CATALYZE
Accelerating Translation

Tailoring Your Application: Grant Writing for Catalyze Product Definition Funding Opportunities

Diana Severynse-Stevens, Ph.D.- RTI
Kristin Goltry, Ph.D.- NHLBI
Manoj Valiyaveettil, Ph.D.- NHLBI

NIH National Heart, Lung, and Blood Institute

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- Overview of Catalyze Funding Mechanisms- Diana
- How to write a successful grant for Catalyze- Kristin and Manoj

Catalyze Vision

Funding

Unique funding strategy to leverage federal investment with matching commitments and flexibility to adjust to technical challenges

Coordinated Approach

A seamless continuum of programs to advance promising HLBS-related technologies from validation to first-in-human trials

Individualized Support

Milestone-driven project management and support to mitigate technical risk

Program Flexibility

Evaluation and oversight to adjust the program based on trends and challenges, and to share best practices

Network of Support

Ability to access key technical experts on an as needed basis

Advisory services from Catalyze CC, NHLBI, and mentoring network

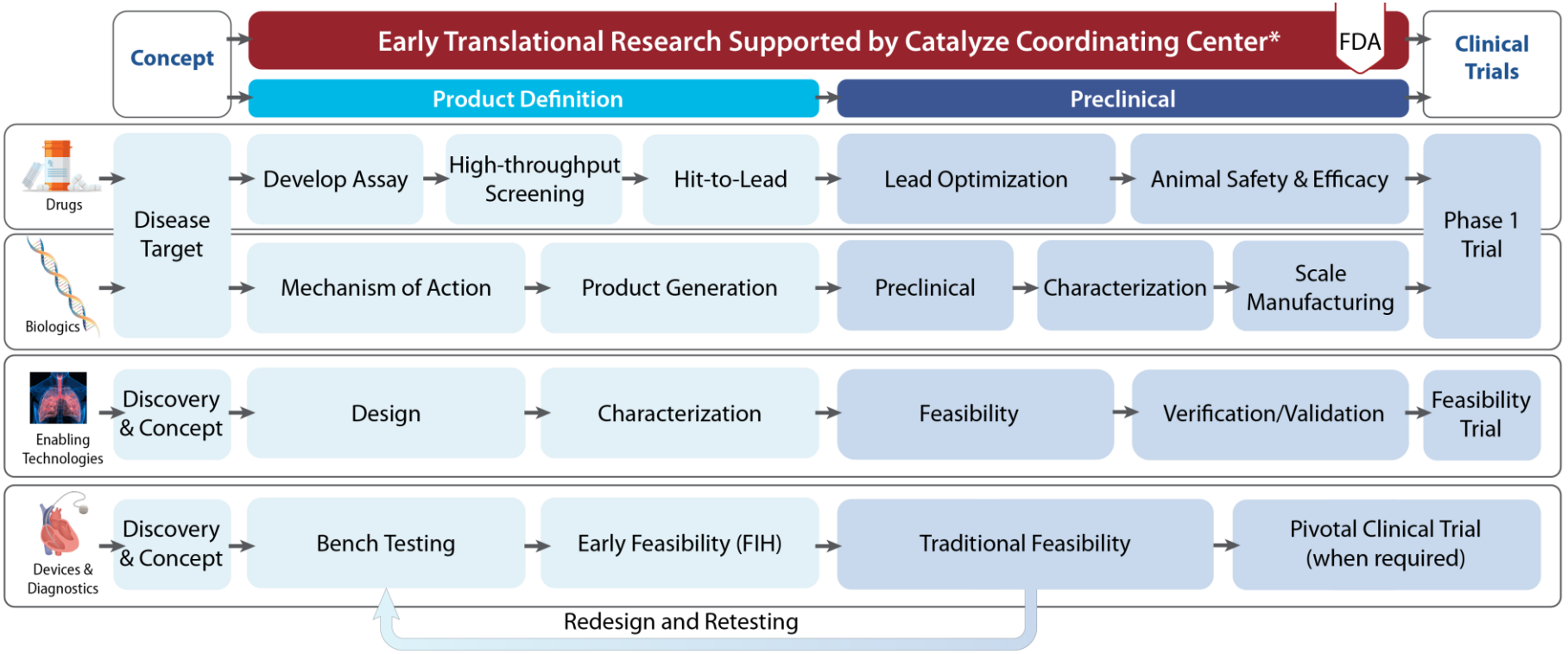
Entrepreneurial and product development education and training

