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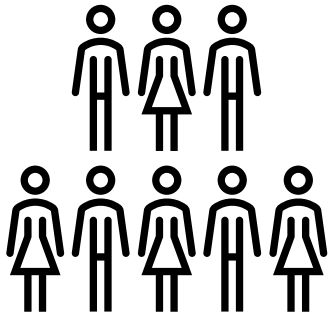
Applying to the Catalyze Program:

Tips from the director and programmatic offerings that set us apart

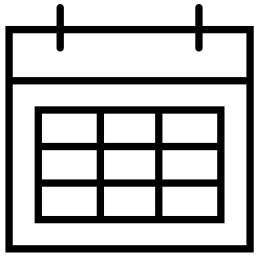
Diane Earp
Emily Vernon
Brailey Faris
Dr. Mike Pieck

NIH National Heart, Lung, and Blood Institute

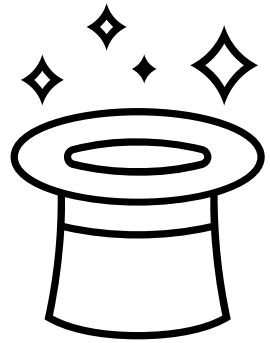
Welcome! We're so glad you are here!



Primarily targeting applicants or potential applicants ready to submit their Catalyze application this year



Next Catalyze receipt date is **July 21st, 2022,** but we offer 3 receipt dates per year that are defined through 2024

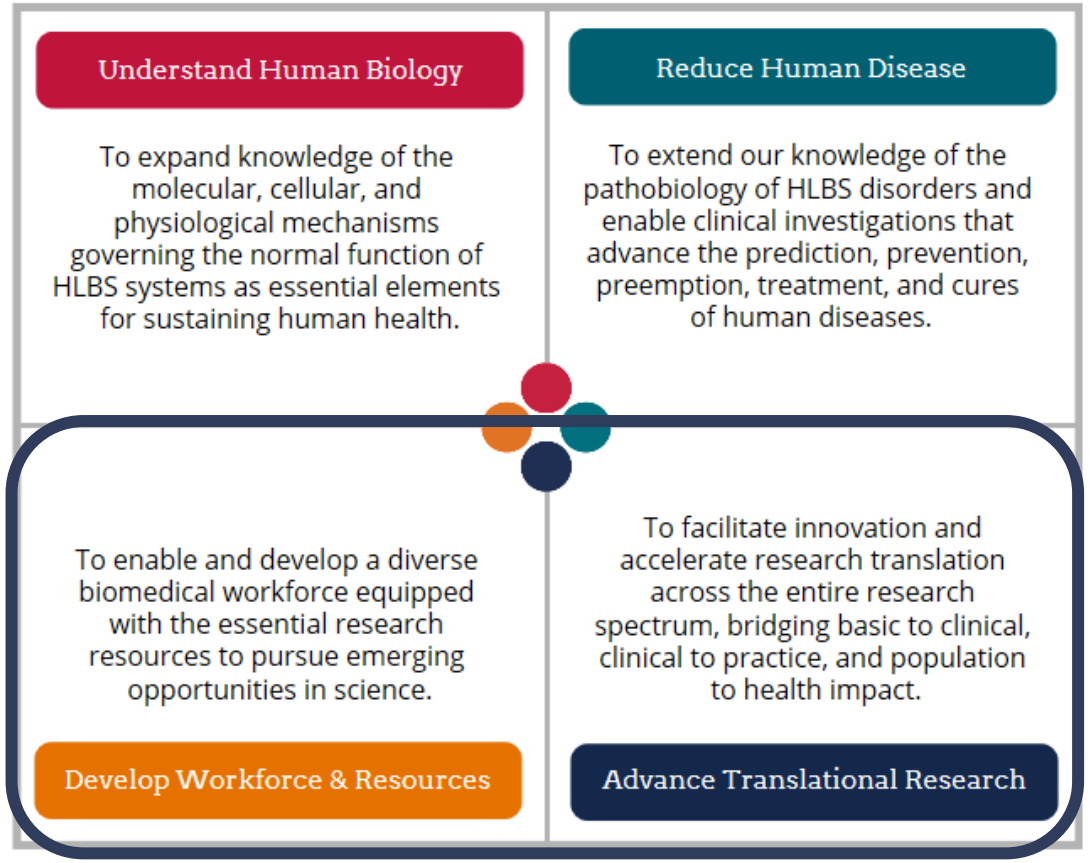


The Catalyze Scientific Director will cover application **tips and tricks** in the final segment of this webinar

