence or timetable for the project and identify the milestones by which the success of the proposed research could be measured.

6. **Significance and Therapeutic Impact.** If the specific aims are achieved, state how clinical practice will be advanced.

7. **Collaboration.** Describe the value-added activities of the team/unique benefits afforded by the collaboration of SU2C Catalyst Genentech Team members and, as appropriate, the plan for coordinating the research across the performance sites.

**NOTE:** More details on the proposed research will be requested for applications selected for SU2C Catalyst Research Grant: Genentech-Supported Project funding.

E. **Facilities.** Limited to one (1) page per institution. Please provide a description of the research facilities, equipment and other resources available for this project.

F. **References cited in the Proposal Narrative.** There is no page limit for References.

G. **Other Support.** Provide details of any current funding or funding applications in progress to support any component/subproject of the proposed research project.

IV. **Budget.** Applicants may apply for total support of up to $3 million over a 3-year term. Provide budgets for the overall project, as well as separate budgets for expenses related to the research components/subprojects conducted by the Principal Investigator, Clinical Lead/Co-leader and Investigators. Indicate expenses directly attributable to the proposed research. These expenses include salary, supplies, certain travel related to the research project, and expenses related to publication of the research. 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 the Institution but will not exceed 25 percent of the total budget. Indirect costs are included in the total budget. See “Grant Terms, Use of Funds” on page 7 for further details.

V. **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 Principal Investigator, Clinical Lead and Investigators. Provide the names of individuals whose salaries will be supported by the grant funds and justify the amount of support requested.

VI. Biographical Information of the Principal Investigator, Clinical Lead and Investigators. Upload your NIH Biosketch (only required for Principal Investigator, Clinical Lead and Investigators). No template is provided. (The NIH biosketch template is available for download at http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx). Do not exceed five (5) pages per individual.

VII. Organizational Assurances. The assurances/certifications are made and verified by the signature of the Institutional Official signing the application. Signatures from official representatives of each of the Principal Investigator and Key Personnel Institutions certifying the SU2C Catalyst Research Grant application will be required at time of submission. It is the responsibility of the Principal Investigator and Lead Institution to ensure that organizational assurances/certifications from all Key Personnel Institutions are obtained. Proof of organizational assurances/certifications from all collaborating Institutions must be received before payments will be released. In addition, letters of endorsement from the Dean, Department Head, or Director of all institutions represented by the SU2C Catalyst Genentech Team members, certifying contents of application package, written in English, may be required prior to payment.

VIII. Letters from Collaborators. Should confirm the scope of the Collaborators’ involvement in the proposed research.

IX. Project Milestones. The milestones will be used to define a timeline for the research activities that you propose to accomplish over the duration of your project. Reporting progress towards milestones will be incorporated into the semi-annual reporting requirements for the project if funded. When filling out the Project Milestones Excel document, place an “X” in every cell corresponding to the month(s) of the grant term in which you are planning to work on this milestone.

X. Appendices.
- The Investigator Initiated Study (IIS) New Proposal Application Form (“X_Genentech IIS Proposal Synopsis Form”) is a required appendix (template provided).
- Please note that the Principal Investigator’s Curriculum Vitae and evidence of qualification (as noted in the aforementioned appendix) are not required materials to be submitted with the proposal, but invited finalists will be asked to submit these documents at a later date.
- Additional appendices, such as preliminary data from a clinical trial or summaries of clinical trial protocols may be included. If not provided with the original application, a clinical trial protocol (in draft or final form) will be requested for the finalists invited to defend their proposal during the Selection Meeting.
- Figures, tables, and other references to information contained within the Proposal Narrative are not allowed. Publications are not allowed. References to publications must be made in the Proposal Narrative. The appendix may not be used to circumvent the three-page limit for the Research Narrative.
**Uploading the attachments into your application**

Once you have converted your attachment to PDF files, the next step is to upload the files to your online application:

- Make certain that the converted PDF files are closed on your computer;
- Open your application and go to the section for attaching files;
- Enter your own description of the file in the “Describe Attachment” field;
- Select the appropriate type of attachment from the drop-down list. *NOTE: After selecting attachment type, the screen will show the allowable file types (e.g., PDF, .doc) that are allowed for that type of attachment*;
- Click on the “Browse” button to select the file from your computer;
  - A ‘choose file’ dialog box opens for you to search for the template file on your computer’s hard disk or local area network.
  - Select the file and click “Open.”
  - The file location and name will display in the window adjacent to the Browse button.
- Click on the “Upload Attachment” button. You will get a confirmation message on your screen that the file was uploaded successfully. You will also see that your file is now listed in the Uploaded Attachment section of the screen. Two links are available in each row of an uploaded attachment: DEL and SHOW. “Del” allows you to delete the file, if necessary, and “Show” opens the uploaded file. **It is strongly recommended that you open and review your uploaded file.**

