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Product Definition Informational Webinar 2022

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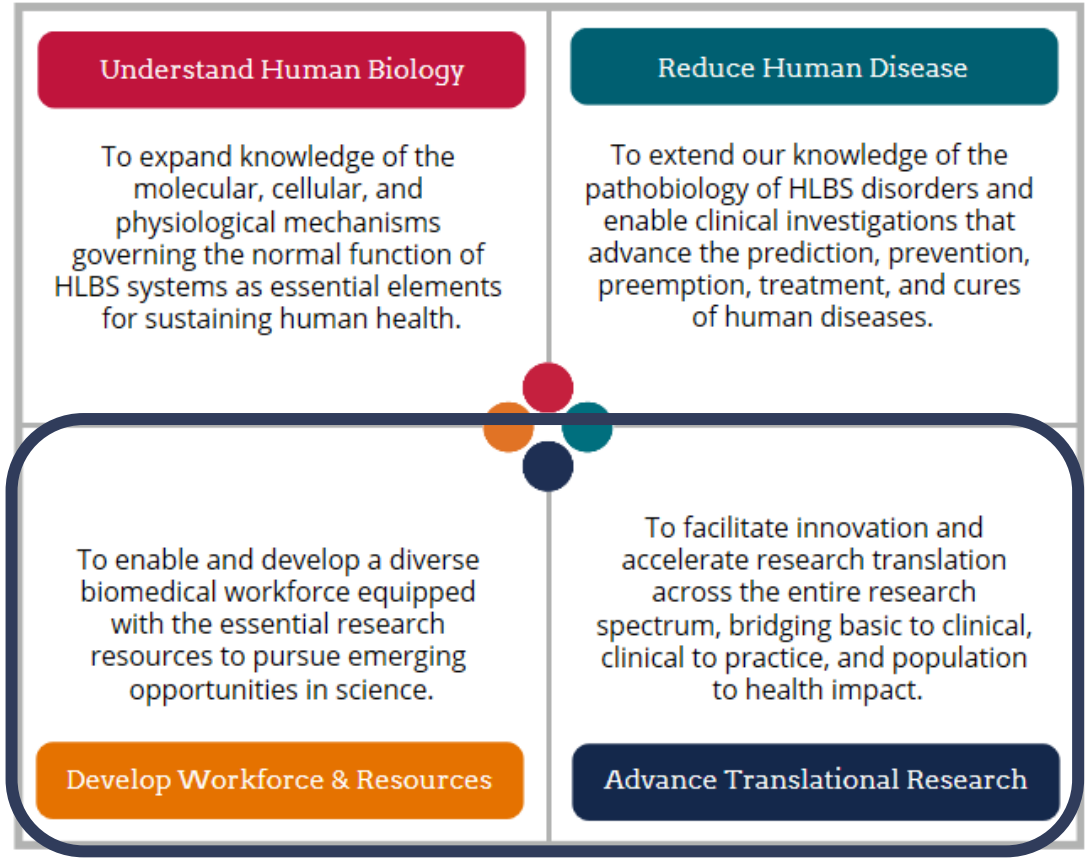
NIH National Heart, Lung, and Blood Institute

Background

NHLBI Strategic Vision

4 Mission-Driven Goals



NHLBI Catalyze Program

Provides a bridge from basic to clinical research across the entire Heart, Lung, Blood, Sleep research spectrum

Trains a diverse scientific workforce fluent in product development and entrepreneurship

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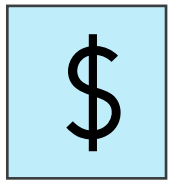
Background



- Funding gap between basic research discovery and early-stage technology development

- Lack of knowledge by innovators about how discoveries are developed into new commercial technologies

- Need to access technology development and commercialization experts, essential for early-stage technology development

