Technology Development Program

Special Therapeutics Projects Funding Opportunity

Request for Applications • January 2016

Timeline

- Award notices – April 2016.

This RFA and appendices are available for download at www.ncai-cc.ccf.org.

Note: Federal funding under the program must be matched with funding from the home institution.

For information Contact:

Email: NCAI-CC@ccf.org
Telephone: 216-444-5322

Table of Contents

1. NIH Center for Accelerated Innovations
   1.1 Purpose
   1.2 Center Organization and Goals

2. General Program Description
   2.1 General Evaluation Criteria

3. Special Therapeutics Projects Funding Opportunity
   3.1 Description
   3.2 Eligibility
   3.3 Funding Available
   3.4 Program Process
     3.4.1 RFA Release
     3.4.2 Application Preparation, Submission and Review
     3.4.3 Award Implementation
     3.4.4 Project Execution and Management
     3.4.5 Reporting Requirements

4. Application Requirements
   4.1 General Instructions
   4.2 Application Contents
     4.2.1 Application Information Form
     4.2.2 Project Title and Description
     4.2.3 Translational Opportunity and Background
     4.2.4 Preliminary Data
     4.2.5 Project Plan
     4.2.6 Project Team/Resources
     4.2.7 Budget
     4.2.8 References

5. Forms
   A. Application Information Form
   B. Budget Form
1. NIH Center for Accelerated Innovations

1.1. Purpose

The National Institutes of Health has launched a major initiative to improve how basic science discoveries and new technologies are translated into commercially viable products that improve patient care and advance public health.

The NIH Centers for Accelerated Innovations (NCAI) program, funded by NIH’s National Heart, Lung, and Blood Institute (NHLBI), targets technologies to improve the preventions, diagnosis, treatment, and management of heart, lung, blood, and sleep disorders and diseases.

According to NHLBI’s Fact Book for the 2012 fiscal year, the estimated economic cost for cardiovascular, lung, and blood diseases was $424 billion—23 percent of the total economic costs of illness, injuries, and death in the United States. In addition, cardiovascular and lung diseases accounted for three of the four leading causes of death in the United States and four of the 10 leading causes of infant death.

NCAIs will provide an integrated, systematic, and comprehensive approach to navigating the translation of early stage biomedical innovations from the research laboratory to commercial development and successful deployment to patients. Three inaugural NCAIs have been established, including the NCAI-Cleveland Clinic.

1.2. Center Organization and Goals

The NCAI led by Cleveland Clinic (NCAI-CC) is a multi-institutional consortium of leading Ohio clinical and academic institutions including Case Western Reserve University, The Ohio State University, the University of Cincinnati, and Cincinnati Children’s Hospital Medical Center. The Center was established in 2013 with $10.2 million in grant funding from NHLBI, complemented with a $1.5 million grant from the Ohio Third Frontier, and $2.5 million in federal supplements. In addition, each participating institution has committed matching funds to each project selected for funding from that institution.

The goals for the NCAI-CC program are:

- To advance development of commercially-promising projects related to the prevention, diagnosis, treatment and management of cardiovascular, lung, blood and sleep disorders and diseases, involving projects which span the technology range of diagnostics, devices, therapeutics and tools.

- To select, fund, and guide projects through a process of rigorous peer-review, emphasis on commercialization criteria in project planning, and milestone-driven project management.

- To organize new and existing resources into a broadly accessible community for educating and mentoring researchers, clinicians and developers in the processes of biomedical innovation, entrepreneurism, and commercialization.

2. General Program Description

The NCAI-CC Technology Development Program is targeted to assist the validation and advancement of early stage technologies to establish commercial product potential.