Cohort-based learning

Catalyze Program

- Provides a bridge from basic to clinical research
- Trains a diverse scientific workforce fluent in product development and entrepreneurship

Program Components



Catalyze CC Resources

Product Development Support

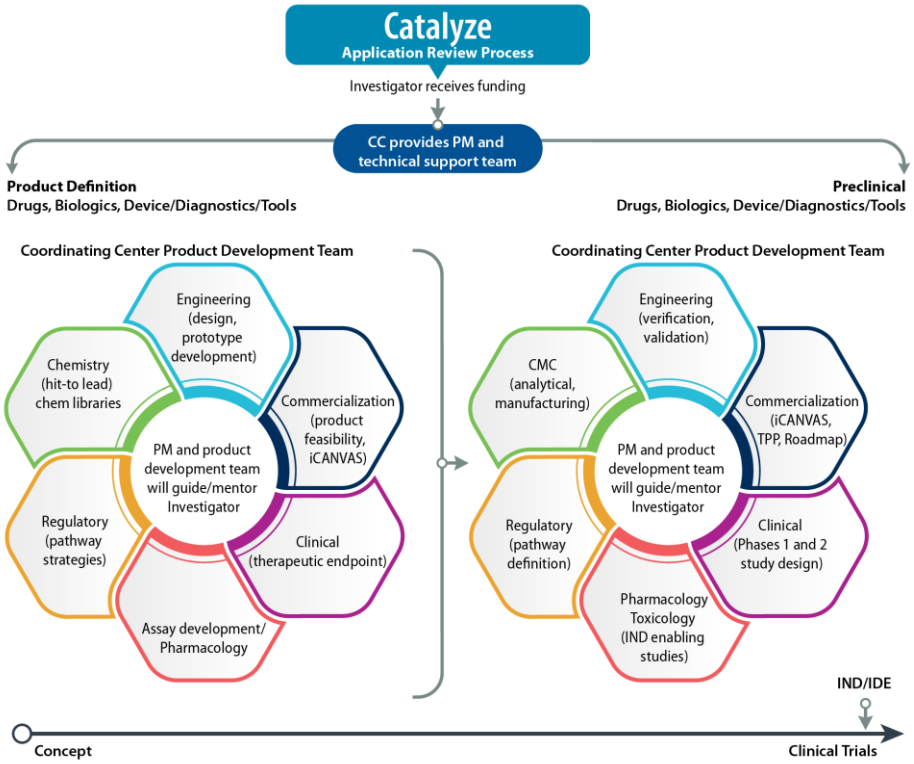
- Therapeutics
  - Chemistry
  - Pharmacology
  - Assay development
  - Toxicology
- Engineering support
  - Prototype development
  - Design verification and validation
- Regulatory Affairs
  - Strategy development
  - FDA Submissions

Commercialization Support

- Technology readiness
- Market analysis
- Intellectual property

Skills Development

- Courses, workshops



Product Definition

- Grant Mechanism R61/R33
- Technology Readiness Level 1-3

- **Online submission through GRANTS.GOV**

- **Five funding opportunities:**
  - Two for therapeutics
  - Two for devices, diagnostics, and tools
  - One for enabling technologies and transformative platforms

- **Special Application Requirements**
  - Project Management
  - Milestones and Timeline
  - Intellectual Property and Regulatory strategy
  - Rigor and Reproducibility
  - Matching Funds expectation (R33 only)
  - Accelerator Partner (R33 only)

Application deadlines: July 21 and Nov 21, 2023

Preclinical

- Preclinical Services (not funds) through RTI
- Technology Readiness Level 3-8

- **Online application to request services (EOI, full application)**
  - Focus on gap filling studies:
    - PK/PD, Toxicology
    - Manufacturing
    - Engineering validation/verification
    - Regulatory support/ submissions
  - Awardees will be expected to achieve negotiated commercial milestones

- **Special Application Requirements**:
  - Competitive Landscape
  - Market Size
  - Regulatory Path (FDA communications)
  - Intellectual Property
  - Reimbursement