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

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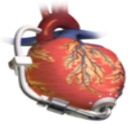
Program Components


drugs


biologics


devices
diagnostics
tools

Concept — Early Translational Research — FDA — Clinical Trials

Product Definition | **Preclinical** * *under development*

Disease Target	Develop Assay	HTS	Hit-to-Lead	Lead Optimization	Animal safety, efficacy		Phase 1 trial
Disease Target	Mechanism of Action	Product Generation		Pre-clinical	Characterization	Scale Manufacturing	Phase 1 trial
Concept	Design	Prototype Development		Verification, Validation	Scale Manufacturing	Animal Testing	Feasibility trial

Enabling Technologies & Transformative Platforms
(assays/tools/animal models/biomarkers)

Coordinating Center

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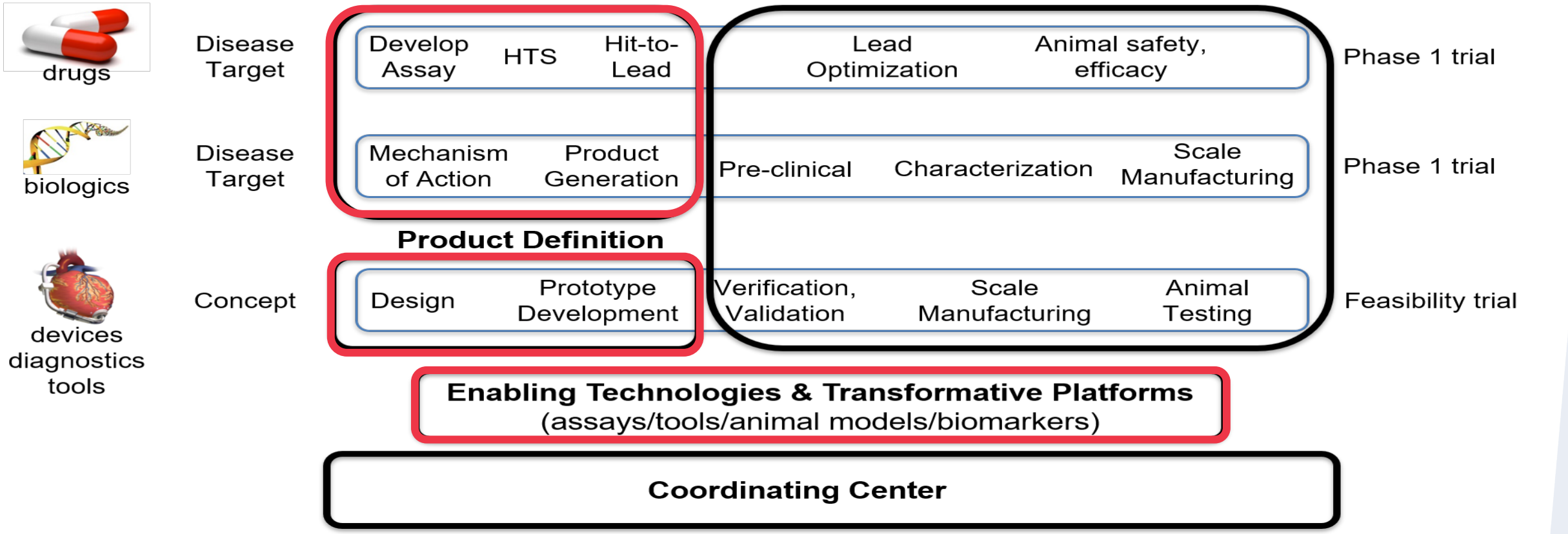
Program Components



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Product Definition Funding Opportunities

Application Deadline **March 21, 2022**

Enabling Technologies

- Enabling Technologies and Transformative Platforms for HLBS Research (RFA-HL-23-010)

Small Molecules and Biologics

- Target Identification and Validation, Preliminary Product/Lead Series Identification (RFA-HL-23-011)
- Preliminary Product/Lead Series Identification (RFA-HL-23-012)

Devices and Diagnostics

- Protype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Dev. (RFA-HL-23-013)
- Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development, and Design Characterization, and Research Tool Testing and Validation (RFA-HL-23-014)

» US-based academic, non-profit institutions, and US-owned for-profit institutions are eligible to apply