The program operates under a periodic Request for Applications (RFA) basis to solicit projects from NCAI-CC partner institutions for funding and project support. Funds under the program are allocated to specific, measurable project development activities that are key to establishing commercial opportunity. Project scope typically encompasses work which leads to achieving critical project milestones, and which serve to enable follow-on funding from later stage investment sources such as other federal programs (e.g., SMARTT, SBIR/STTR), other state programs (e.g. Ohio Third Frontier, Global Cardiovascular Innovation Center), venture capital or industry.
NCAI-CC has formed an independent External Selection Committee (ESC) comprised of prominent clinicians and scientists in cardiovascular and pulmonary medicine, industry representatives, business development experts, and members of the venture capital community. The ESC provides technical and commercial evaluation and guidance to the selection of projects for funding.

NCAI-CC staff includes industry-experienced project managers and developers who will work closely with each selected project to provide commercial assessment, project guidance and access to resources to help in project planning and successful achievement of project milestones.

2.1. General Evaluation Criteria

Applications will be evaluated based on the following general criteria:

Fit with NHLBI mission, domain and NCAI program.

Projects directed towards development of products in clinical application areas directly related to cardiovascular, lung, blood or sleep disorders.

A. Commercialization Focus and Opportunity

- Clinical significance
- Market opportunity
- Commercial value proposition
- Innovation and novelty
- Competitive advantage
- Intellectual property protection
- Regulatory pathway
- Third party reimbursement

B. Project Plan

- Project definition
- Specific project goals and milestones
- Research and development to-date
- Development timeline
- Development cost and strategy for follow-on funding
- Budget
- Project team

3. Special Therapeutics Projects Funding Opportunity

3.1. Description

The goal of this special funding opportunity is to identify, select, and advance qualified early stage drug development projects that are directed towards treatment or management of cardiovascular, pulmonary, blood or sleep-related disorders.

This funding opportunity is specifically targeted and limited to therapeutics technologies (drugs/biologics).

The project activity appropriate for this funding opportunity is identification and qualification of a lead compound from among a series or class of hit compounds that have been tested for activity in one or more validation assays for the disease, which appear to be chemically stable and able to be synthesized, and for which a composition of matter (new chemical entity) patent filing is appropriate.

The scope of work for the project may include activities such as:

- Design or synthesis of new analogs to support structure activity relationship testing.
- Demonstrating specific selectivity against targets.
- Determining in vitro Absorption, Metabolism, Distribution, Excretion, Toxicity, (ADMET) properties for select analogs in the series.
- Conducting preliminary pharmacokinetic or pharmacodynamic (PK/PD) assessment.

Scope of work that would be considered too early for the project would include high throughput screening or assay development.

The key outcome is to select a lead compound (or at most a few compounds) that are ready to enter the lead optimization phase of drug discovery.

Upon successful completion of work under this project level, it is expected that the technology can qualify for additional technology development funding.
3.2. Eligibility

Applications are accepted from investigators at NCAI-CC partner institutions Cleveland Clinic, Case Western Reserve University, The Ohio State University, the University of Cincinnati, and Cincinnati Children's Hospital Medical Center.

To assure eligibility for this special funding opportunity, we require that investigators contact the NCAI-CC program office to arrange a discussion about the contemplated project with one of our project directors. Please send a request via email to NCAICC@CCF.ORG.

Applications submitted should be for projects directed towards achievement of critical development milestones with the objective of advancing the technology towards commercialization. Use of NCAI funds should be directly allocated to specific, measurable project activities, key to advancing commercial opportunity, and on a project timeline covering a period of six months.

3.3. Funding Available

Awards for this special funding opportunity will be in the form of a grant. A total of up to $50,000 may be awarded, comprised of up to $25,000 in federal funds from the NCAI program plus required matching funds from the home institution in a ratio of $1 to $1.

Distribution of funds will be authorized on a phased basis dependent on achievement of pre-defined project milestones.

3.4. Program Process

3.4.1. RFA Release

This is a special Request for Applications (RFA) under the Technology Development Program.

See cover page of this document for specific dates pertaining to the funding opportunity.

This RFA is publically available for download at www.ncai-cc.ccf.org.

3.4.2. Application Preparation, Submission and Review

Applicants are strongly urged to engage with their local technology transfer/commercialization office, NCAI site representatives and NCAI staff during development of the application.

