

TECHNOLOGY DEVELOPMENT PROGRAM

REQUEST FOR APPLICATIONS ■ JULY 2015

TIMELINE

- Request For Applications Released – July 22, 2015.
- Letters of Intent Due – August 19, 2015.
- Selected LOI Submissions Invited to Submit Applications – September 9, 2015.
- Full Project Applications Due – October 21, 2015.
- Award Notices – January 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.

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TECHNOLOGY DEVELOPMENT PROGRAM

REQUEST FOR APPLICATIONS ■ JULY 2015

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 \$11 million in grant funding from NHLBI, complemented with a \$1.5 million grant from the Ohio Third Frontier. 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:

1. 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.
2. 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.
3. 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, entrepreneurship, and commercialization.

2. Program Description

2.1. Overview

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 that can be accomplished within a period of approximately one year, 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 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.

2.2. Eligibility

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

The NCAI technology development program encompasses and seeks a broad portfolio of NHLBI-related projects directed to the prevention, diagnosis, and treatment of cardiovascular, lung, blood, and sleep disorders and diseases spanning the technology range of diagnostics, devices, therapeutics, and tools.

Please contact NCAI-CC for clarification if you are unsure if your project falls within the NCAI domain.

Proposals 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 establishing commercial opportunity and on a timeline covering a period of approximately one year from grant of the award.

Note: for therapeutics development projects, having a lead compound identified and initial indication of efficacy in-vivo is strongly recommended in order for the project to be considered at an appropriate stage for program funding. If there is question regarding project stage or readiness, please contact program personnel.

2.3. General Evaluation Criteria

Proposals will be evaluated based on the following general criteria:

- A. Fit with NHLBI mission, domain and NCAI program.
 - Projects directed towards development of diagnostics, devices, therapeutics or tools in clinical application areas directly related to cardiovascular, lung, blood or sleep disorders.
- B. Commercialization Focus and Opportunity
 - Clinical significance
 - Market opportunity
 - Commercial value proposition
 - Innovation and novelty
 - Competitive advantage
 - Intellectual property protection
 - Regulatory pathway
 - Third party reimbursement
- C. Project Plan
 - Project definition
 - Specific project goals and milestones for which award funding will be used
 - Research and development to-date
 - Development timeline
 - Development cost and strategy for follow-on funding
 - Budget
 - Project team

More detailed technology review criteria are provided in Section 4.

2.4. Awards

Funding awards will be in the form of a grant. A total of up to \$150,000 may be awarded, comprised of up to \$75,000 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.

2.5. Engagement and Reporting Requirements

Involvement of the institution's Technology Transfer Office is highly encouraged.

NCAI project managers will be assigned to work with awardees to assist in planning and guiding project objectives, milestones, and progress. The project managers will engage in regular and frequent project reviews with awardees. Project funding is contingent on achieving progress towards meeting stated project milestones. Invoices will be required to document appropriate expenditure of funds.

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

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

3. Program Process

The program process consists of the following steps:

1. Release of RFA.
2. Letter of Intent submission.
3. Initial review, applicant selection, invitation to submit full proposal.
4. Full application submission and review.
5. Funding decision and award implementation.
6. Project execution and management.
7. Follow-on progress reports.

3.1. RFA Release

Requests for Applications (RFA) under the Technology Development Program are issued twice per year and communicated broadly among the Center's partner institutions.

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

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

3.2. Letter of Intent

The Letter of Intent (LOI) shall include the following contents, submitted in single combined unlocked PDF file. See the NCAI website Funding page for submission instructions.

Letter of Intent Information Page. Download from the NCAI Website Funding Page.

Project Description. Narrative including the following sections and content. Limit 2 pages in total.

A. Project Definition. Provide a clear and succinct definition of the proposed product/solution incorporating one selection each from the lists of product categories, purposes, and clinical application categories below.

- Product category
 - diagnostic assay
 - biomarker
 - diagnostic system
 - device
 - small molecule drug
 - biology drug/therapy
 - therapeutic
 - combination product
 - monitoring product/system
 - healthcare information/mHealth product
- Purpose
 - prevention
 - diagnosis
 - treatment
 - monitoring
 - management
- Clinical application category
 - cardiovascular
 - pulmonary
 - blood (non-cancer)
 - sleep disorder

B. Unmet Need and Market Opportunity. Describe the significant unmet need and market opportunity to be addressed. Describe the specific patient population or market segment including the target market size in terms of numbers of patients and/or procedures, both in the U.S. and worldwide. Describe how the product/solution will provide measurable and meaningful advantages and benefits in the area of speed, size, cost-saving, ease of use, safety, efficacy, accuracy or combination of areas.

Letter of Intent, cont.

C. Project Background. Describe the scientific rationale for the project and approach. Summarize research and development conducted to-date leading to readiness for commercially-directed project activities.