Product Development Enabling Technologies

Enabling Technologies and Transformative Platforms for HLBS Research (RFA-HL-23-010)

- **Grant Mechanism:** R33
- **Duration:** 2 years
- **Budget:** $300,000 direct cost per year
- **Special Requirements:** none

- **To develop enabling technologies and transformative platforms to catalyze next-generation predictive, diagnostic, and therapeutic products**
- **Projects should accelerate and/or transform the practice of early detection & screening, model development, clinical diagnosis, treatment, control, prevention, or epidemiology**
- **Feasibility must be previously established. This award intends to improve robustness and reproducibility and requires a rigorous validation plan.**

Product Development
Small Molecules and Biologics

Target Identification and Validation, Preliminary Product/Lead Series Identification (RFA-HL-23-011)

- Target Identification and Validation, Assay Development, and Screening to identify a lead compound series

- **Grant Mechanism:** R61/R33
- **Duration:** 3 years
- **Budget:** $350,000 direct cost per year
- **Special Requirements:**

Accelerator partner and non-federal matching funds **to transition** from R61 to R33

Preliminary Product/Lead Series Identification (RFA-HL-23-012)

- Lead Series Preliminary Product/Lead Series Identification (to develop and move a lead compound forward)

- **Grant Mechanism:** R33
- **Duration:** 2 years
- **Budget:** $350,000 direct cost per year
- **Special Requirements:**

Accelerator partner and non-federal matching funds **at time of application**

Product Development
Devices, Diagnostics and Tools

Protype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Development (RFA-HL-23-013)

- **Grant Mechanism:** R61/R33
- **Duration:** 3 years
- **Budget:** $250,000 direct cost per year
- **Special Requirements:**

Accelerator partner and non-federal matching funds **to transition** from R61 to R33

Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development, and Design Characterization, and Research Tool Testing and Validation (RFA-HL-23-014)

- **Grant Mechanism:** R33
- **Duration:** 2 years
- **Budget:** $250,000 direct cost per year
- **Special Requirements:**

Accelerator partner and non-federal matching funds **at time of application**

Product Definition Special Requirements

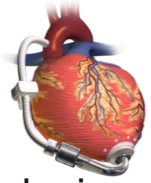
Product Definition

drugs

biologics

Phased Award (R61/R33)

R33 Award



devices
diagnostics
tools

Phased Award (R61/R33)

R33 Award

Special Requirements

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

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Special Requirements- Project Management

https://nhlbicatalyze.org/resources/project-management

- Each project is expected to use milestone-driven project management processes that make it possible to assess progress on a continuous basis, relative to established milestones
- A dedicated project manager should be identified in the application and budgeted for

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Special Requirements- Milestones

Required at time of application;

Phased awards (R61/R33) two sets

Specific Aims ≠ Milestones

NINDS Milestones Description

- Specific, measurable, achievable, relevant, and time-bound
- Milestones are an event or moment in time in a project that indicate progress toward a Specific Aim has been made or a Specific Aim has been completed
- Specific Aims and milestones should be displayed as a timeline or GANTT chart in the application
- Must be identified in the application, and based on comments of the peer review panel, they may be negotiated pre-award by the NHLBI team
- NHLBI will monitor progress toward milestones through quarterly meetings with the PI and Coordinating Center
- Milestone progress will also be used by NHLBI staff to make non-competing award decisions annually and for determining R61 to R33 transition

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Special Requirements- Intellectual Property and Regulatory

- Projects that are appropriate for these FOAs should be at the stage of development where IP and regulatory strategies are being considered or developed.
- For phased awards, continued development of IP and regulatory strategies will be required and considered for a transition from the R61 phase to the R33 phase of the award.
- Applicants are required to submit their IP and regulatory strategies in their applications.
- While IP and regulatory strategies are not required for the Enabling Technologies and Transformative Platforms funding opportunity (RFA-HL-23-010), awardees are expected to work with the Catalyze program to develop IP and regulatory strategies during the program.