Upon submission, applications are subject to an initial review during which compliance with the eligibility criteria and requirements of this RFA will be assessed. Applications found not to meet RFA requirements may not be reviewed further.

Applications will be reviewed by NCAI-CC and partner institution personnel and by an External Selection Committee (ESC). The process may include making an oral presentation to or having discussions with the selection committee.

3.4.3. Award Implementation

Upon successful review of an application, members of the NCAI program office will set up a pre-award meeting with the applicant to review particulars of the application, project plan, budget, funding process, and reporting requirements. Upon mutual agreement of the plan and program requirements, a Notice of Award will be issued.

Funding awards will be provided 50% from NCAI funds and 50% from institutional cost share provided by the home institution. Award management will be conducted under terms of a subgrant agreement in the case of funding awards to partner institutions, or a letter of commitment in the case of awards made to Cleveland Clinic investigators. In either case, the agreement will specify terms of funds distribution, providing of cost share, and methods for funds disbursement.

A documentation packet consisting of instructions, forms and agreement guidelines will accompany notice of an award.

3.4.4. Project Execution and Management

Experienced NCAI-CC project managers will collaborate with investigators to develop milestone driven, commercially relevant project plans, and will engage throughout the project to provide guidance and support to the project as needed. Progress will be reviewed and managed using commercial project management processes and methodologies (e.g. phase gate process) to facilitate and accelerate achievement of project milestones. Invoices will be required to document appropriate expenditure of funds. Continued funding of projects will be based on demonstrated progress and successful achievement of the defined project milestones.
3.4.5. Reporting Requirements

Progress updates will be required on an ongoing basis during and after the project period to facilitate tracking technology development. Upon completion of the project period, submission of a final report will be required.

All updates and reports will be submitted in the form and format required by NCAI.

After completion of the NCAI-funded project activities, awardees will be requested to provide follow-on status reports in order to facilitate measurement of continued project development and progress towards commercialization endpoints.

4. Application Requirements

4.1. General Instructions

- Applications must be received by NCAI-CC by the appropriate dates and times indicated on the cover page of this RFA.
- Margins must not be less than 0.75 inches on all sides.
- Font must be Arial, Helvetica, Palatino Linotype, or Georgia typeface, 11 points or larger, black.
- All pages must be numbered. The institution name and project title must appear in the footer of each page.
- The contents shall include and follow the order they are presented in Section 4.2 of this RFA. The Application Information Form shall be the application cover page.
- Only electronic submissions will be accepted. The application will be submitted via upload to the NCAI-CC website. An upload link will be enabled on the NCAI-CC website Funding Page approximately 2 weeks prior to the application submission deadline.

4.2. Application Contents

Applications must include the following contents:

- Application Information Form
- Project Title and Description
- Translational Opportunity and Background
- Preliminary Data
- Project Plan
- Project Team/Resources
  - PI Biosketch
- Budget
  - Budget Form(s)
  - Budget Justification Narrative
- References

4.2.1. Application Information Form

The Application Information Form is the cover page for the application and includes the project title, institution information, budget request, project description, project categories, and basic contact information. A copy of the form is appended to his document for reference. Forms for incorporation into the submission are available on the website.

4.2.2. Project Title and Description

Provide a short (no longer than 10 words) title for the project and a clear, concise one paragraph summary of the purpose, proposed development activity, and goals to be achieved.

4.2.3. Translational Opportunity & Background

(Limit 1 page)

What is the unmet clinical need in the diagnosis, treatment or management of the disease being targeted? What are the current and competing therapies available for the disease?

Describe the therapeutic solution you are proposing to address the potential unmet clinical need? What are the expected benefits? Why is the solution better than current therapies/standard of care? OR what are the differentiating factors of the proposed solution?

4.2.4. Preliminary Data

(Limit 2 pages)

Provide a summary of the preceding work and preliminary data (e.g., target validation and lead identification) that establish the basis and rationale for the proposed next stage of work to be conducted.
4.2.5. **Project Plan** (Limit 2 pages)

List 1 or 2 project goals and outcomes that will be accomplished at the end of the grant period that will help to make a go/no-go decision for the project to move forward for continued development.