D. Project Plan and Milestones. Describe the project plan and goals, including specific milestones to be achieved within a period of approximately one year and with the budget to be requested. Describe how successful completion of the project will advance the technology towards commercialization (e.g., licensing, investment, or value inflection point, such as lead compound development or prototype generation).

References and Biosketches. In addition, include a list of references or citations (not to exceed one page), plus abridged NIH biosketches for the Principal Investigator plus up to two (2) co-investigators/ collaborators. Include prior experience in product development and commercialization activities. Limit 4 pages per biosketch.

3.3. Initial Review

NCAI-CC personnel and partner institution representatives will review the submitted LOIs to evaluate fit for the NCAI-CC Technology Development Program funding opportunity, including cardiovascular, lung, blood and sleep disorders domain, phase of development, project goals and feasibility, clinical need or opportunity to be addressed, and potential for commercial success.

Selected projects will then be invited to submit a full application for the next phase of evaluation. Only invited applications will be considered for further evaluation.

3.4. Full Application 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 full application.

Upon submission, applications are subject to an initial review during which compliance with the criteria and requirements of this RFA will be assessed.

Proposals 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.

Applications selected as finalists from the ESC review will then be reviewed by the NHLBI NCAI Program Technology Review Committee (TRC). The NHLBI TRC review is a final step which includes review and feedback by representatives of NIH, FDA, U.S. Patent and Trademark Office, Center for Medicare and Medicaid Services.

3.5. Funding Decision and Award Implementation

Funding decisions will be communicated via notice of grant award. 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.

3.6. 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. Continued funding of projects will be based on demonstrated progress and successful achievement of the defined project milestones.

3.7. Follow on Progress Reports

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. Proposal Requirements

4.1. General Instructions

- LOIs and invited 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 order of the sections should follow the order they are presented in Section 4.2 of this RFA. The application information page shall be the proposal cover page.
- Only electronic submissions will be accepted. The proposal will be submitted via upload to the NCAI-CC website. Specific instructions will be provided at the time of invitation to submit full applications.

4.2. Application Contents

Applications must include the following contents:

- Application Information Page
- Executive Summary
- Project Description
 1. Background
 2. Unmet Need
 3. Definition of Proposed Product/Solution
 4. Market Opportunity
 5. Competitive Landscape
 6. Intellectual Property
 7. Differentiation
 8. Clinical and Regulatory Path
 9. Payment and Reimbursement Path
 10. Funding Requirements
 11. Project Plan and Milestones
 12. Potential Risks/Mitigation
 13. Personnel
 14. References
- Appendices
 - Budget Justification
 - Biosketches
 - Budget Pages

4.2.1. Application Information Page

The proposal cover page is an information sheet that includes project title, a brief project description, and basic contact information. A copy of the form is appended to this document for reference. Forms for information entry and submission are available on the website.

4.2.2. Executive Summary (Limit 1 page)

The executive summary shall consist of an abstract defining the proposed project, describing the commercial rationale and opportunity, and detailing the goals to be achieved with the proceeds of the requested funding.

4.2.3. Project Description (Limit 12 pages)

4.2.3.1. Background

This section should include a statement of the problem addressed by the proposed project, a discussion of the scientific and clinical rationale, and the research/development accomplished to-date.

Reviewers will be considering the following questions:

- Has sufficient background been provided to help evaluate the need and the solution?
- What is the market “space” in which this product would operate?
- What is the current standard of care?
- Is the proposed project directed towards development and commercialization goals as opposed to a continuation of research aims?

4.2.3.2. Unmet Need

Projects must address a significant unmet need in the prevention, diagnosis, treatment, or management of an NHLBI-relevant disease state.

Review criteria include:

- Has the need been clearly stated?
- Has evidence of the need been provided?

4.2.3.3. Proposed Product/Solution

A clear and succinct definition of the proposed product/ solution should be provided. The product/solution definition should be supported by the following information.

- What is the proposed product/solution?
In which category below does it fit?
 - diagnostic assay
 - biomarker
 - diagnostic system
 - device
 - small molecule drug
 - biology drug/therapy
 - therapeutic
 - combination product
 - monitoring product/system
 - healthcare information/mHealth product
- What is the clinical application area?
In which category below does it fit?
 - Heart, cardiovascular
 - Lung, airway, pulmonary
 - Blood disease or condition (non-cancer)
 - Sleep disorder.

- To what patient subset is this applicable?
- What is the expected benefit with this product/solution, and what is the evidence to support the expected benefit?
- Is the benefit a major advance or incremental in the area of speed, size, cost-saving, ease of use, safety, efficacy, accuracy or combination of areas?
- How would use of the product/solution fit with current physician practice / standard of care?

4.2.3.4. Market Opportunity

Describe the specific market segment that is addressed, including:

- What is the specific target market size that can be addressed with the product/solution? Number of patients? Number of procedures? U.S. and worldwide?
- What is the expected pricing of the product/solution? How can it be justified relative to other solutions (comparable, cost saving, value/price trade-offs)?