EOI submission ended March 17, 2023, next application cycle TBD

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FOA # and Title	Funding Mechanism	Funding Purpose
RFA-HL-23-010 **Enabling Technologies and Transformative Platforms**	R33 (Direct to R33) 2 years $300,00 direct costs/year	• To develop enabling technologies and transformative platforms to catalyze next-generation predictive, diagnostic, and therapeutic products. • Feasibility must be previously established. This award intends to improve robustness and reproducibility and requires a rigorous validation plan
RFA-HL-23-011 **Product Definition - Small Molecule and Biologic Target Identification and Validation, Assay Development, and Screening**	R61/R33 phased award 3 years $350,00 direct costs/year	• To identify, validate, and screen compounds of interest and to identify a lead compound series to move into preclinical testing for optimization, safety, and efficacy
RFA-HL-23-012 **Product Definition - Small Molecule and Biologic Lead Series Preliminary Product/Lead Series Identification**	R33 (Direct to R33) 2 years $350,00 direct costs/year	• To develop and move a lead compound series forward to preclinical testing • For projects that have already identified, validated and screened compounds of interest and are therefore far enough along in development to skip R61 stage
RFA-HL-23-013 **Product Definition - Device Prototype Design/Testing and Diagnostic Disease Target Identification and Assay Development, Research Tool Development**	R61/R33 phased award 3 years $250,00 direct costs/year	• For initial development of prototypes through testing, identifying diagnostic disease targets and developing associated assays, and developing research tools
RFA-HL-23-014 **Product Definition - Device prototype testing and Diagnostic disease assay development, and Research Tool Development**	R33 (Direct to R33) 2 years $250,00 direct costs/year	• To develop and test existing device prototypes, explore assay components for diagnostics validation, and develop research tools • For projects that have already identified and tested initial prototype designs, that have identified a disease target and generated experimental design, or that identified, tested and piloted research tools, and are therefore far enough along in development to skip R61 stage

Submission and Review of Catalyze Grant Applications

Kristin Goltry and Manoj Valiyaveettil
Scientific Review Officers
National Heart, Lung, and Blood Institute

July 11, 2023

National Heart, Lung, and Blood Institute

NHLBI Catalyze Program

The NHLBI Catalyze program is designed to provide a suite of comprehensive support and services to facilitate the transition of basic science discoveries into new treatments for diseases and disorders that fall under the NHLBI mission.

Catalyze Innovation Grants:

- To advance projects to the point where they are ready for preclinical product optimization and characterization.
- There are 5 separate Requests for Applications (RFAs) as part of the Innovation Grants
  - Enabling Technologies and Transformative Platforms (HL23-010)
  - Catalyze: Product Definition
    - Small Molecules and Biologics (HL23-011, HL23-012)
    - Devices, Diagnostics, and Assay Development (HL23-013, HL23-014)

Know your RFA: Part I

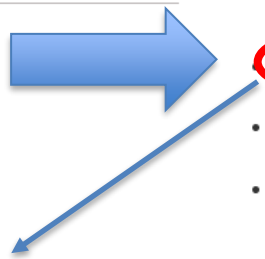
- **Part I Overview Information**
  - Participating Organization(s) NIH
  - Components of Participating Organizations NHLBI
  - Funding Opportunity Title
  - Activity Code
  - Announcement Type
  - Related Notices
  - FOA (NOFO) Number
  - Funding Opportunity Purpose
  - Key Dates (due dates, review dates, council date, earliest start date)

Please note: FOA (Funding Opportunity Announcement) is being replaced by NOFO (Notice of Funding Opportunity)

Know your RFA: Part I

- Review the Related Notices:

Funding Opportunity Title	Catalyze: Enabling Technologies and Transformative Platforms for HLBS Research (R33 - Clinical Trials Not Allowed)
Activity Code	R33 Exploratory/Developmental Grants Phase II.
Announcement Type	Reissue of RFA-HL-20-022
Related Notices	See Notices of Special Interest associated with this funding opportunity • NOT-OD-23-012 Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available • NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 • **March 24, 2022** - Notice of Application Submission and Due Date Changes for RFA-HL-23-010. See Notice NOT-HL-22-015.