Describe a project plan and steps for each of the project goals that are necessary to generate the outcomes described above within the scope of the project funding and six month project period. Identify milestones and go no/go decision points.

4.2.6. **Project Team/Resources** (Limit 1 page)

List the project team members and any service providers/companies to be involved with the project. Describe their pertinent experience and skills.

Insert an abridged NIH biosketch for the Principal Investigator. Include prior experience in product development and commercialization activities. (Limit 4 pages).

4.2.7. **Budget**

Budget forms shall be used to present the total budget plan for the proposed project, including both federal and matching funds sources.

Include direct costs only and only for costs directly applicable to achieving the project plan objectives. Upon award, indirect costs (F&A) will be added at the institution’s federally approved rate to supplement the amount of federal direct costs awarded.

Please include one budget form for the total project and one form for each major project milestone detailed in the project plan. A copy of the form is appended to his document for reference. Forms for incorporation into the submission are available on the website.

A budget justification narrative (limit 2 pages) must also be included to provide a detailed explanation of the overall budget by category and milestones.

4.2.8. **References** (Limit 1 page)

Insert pertinent references, citations here.

5. **Forms**

Copies of the Application Information Form and Budget Forms follow for reference. Forms that may be filled out and incorporated into the application are available from the website.
# TECHNOLOGY DEVELOPMENT PROGRAM
**SPECIAL THERAPEUTICS PROJECTS FUNDING OPPORTUNITY**

**APPLICATION INFORMATION FORM**

<table>
<thead>
<tr>
<th><strong>Project Title</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Institution/Department</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Address</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>City</strong></th>
<th><strong>State</strong></th>
<th><strong>Zip Code</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Total Project Budget</strong></th>
<th><strong>NCAI Funds Request (not to exceed ½ total budget)</strong></th>
<th><strong>Institutional Cost Match</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Project Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Resubmission?</strong></th>
<th>Yes _______ No _________</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Disease Space</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular, Lung, Blood, Sleep Disorder, Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Technology Category (Select one)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Molecule Drug, Biologic Drug/Therapy, Other Therapeutic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Primary Investigator</strong></th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Title</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
</tr>
<tr>
<td></td>
<td>Email</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Grants Office Contact</strong></th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Title</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
</tr>
<tr>
<td></td>
<td>Email</td>
</tr>
</tbody>
</table>
# DETAILED BUDGET FOR INITIAL BUDGET PERIOD

**DIRECT COSTS ONLY**

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE ON PROJECT</th>
<th>Cal. Mths</th>
<th>Acad. Mths</th>
<th>Summer Mths</th>
<th>INST BASE SALARY</th>
<th>SALARY REQUESTED</th>
<th>FRINGE BENEFITS</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD/PI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SUBTOTALS**

<table>
<thead>
<tr>
<th>CONSULTANT COSTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EQUIPMENT (Itemize)</td>
<td></td>
</tr>
<tr>
<td>SUPPLIES (Itemize by category)</td>
<td></td>
</tr>
<tr>
<td>TRAVEL</td>
<td></td>
</tr>
<tr>
<td>INPATIENT CARE COSTS</td>
<td></td>
</tr>
<tr>
<td>OUTPATIENT CARE COSTS</td>
<td></td>
</tr>
<tr>
<td>ALTERATIONS AND RENOVATIONS (Itemize by category)</td>
<td></td>
</tr>
<tr>
<td>OTHER EXPENSES (Itemize by category)</td>
<td></td>
</tr>
</tbody>
</table>

**CONSORTIUM/CONTRACTUAL COSTS**

| DIRECT COSTS |   |

**SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** (Item 7a, Face Page) $  

<table>
<thead>
<tr>
<th>CONSORTIUM/CONTRACTUAL COSTS</th>
<th>FACILITIES AND ADMINISTRATIVE COSTS</th>
</tr>
</thead>
</table>

**TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD** $