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

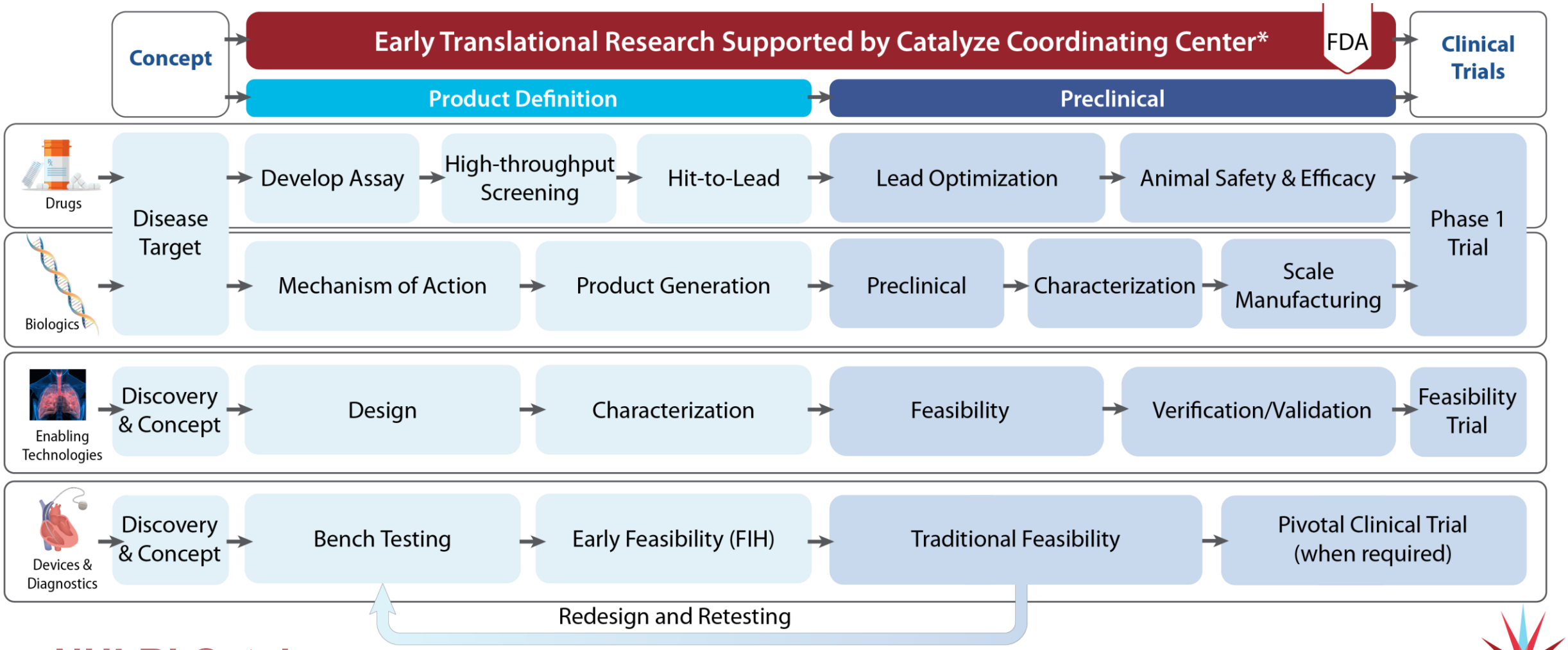
Cohort-based learning

Catalyze Program

Provides a bridge from basic to clinical research

Trains a diverse scientific workforce fluent in product development and entrepreneurship