If, for any reason, you wish to modify the attached file, make the revisions to your *original* file on your computer (off-line), convert the file to PDF and use the same process above to attach the newly revised file. **Delete any previously submitted versions of the file before submitting your application.**

**SUBMITTING COMPLETE APPLICATION**

1. **PI DATA SHEET.** This is an automatically populated data sheet based on applicant’s proposalCENTRAL profile. Information for gender, race, and ethnicity must be provided to the AACR. If fields are not populated, go to Section 4, Applicant, and select the “Edit Professional Profile” tab in the center of the screen. The Applicant must then go to the column on the left-hand side of the screen, select “4) Personal Data for Application,” and enter his or her race, gender, and ethnicity. This information is for demographic purposes only. The SU2C Catalyst Genentech Steering Subcommittee and SU2C Catalyst Executive Committee do not receive this information.

2. **VALIDATE.** Validate the application on proposalCENTRAL. This is an essential step. An application that has not been validated cannot be submitted. ‘Validate’ checks for required data and required attachments. You will not be able to submit if all the required data and attachments have not been provided.

3. **SUBMIT.** After the application has been validated the application must be submitted. The submit button will only appear after the document has been validated. Click the “SUBMIT” button.

**IMPORTANT:** A confirmation email will be sent once the proposal is submitted. If you do not receive this email and believe that you have submitted your proposal you should immediately contact proposalCENTRAL. It is the *responsibility of the applicant* to ensure the application was completed correctly, all required information is present, and that the proposal was officially submitted through proposalCENTRAL.
CHANGES TO THE APPLICATION

Withdrawal of application: The Principal Investigator should advise the AACR’s SRGA Office promptly, in writing, should he/she decide to withdraw the application for any reason. The letter (or e-mail) should include the Principal Investigator’s name, the title of the proposal, and the reason for withdrawal.

Change of address: Notify the AACR’s SRGA Office in writing of any changes of address, e-mail or phone number for any SU2C Catalyst Genentech Team member, following the submission of an application. Include your name and the proposal title.

Change of institution: If any SU2C Catalyst Genentech Team member changes institution, the Principal Investigator should contact the AACR’s SRGA Office to determine whether your application can be reviewed.

INQUIRIES

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to the AACR’s SRGA Office at:

Phone: (215) 446-7242
E-mail: su2c@aacr.org
PHARMACEUTICAL COMPANY SPONSOR AND COMMITTEE MEMBER
CONFIDENTIALITY AND NON-DISCLOSE AGREEMENT

This CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT is made as of this ____ day of _________________, 2018, by and among THE AMERICAN ASSOCIATION FOR CANCER RESEARCH (“AACR”); _________________________ (the “Company”), a pharmaceutical company sponsoring cancer research as part of the Stand Up To Cancer Catalyst® (“SU2C Catalyst”); and _________________________ (“Company Employee”), an employee of the Company. (Company and Company Employee may hereafter be referred to as a “Recipient” or “Recipients”).

WHEREAS, Stand Up To Cancer (“SU2C”) is a division of the Entertainment Industry Foundation (EIF) engaged in funding cancer research projects administered by AACR as the scientific partner to SU2C;

WHEREAS, the SU2C Catalyst brings together funding sources from the private sector, including pharmaceutical companies such as the Company, for sponsorship of selected cancer research projects;

WHEREAS, AACR on behalf of SU2C will solicit applications from individual researchers and research institutions (“Applicants”) for research grants to be awarded through the SU2C Catalyst program to individuals or institutions selected (“Grantees”), through a process administered by AACR;

WHEREAS, the administrative structure of the SU2C Catalyst involves committee membership of employees of the Company on particular projects funded by the Company, including on committees reviewing applications that may not be selected to receive funding from the Company; and
WHEREAS, Applicants may only be willing to disclose research project proposals and participate in funded projects if the information disclosed in the proposals and projects is protected by the terms and provisions of this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and intending to be legally bound hereby, the Parties agree as follows:

1. **Confidential Information.** For purposes of this Agreement, “Confidential Information” shall mean any 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. By way of example, “Confidential Information” may include without limitation descriptions of proprietary assays, unpublished data, algorithms or analytical models. Notwithstanding the foregoing, however, “Confidential Information” shall not include ideas or information about a Genentech or Roche marketed or investigational pharmaceutical or diagnostic product, or about the class of products to which a Genentech or Roche product belongs. Further 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 the Recipient; (b) becomes available to the Recipient 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 the Recipient immediately prior to the time of disclosure as shown by the Recipient’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 the Recipient who did not have access to the Confidential Information.