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Special Requirements- Rigor and Reproducibility

- Attention to principles of study design and transparency are essential

- Follow instructions to address Rigor and Reproducibility https://grants.nih.gov/policy/reproducibility/index.htm

- Scope and milestones may be adjusted during the Catalyze program to ensure rigor and reproducibility in the study design

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Special Requirements- Accelerator Partner

Required for transition from R61 to R33 or at time of application for direct to R33

- Commercialization experts working as development partners with Catalyze innovators
- Accelerator Partners help innovators achieve the necessary multidisciplinary approach for developing technologies.
- Accelerator Partners provide skills development and mentoring to enable innovator- researchers to assess the medical and commercial potential of their projects.
- Help advance the proposed projects to a stage suitable to continue product development in the private sector or to apply for support through the NHLBI Catalyze Preclinical or other translational programs

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Special Expectation- Matching Funds

- Recommended 0.25:1 non-federal cash match of the federal direct cost for R33 portion of all awards
- Evidence of match at time of R61 to R33 transition, or at time of application for direct to R33
- Matching funds are not expected for the Enabling Technologies and Transformative Platforms funding opportunity (RFA-HL-23-010).

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Special Expectation- Matching Funds

- Examples of matching fund sources
  - Foundations
  - Applicant institutions
  - State/local government
  - Angel investors
  - VCs
  - Individual benefactors

- In-kind contributions are encouraged but do NOT fulfill matching expectation

- Matching funds are not expected for the Enabling Technologies and Transformative Platforms funding opportunity (RFA-HL-23-010).

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Special Requirements Checklist

Enabling Technologies and Transformative Platforms (R33)

RFA-HL-23-010

- ❑ Preliminary data is provided to demonstrate major feasibility gaps have been overcome
- ❑ Research Strategy Section
  - Include a dedicated section labeled "***Performance Measures***"
- ❑ **Separate Attachment labeled "*Milestones, timeline and project management*"**
  - Dedicated project manager is identified and budgeted for
  - Each Specific Aim is specific, measurable, achievable and time-bound and includes at least 1 milestone
- ❑ **Include Other Attachment labeled "*Statement of Potential Impact*"**
  - *1-page description of how the proposed technology will transform HLBS research and clinical practice*

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Special Requirements Checklist

Product Definition phased applications (R61/R33)

RFA-HL-23-011

RFA-HL-23-013

- Project Management
  - Dedicated project manager is identified
- Milestones
  - Each Specific Aim is specific, measurable, achievable and time-bound and includes at least 1 milestone
  - Separate milestones are included for the R61 and R33 phases
- Budget Justification Section
  - Includes a description of how future non-federal matching funds will be used
- **Include Other Attachment labeled *"IP and Regulatory Strategies"***
  - *Description of IP and Regulatory Strategies that are appropriate for the stage of development and demonstrate an understanding of regulatory and IP requirements for the proposed product.*

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Special Requirements Checklist

Product Definition (R33)

RFA-HL-23-012

RFA-HL-23-014

- ❑ Project Management
  - Dedicated project manager is identified and budgeted for
- ❑ Milestones
  - Each Specific Aim is specific, measurable, achievable and time-bound and includes at least 1 milestone
- ❑ Budget Justification Section
  - Includes a description of amount, type and source of non-federal matching funds and how they will be used
- ❑ ***Letter of support from Accelerator Partner***
- ❑ ***Letter of support from non-Federal source*** *that describes cash contributions to the project and commitment of cost-matching funds*
- ❑ **Include Other Attachment labeled *"IP and Regulatory Strategies"***
  - *Description of IP and Regulatory Strategies that are appropriate for the stage of development and demonstrate an understanding of regulatory and IP requirements for the proposed product.*