NOT-OD-23-012

Related Notices: NOT-OD-23-012

Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

Related Announcements

NOT-OD-22-198– Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023

NOT-OD-22-195– New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

NOT-OD-22-189- Implementation Details for the NIH Data Management and Sharing Policy

NOT-OD-21-013- Final NIH Policy for Data Management and Sharing

…to promote the management and sharing of scientific data generated from NIH-funded or conducted research

Related Announcements: NOT-OD-21-013

Final NIH Policy for Data Management and Sharing

Previously	NEW

Resource Sharing Plan (RSP):

1. Data Sharing Plan
2. Sharing Model Organisms
3. Genomic Data Sharing Plan

Resource Sharing Plan (RSP): *Peer reviewed*

1. Model Organism Sharing Plan
2. Sharing of Research Tools

Data Management and Sharing Plan (DMS) *NHLBI reviewed*

(separate attachment)

1. Data Sharing Plan
2. Genomic Data Sharing Plans (GDS)

Know your RFA: Part 2

- Part 2 Full Text of Announcement
  - Section I. Funding Opportunity Description
  - Section II. Award Information
  - Section III. Eligibility Information
  - Section IV. Application and Submission Information
  - Section V. Application Review Information
  - Section VI. Award Administration Information
  - Section VII. Agency Contacts
  - Section VIII. Other Information

- Pay attention to wording in RFA: “must” and “required”

Section I: Funding Opportunity Description

- Specific Research Objectives and Scope of this FOA (NOFO)
- Responsive Technologies and Scientific Scope
- Non-Responsive Projects

You are strongly encouraged to contact Scientific/Research Staff listed in Section VII to discuss potential research projects prior to submitting an application.

Special Requirements for this FOA (NOFO)

- Milestones:
  - Define milestones that are specific, measurable, achievable, relevant, and time-bound.
  - The milestones should allow program staff to assess progress during the period of the award.
  - Specific aims or a list of activities are not considered milestones.
  - For Phased Awards, describe the milestones that need to be reached in both R61 and R33 phases. Progress to R33 dependent on reaching R61 milestones.

- Timeline:
  - Provide a detailed timeline with specific milestones for the work proposed in each year of the award.
  - The timeline, specific goals and feasibility milestones should be clear and complete.
  - Indicate when it is anticipated that essential components of the project will be completed.

Special Requirements for this FOA (NOFO)

Project Management

- Describe specific plans for utilizing project management processes to enable continuous assessment of the progress of the project relative to the established milestones and how the progress assessments will be used to make strategic decisions regarding the proposed project.
- While it may not be possible to have a full-time project manager, each project is expected to identify a team member who will hold this responsibility as a part of their project management plan.
- The Catalyze Coordinating Center may support the local project management through resources, educational materials, and regular communications.

Section IV: Application and Submission Information

2. Content and Form of Application Submission includes:

- Page Limitations
- Instructions for Application Submission
- SF424(R&R) Other Project Information
- R&R Budget
- PHS 398 Research Plan

Section IV: Budget

- Budget pages are for funds you are requesting from the federal government

- **Matching Funds**, if required, should be included in the Budget Justification section.
  - Amount
  - Description

  Do not include non-governmental matching funds in the budget pages

- **NEW**: Budget should also include any funds for data management and sharing plan

- Note: For small business applicants, the 7% Fee is not allowed

Section V: Application Review Information

1. Criteria

- Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

Review this section to know what reviewers will be looking for…

Section V: Application Review Information

- **Scored Review Criteria**
  - Significance, Investigators, Innovation, Approach, Environment
  - Specific questions pertaining to the FOA (NOFO)
- **Additional Review Criteria (factor into score)**
  - Human Subjects and Vertebrate Animals
  - Biohazards
  - Resubmissions (address previous reviewers concerns!)
- **Additional Review Considerations (do not factor into score)**
  - Resource Sharing Plan: Model Organisms/Research Tools
  - Authentication of Key Biological and Chemical Resources
  - Budget and Period of Support
  - Intellectual Property and Regulatory Strategy*

NHLBI Catalyze Program: 5 RFAs

- **Enabling Technologies and Transformative Platforms**
  - RFA HL23-010: R33, 2 years

- **Catalyze: Product Definition**
  - Small Molecules and Biologics
    - RFA HL23-011: R61/R33, 3 years
    - RFA HL23-012: R33, 2 years
  - Devices, Diagnostics, and Assay Development
    - RFA HL23-013: R61/R33, 3 years
    - RFA HL23-014: R33, 2 years

Enabling Technologies: Purpose

Enabling Technologies and Transformative Platforms
RFA HL23-010

- Further develop enabling technologies and transformative platforms to catalyze next-generation predictive, diagnostic and therapeutic products to address heart, lung, blood, and sleep (HLBS)-related disorders and diseases

- Applications where major feasibility gaps for the enabling technology or transformative platform have already been overcome, as demonstrated with **supportive preliminary data**, but still requires further development and rigorous validation to encourage downstream demonstration, utilization and adoption.