2. **Non-Disclosure of Applicant Confidential Information.** Company Employee agrees that each Applicant’s Confidential Information will be kept confidential and will not, without the prior written consent of the Applicant, be disclosed by the Company Employee to Company or any other of Company’s employees, agents or representatives, including, without limitation, attorneys, accountants, consultants and financial advisors (collectively, “Representatives”), in any manner whatsoever, in whole or in part, and will not be used by the Company Employee, directly or indirectly, for any purpose other than in
connection with the review of applications for funding under the SU2C Catalyst. Company agrees and accepts as a condition of its employees’ participation in any committee of the SU2C Catalyst that Company Employee will not disclose any Applicant’s Confidential Information to Company or Company Representatives, provided that this Paragraph 2 shall not apply to Applicant Confidential Information if the Applicant is selected as a Grantee and accepts research funding from the Company, in which case the provisions of Paragraph 3 below shall apply. Company Employee agrees to return or destroy all Applicant Confidential Information of Applicants who do not become Grantees within ten (10) business days of the selection of the Grantees.

3. **Non-Disclosure of Grantee Confidential Information.** Recipients’ obligations with regard to Grantee Confidential Information, if any, will be covered in the agreement between Recipients and Grantee for the provision of drug.

4. **Disclosure of Confidential Information Required by Law.** If Company Employee, the Company or any of its Representatives (a “Disclosing Party”) is requested or becomes legally compelled (by oral questions, interrogatories, requests for information or documents, subpoena, criminal or civil investigative demands or similar processes) to disclose any Applicant Confidential Information, the Disclosing Party will provide the Applicant with prompt notice so that the Applicant may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement, and the Disclosing Party shall cooperate with the Applicant in any reasonable effort undertaken to obtain a protective order or other remedy. In the event that such protective order or other remedy is not obtained, or that the Applicant waives compliance with the provisions of this Agreement, the Disclosing Party will furnish only that portion of the Confidential Information which it believes in good faith is legally required and will exercise its best efforts to obtain reliable assurances that confidential treatment will be accorded any such Confidential Information so disclosed.

5. **Records; Return of Materials.** The Recipients shall keep secure any documents or other materials containing Applicant Confidential Information in connection with the SU2C Catalyst. Such material shall be promptly returned by the Recipient to AACR or the Applicant or, at the option of the
Recipients, destroyed, together with all copies of and notes or other summaries relating to such materials or documents, within ten (10) days after notice from AACR that the project has ended.

6. **Miscellaneous.** This Agreement shall be binding upon and for the benefit of the AACR and the Recipients, and their respective heirs, executors, administrators, successors and assigns; provided that the right to receive Confidential Information may not be assigned without the prior written consent of AACR. Failure to enforce any provision of this Agreement by AACR shall not constitute a waiver of any term hereof.

7. **Remedies.** The Recipients agree that their obligations provided herein are necessary and reasonable in order to protect Applicants’ Confidential Information, and the Recipients expressly agree that monetary damages may in some cases be inadequate to compensate the Applicant for any breach of the covenants and agreements set forth herein. Accordingly, the Recipients agree and acknowledge that any such violation or threatened violation may in some cases cause irreparable injury to the Applicant and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Applicant, or the AACR on their behalf, shall be entitled to seek injunctive relief against the threatened breach of this Agreement or the continuation of any such breach by the Recipients.

8. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument.

(SIGNATURE PAGE FOLLOWS)
IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the day and year first above written.

AMERICAN ASSOCIATION FOR CANCER RESEARCH

By:________________________________________
Name:_____________________________________
Title:_______________________________________

COMPANY

___________________________________________
By:_______________________________________
Name:_____________________________________
Title:_______________________________________

COMPANY EMPLOYEE

Witness:_____________________________________
Name:_____________________________________
Title:_______________________________________

Name:_____________________________________
Title:_______________________________________