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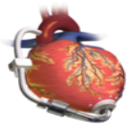
Program Components


drugs


biologics


devices
diagnostics
tools

Concept — Early Translational Research — FDA — Clinical Trials

Product Definition | **Preclinical** *Launching in 2021

Disease Target	Develop Assay	HTS	Hit-to-Lead	Lead Optimization	Animal safety, efficacy	Phase 1 trial
Disease Target	Mechanism of Action	Product Generation	Pre-clinical	Characterization	Scale Manufacturing	Phase 1 trial
Concept	Design	Prototype Development	Verification, Validation	Scale Manufacturing	Animal Testing	Feasibility trial

Enabling Technologies & Transformative Platforms
(assays/tools/animal models/biomarkers)

Coordinating Center

Catalyze Coordination and Investigator Support

NHLBI Catalyze Program

NHLBI Program Officer from extramural divisions

On demand access to NHLBI Innovation Office (OTAC)

Catalyze Coordinating Center Resources

Product Development Support

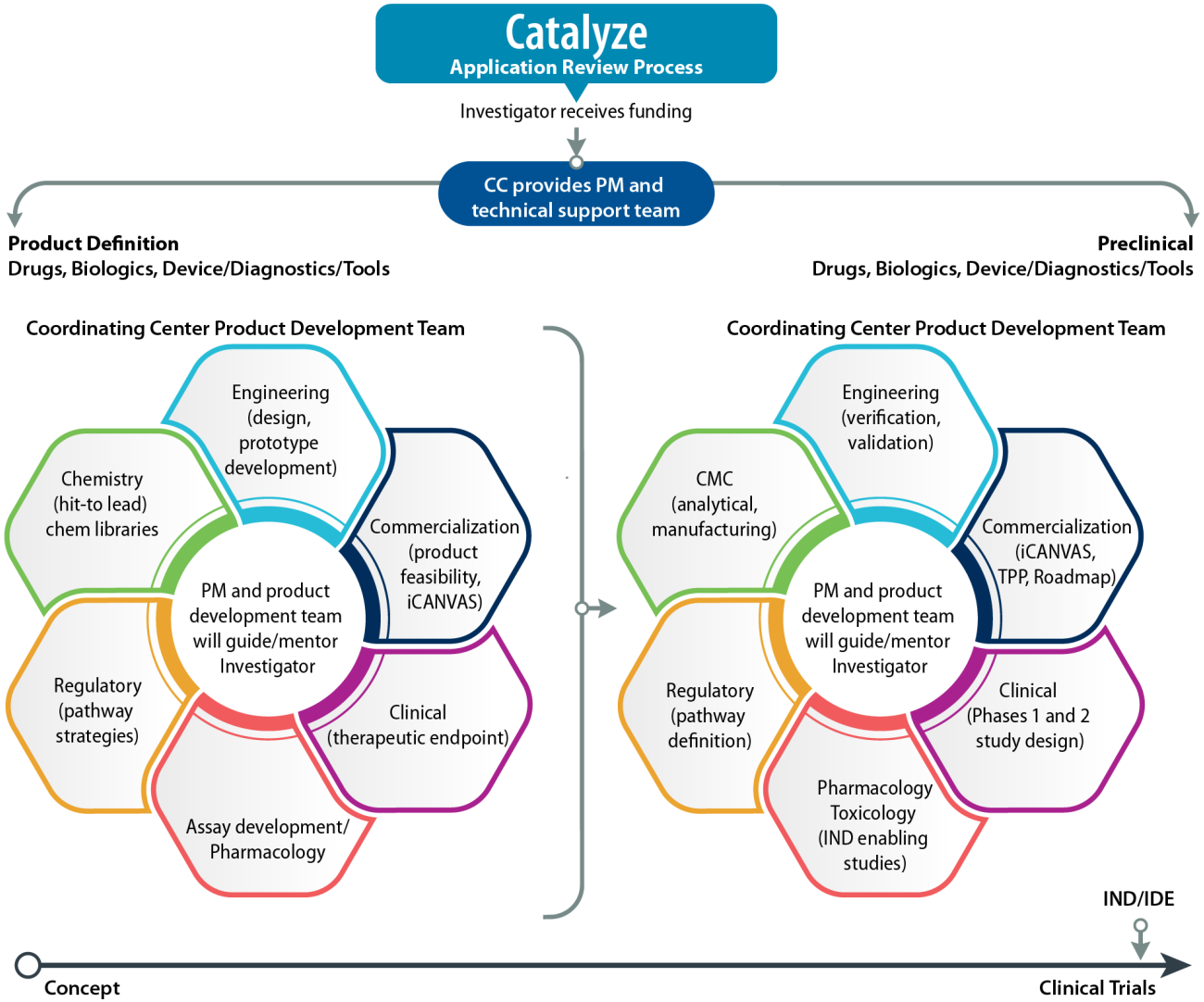
- Therapeutics
  - Chemistry
  - Pharmacology
  - Assay development
  - Toxicology
- Engineering support
  - Prototype development
  - Design verification and validation
- Regulatory Affairs
  - Strategy development
  - FDA Submissions