- Potential to accelerate and/or transform the areas of early detection and screening, model development, clinical diagnosis, treatment, control, prevention or epidemiology.

Enabling Technologies: Objectives

- The proposed projects must be focused on development and validation of an enabling or platform technology in a representative biologically or clinically relevant system:
  - Offers novel capabilities that may be potentially transformative in laboratory and/or clinical settings,
  - Beyond providing incremental improvements to existing capabilities;
  - Rigorous study design with a verifiable approach, based on well-defined, performance measures.

- At the core of any project must be a novel analysis or targeting capability (encompassing novel devices, materials, or chemical/biochemical approaches) with an accompanying validation plan.

RFA HL23-010: Related Notice

- Related Notice:
  - March 24, 2022 - Notice of Application Submission and Due Date Changes for RFA-HL-23-010. See Notice NOT-HL-22-015.
- The following section of RFA-HL-23-010, Part 2. Full Text of Announcement Section IV has been modified to **remove the following language**:
  - Milestones, timeline and project management plan (required)
  - The filename "Milestones, timeline and Project management plan.pdf" should be used. The attachment may not exceed three pages.

RFA HL23-010: Related Notice

- **Section IV. Application and Submission Information**
- **PHS 398 Research Plan**
  Research Strategy
- ~~Milestones, timeline and project managment plan (required)~~
- ~~The filename "Milestones, timeline and Project managment plan.pdf" should be used. The attachment may not exceed three pages.~~
- Milestones: Define milestones that are specific, measurable, achievable, relevant, and time-bound. The milestones should allow program staff to assess progress during the period of the award. Specific aims or a list of activities are not considered milestones. Describe the milestones that need to be reached in the R33 phase to address the specific aims and ensure the successful completion of the entire project.
- Timeline: Provide a detailed timeline with specific milestones for the work proposed in each year of the award. The timeline, specific goals and feasibility milestones should be clear and complete. Indicate when it is anticipated that essential components of the project will be completed. The proposed timeline with specific milestones should be clearly delineated and should be referenced in the Research Strategy Section.
- Project Management: Describe specific plans for utilizing project management processes to enable continuous assessment of the progress of the project relative to the established milestones and how the progress assessments will be used to make strategic decisions regarding the proposed project. While it may not be possible to have a full-time project manager, each project is expected to identify a team member who will hold this responsibility as a part of their project management plan. The Catalyze Coordinating Center may support the local project management through resources, educational materials, and regular communications.

RFA HL23-010 Application

- Pay attention to wording in the RFA:
  - Application budgets **must not** exceed $300,000 direct costs per year.
  - The maximum project period is two years.
  - Within Research Strategy there **must be** a dedicated subsection labeled "Performance Measures"
  - Other Attachments: Statement of Potential Impact (**Required**) The filename "Statement of Potential Impact.pdf" should be used.

Catalyze Product Definition FOAs

Drugs and Biologics:

- Catalyze: Product Definition for Small Molecules and Biologics - Target Identification and Validation, and Preliminary Product/Lead Series Identification (R61/R33 or R33 – Clinical Trials Not Allowed): RFA-HL-23-011 or RFA-HL-23-012

Device and Diagnostics:

- Catalyze: Product Definition – Device Prototype Design and Testing, Diagnostic Disease Target Identification and Assay Development, and Research Tool Development (R61/R33 or R33 - Clinical Trial Not Allowed): RFA-HL-23-013 or RFA-HL-23-014

Drugs and Biologics
(RFA-HL-23-011 or RFA-HL-23-012)