4.2.3.5. Competitive Landscape

Describe current and anticipated players in the space.

- What competitive products are selling?
- What other competitive products are in development or anticipated to be introduced?
- What are the adjacent spaces and substitution options?
- How is the landscape shifting or projected to shift?

4.2.3.6. Intellectual Property

Describe Intellectual Property (IP) related to the technology that has been disclosed and protected.

Relevant questions that will be assessed by reviewers include:

- What does the IP cover and how is it directly related to the technology being developed?
- Have patent applications been filed? If so, please provide:
 - a) Patent application number, issued patent number, trademark registration number, copyright number, etc.
 - b) Title, status and date
 - c) Major types of claims.

4.2.3.7. Differentiation

Describe the advantages expected from the proposed product/solution, and how they will be demonstrated or validated.

- How is the product/solution better than others that are currently in use?
- How is the product/solution better than what is expected to come to the market?
- What data needs to be generated to support the differentiation?

4.2.3.8. Clinical and Regulatory Path

Describe the likely clinical and regulatory requirements for marketing the product, including:

- What is the expected regulatory pathway?
- What safety or efficacy data will be required, and what is the scope of the clinical program to obtain such data?
- To which branch/division within the FDA would this product be submitted for approval?

4.2.3.9. Payment and Reimbursement Path

How will the product/solution be paid for by the healthcare system?

- What comparable products or services are currently being covered?
- What are the relevant CPT/DRG/APC payment codes?
- What are the reimbursement rates for the relevant codes? What has been the trend in these reimbursement rates over time and expected in the future?
- If no reimbursement code(s) exist, what would be the necessary next steps to obtain reimbursement?

4.2.3.10. Budget and Funding Requirements

Budget forms (appended to this document and available on the website) 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. A budget narrative must also be included in the appendix to provide an explanation of the overall budget by category and milestones.

Funding awards will be provided 50% from NCAI funds and 50% from institutional cost share provided by the home institution.

Reviewers will be considering the following questions:

- Is the budget realistic and appropriate for achieving the stated project milestones?
- Is the budget tied to Go/No-go decisions?
- What is the source of matching funds, and is it available to be charged to the project?
- How much more funding is required to get to the next inflection point?

4.2.3.11. Project Plan and Product Development Milestones

This section shall include the project definition and project schedule. Please include the details of the project plan to be undertaken and specific milestones to be achieved within the scope of the requested project funding. The project plan and schedule should encompass a period of work of approximately one year duration.

The schedule should graphically display (i.e. Gantt chart) the specific tasks and the timing of deliverables and other key milestones. It is recommended that the graphical schedule reflect a monthly schedule and not be based on fixed dates.

Reviewers will be considering the following questions:

- What is the ultimate endpoint of the product development plan?
- Have Go/No-Go decision milestones been established?
- Are the project milestones relevant to establishing commercial viability of the projects?
- What is the critical path?
- What are the near-term value-inflection points? How have they been validated? By which stakeholders?

4.2.3.12. Potential Risks/Mitigation

Briefly describe any potential risks that exist in any of the foregoing sections 4.2.3.1 through 4.2.3.11 and how they can be mitigated.

4.2.3.13. Personnel

List and describe the personnel that will comprise the project team. Provide abbreviated biosketches for up to three of the top key team members in Appendix .

Reviewer consideration will include:

- Is this the correct team for the present stage of the technology?
- What business expertise exists on the team?

4.2.3.14. References

Insert pertinent references, citations here.

4.2.4. Application Appendices

4.2.4.1. Budget Justification (Limit 2 pages)

The budget narrative shall provide a detailed explanation of the overall budget by category and milestones.

4.2.4.2. Biosketches (Limit 3)

Insert abridged NIH biosketches for the Principal Investigator and up to two co-investigators/ collaborators. Include prior experience in product development and commercialization activities. Limit 4 pages per biosketch.

4.2.4.3. Budget Pages (by Milestone)

Insert budget form pages here. Please include one page for the total project and one page for each major project milestone detailed in the project plan. Budget forms can be obtained from the website.

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
APPLICATION INFORMATION PAGE

Project Title					
Institution/ Department					
Address					
City		State		Zip Code	
Total Project Budget	\$	NCAI Funds Request (not to exceed ½ total budget)	\$	Institutional Cost Match	\$
Project Description					
Resubmission?	Yes _____ No _____				
Disease Space	Cardiovascular, Lung, Blood, Sleep Disorder, Other				
Technology Category (Select one)	Diagnostic Assay, Biomarker, Diagnostic System, Device, Small Molecule Drug, Biologic Drug/Therapy, Therapeutic, Combination Product, Monitoring Product/System, Healthcare information/mHealth Product, Other (describe)				
Primary Investigator	Name				
	Title				
	Telephone				
	Email				
Research Contact <small>(If different from above)</small>	Name				
	Title				
	Telephone				
	Email				