Commercialization Support

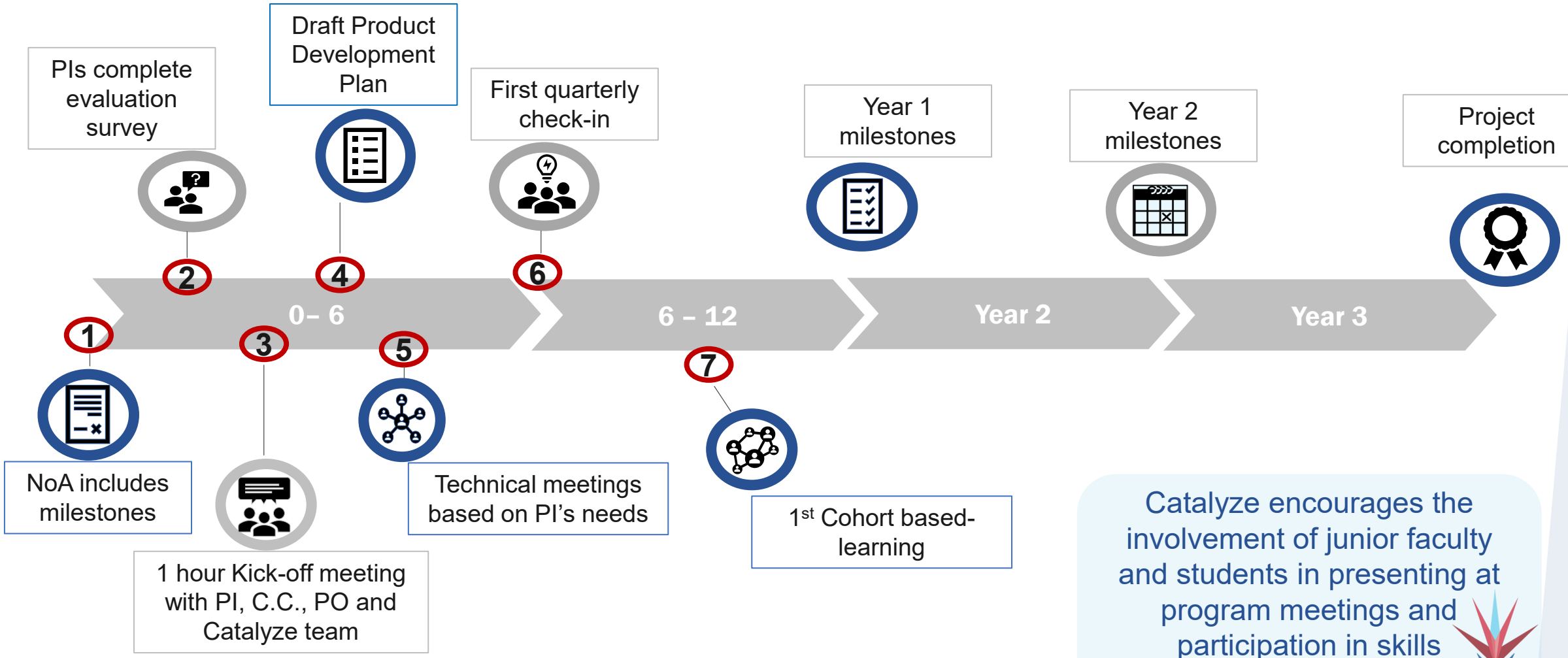
- Technology readiness
- Feasibility
- Intellectual property