- **Novelty:** These FOAs seeks applications that propose to apply new knowledge around novel targets, mechanisms and pathways; significant improvements over existing therapeutics or screening methods; evidence of the unmet gaps and needs to support proposed activities

- **Biological rationale and preliminary data:** strong biological rationale for the intended approach, preliminary data that reflect well-designed experiments (either from the literature, data from other sources, or, when available, from investigator-generated data)

- **Relevance for therapy development:** propose to develop novel therapeutic agents that can be advanced towards development of NHLBI mission-relevant therapies and cures and fulfill the clinical gaps and needs are of high programmatic interest

Device and Diagnostics
(RFA-HL-23-013 or RFA-HL-23-014)

- **Novelty:** These FOAs seeks applications that propose to apply new knowledge around novel devices, diagnostics and research tools. Projects should aim to develop potential products that are significant improvements over existing solutions for HLBS diseases and disorders. It is expected that proposed projects will provide evidence of the unmet gaps and needs to support proposed activities.

- **Biological rationale and preliminary data:** These FOAs will fund projects that have a strong biological rationale for the intended approach, which have preliminary data that reflect well-designed experiments (either from the literature, data from other sources, or, when available, from investigator-generated data).

- **Relevance for development:** Projects that propose to develop novel therapeutic agents that can be advanced towards development of NHLBI mission-relevant therapies and cures and fulfill the clinical gaps and needs are of high programmatic interest.

R61/R33 Applications

- Please pay close attention to the FOAs (RFA-HL-23-011 or RFA-HL-23-013), as they provide critical application information and expectations or requirements

  - Drugs and Biologics (RFA-HL-23-011) - Catalyze: Product Definition for Small Molecules and Biologics - Target Identification and Validation, and Preliminary Product/Lead Series Identification (R61/R33 – Clinical Trials Not Allowed)
  - Device and Diagnostics (RFA-HL-23-013) - Catalyze: Product Definition – Device Prototype Design and Testing, Diagnostic Disease Target Identification and Assay Development, and Research Tool Development (R61/R33 - Clinical Trial Not Allowed)

R61/R33 Applications

A bi-phasic approach to funding exploratory and/or developmental research

Drugs and Biologics (RFA-HL-23-011) :

- Maximum project period 3 years
- R61 Phase: Identify, validate and screen therapeutic compounds of interest (maximum project period 2 years)
- R33 Phase: Identify promising lead compounds for pre-clinical testing and development (maximum project period 2 years)
- Budget must not exceed direct cost of $350K per year
- The R61 and the R33 can't be awarded in the same fiscal year

Device and Diagnostics (RFA-HL-23-013):

- Maximum project period 3 years
- R61 Phase: To develop and test initial prototype design, or to identify a disease target and generate experimental design (maximum project period 2 years)
- R33 Phase: Further prototype development and testing, or product generation, exploration of assay components and characterization of a load design (maximum project period 2 years)
- Budget must not exceed direct cost of $250K per year
- The R61 and the R33 can't be awarded in the same fiscal year

R33 Applications

- Please pay close attention to the FOAs (RFA-HL-23-012 or RFA-HL-23-014), as they provide critical application information and expectations or requirements

  - Drugs and Biologics (RFA-HL-23-012) - Catalyze: Product Definition for Small Molecules and Biologics - Preliminary Product/Lead Series Identification (R33 - Clinical Trial Not Allowed)
  - Device and Diagnostics (RFA-HL-23-014) - Catalyze: Product Definition – Device Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development and Design Characterization, and Research Tool Testing and Validation (R33 - Clinical Trials Not Allowed)

R33 Applications

Single phase approach to funding exploratory and/or developmental research

Drugs and Biologics (RFA-HL-23-012) :

- Maximum project period 2 years
- To support projects that propose to identify a lead compound series for pre-clinical testing and development
- Budget must not exceed direct cost of $350K per year
- Matching Funds: The recipient is expected to provide at least a 0.25:1 non-Federal match

Device and Diagnostics (RFA-HL-23-014):

- Maximum project period 2 years
- Device: Allows prototype development and testing, in addition to modifying design features and user feedback
- Diagnostics: Allows product generation, exploration of assay components and characterization of a load design
- Budget must not exceed direct cost of $250K per year
- Matching Funds: The recipient is expected to provide at least a 0.25:1 non-Federal match