Skills Development

- Courses, workshops



What to expect as a Catalyze Awardee:



Catalyze encourages the involvement of junior faculty and students in presenting at program meetings and participation in skills development activities

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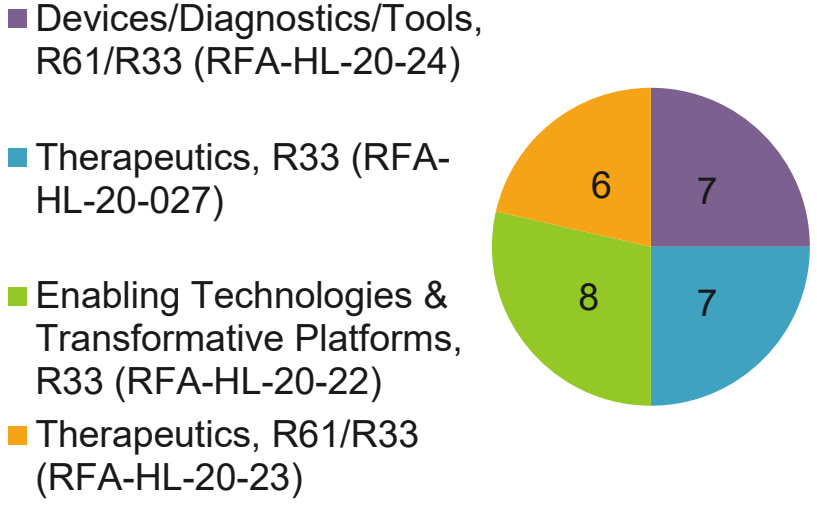
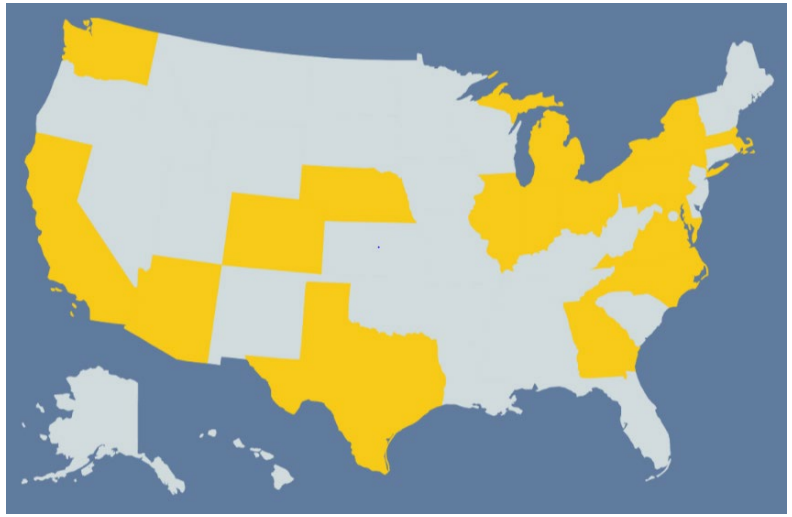
Product Definition 3 cohorts

7 | 12 | 10

Type of awards by RFA



Geographical representation



Technology Type

Therapeutics	12
Research tool	8
Diagnostic/Devices	7
Combinational product	2

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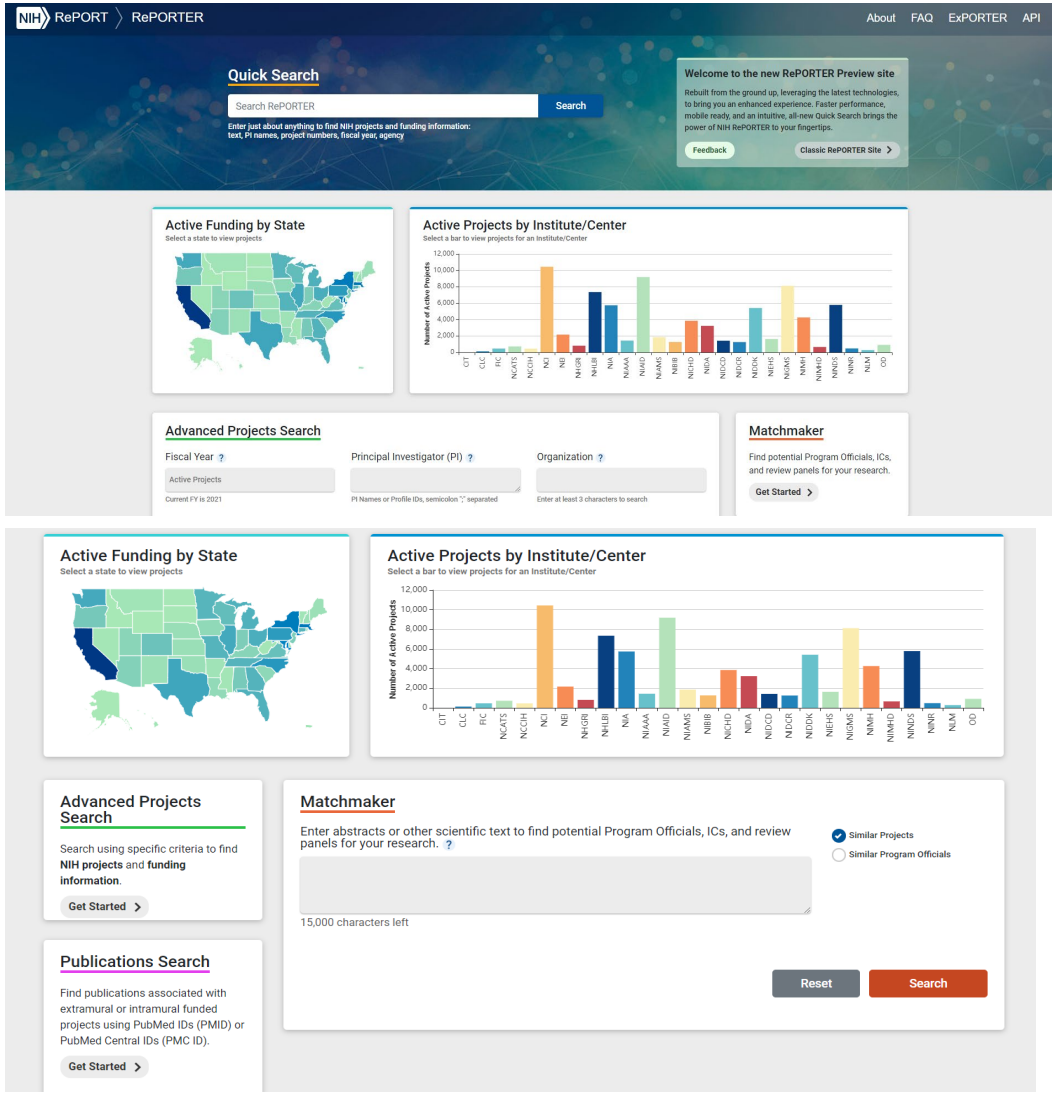
Is my project a good fit for NHLBI?

NIH RePORTER Database



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Q&A

NHLBI Catalyze Information

- Website: www.nhlbicatalyze.org
- Email: NHLBI_catalyze@mail.nih.gov
- Catalyze Product Definition funding announcements (RFAs)
  - Application Deadline: March 21, 2022
  - Eligibility: US academic, non-profit and for-profit institutions
  - NHBLI Catalyze FAQ page

Additional NHLBI Resources

- Office of Translational Alliances and Coordination
  - Innovation Advisory Services
  - Manage SBIR/STTR programs www.sbir.nih.gov/nhlbi
- NIH RePORTER funding database