Application Outline

- **Specific Aims – 1 page**
  - Should include headers titled R61 Phase Specific Aims and R33 Phase Specific Aims

- **Research Strategy – 12 pages**
  - Describe R61 and R33 phases
  - Evidence of unmet medical need
  - History of product development in disease area
  - Novelty of the design
  - Summary of project status
  - Rationale for experimental design and path forward

Application Outline

- **Research Strategy – Additional Elements**
  - Accelerator Partner (for R33 Phase only)
    Describe expertise/gaps a partner might fill
  - Milestones
    -Defined for both R61 and R33 phases
    -R61 Milestones must be met for progression to R33
    -Relevant, measurable, feasible, scientifically justified, results-focused, time-bound
  - Timeline
    Contains specific goals and milestones for R61 and R33
    Last element of the Research Strategy section
  - Project Management
    Describe selected project management processes
  - Rigor and Reproducibility

Application Outline

- **Budget Justification**
  - 0.25:1 Cash Match of Direct Costs for R33 Phase Only
  - Description of how matching funds will be used
  - Proof of matching funds not required at time of application

- **IP and Regulatory Strategies**
  - Required attachment
  - Preliminary IP and regulatory plans

- **Appendices**
  - No required appendices, although some applications have items in the appendix

Administrative Requirements

Summary of required attachments/documents: (otherwise could be returned without peer-review)

- **For R61/R33 applications:**
  - IP & Regulatory Strategy
  - Total direct cost should not exceed $350K (Drugs & Biologics) or $250K (Device & Diagnostics) per year
  - Cost-matching with budget justification (for R33 phase only)

- **For R33 applications:**
  - IP & Regulatory Strategy
  - Total direct cost should not exceed $350K (Drugs & Biologics) or $250K (Device & Diagnostics) per year
  - Accelerator Partner with a Letter of Support
  - Cost-matching with budget justification
  - Letter of Support for cost sharing

After submission:

1. **Division of Receipt and Referral/Center for Scientific Review:**
   - Upon receipt, applications will be evaluated for completeness and compliance with application instructions

2. **NHLBI:**
   - Applications will be evaluated for responsiveness by NHLBI staff

Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed

Review of your Application

1. **Initial level of review by a Special Emphasis Panel:**
   - Evaluate the scientific and technical merit of each application. Likelihood for the project to exert a sustained, powerful influence on the field.
   - Scientific Peer Review organized by the NHLBI Office of Scientific Review

2. **Second level of review by the National Heart, Lung and Blood Advisory Council.**

3. **The following will be considered in making funding decisions:**
   - Scientific and technical merit of the proposed project as determined by scientific peer review.
   - Availability of funds. Applications will compete for available funds with all other recommended applications submitted in response to this FOA.
   - Relevance of the proposed project to program priorities.

Scientific Peer Review of your Application

The Special Emphasis Panel:

- Recruited specifically for your applications
- Reviewer Qualifications
  - Scientific Expertise (biology, engineering, etc.)
  - Product Development
  - Translational Research
  - Entrepreneurs
  - End Users
- Pre-Review Orientation for Reviewers

Review of your Application

After the peer review meeting:

- Receive a score (10-90) or ND (not discussed)
- Receive Summary Statement
- Contact your Scientific Program Officer
- Wait for funding decision (after Advisory Council meeting)
- Prepare resubmission (A1)

Comments from Reviewers

- Make sure your application is clearly organized and easy to read.
- Make sure figures and figure legends are easy to read (font size, labels, numbers/stats)
- Address all criteria for all studies involving human subjects and/or use of vertebrate animals.
- For resubmissions: make sure to address previous reviewers' comments.
- Include any FDA communications (pre-IND)
- Citations should match up with the reference list.
- Make sure biosketches match the application.
- Beware of cut and paste errors.
- Milestones read more like Specific Aims
- For R33 applications, they haven’t shown feasibility, not enough preliminary data – should be R61.

Questions?

- Before Submission and After Peer Review:
  - Contact Scientific Program Officers

- After Submission up to Peer Review Meeting
  - Contact Scientific Review Officers
  - Kristin Goltry PhD kristin.goltry@nih.gov
  - Manoj Valiyaveettil PhD manoj.valiyaveettil@nih.gov

NIH National Heart, Lung, and Blood Institute