Program Components



NHLBI Catalyze

Catalyze Coordinating Center Resources

Product Development Support

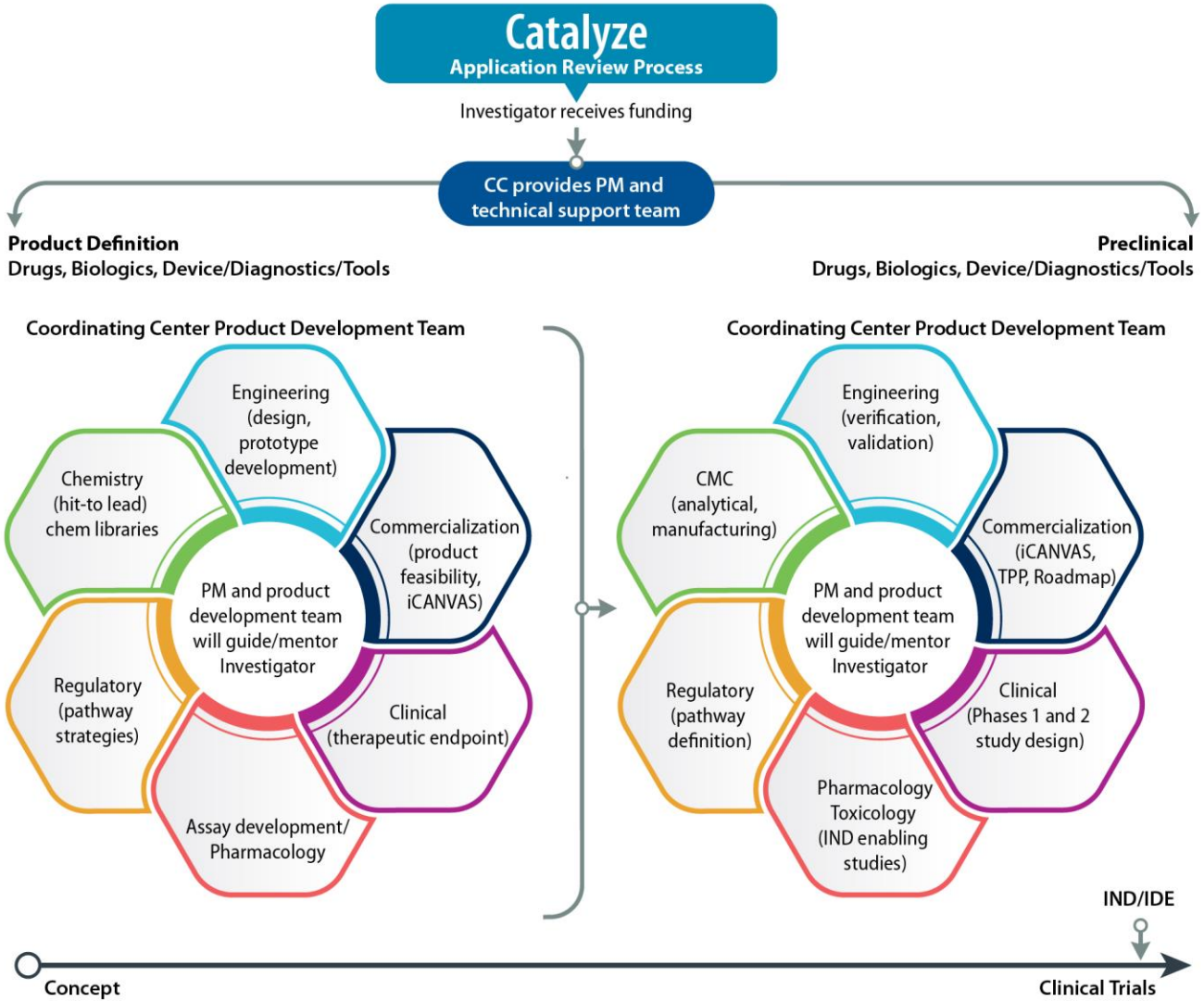
- Therapeutics
  - Chemistry
  - Pharmacology
  - Assay development
  - Toxicology
- Engineering support
  - Prototype development
  - Design verification and validation
- Regulatory Affairs
  - Strategy development
  - FDA Submissions

Commercialization Support

- Technology readiness
- Feasibility
- Intellectual property

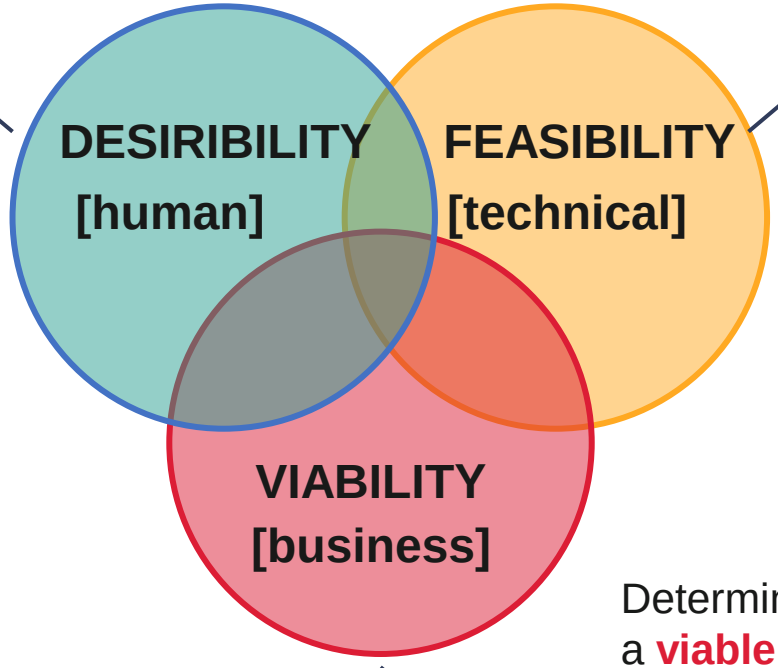
Skills Development

- Courses, workshops



When developing any type of innovation, it's crucial understand the impact from multiple angles, including **desirability**, **feasibility**, and **viability**.

Assesses whether your innovation is **desirable** to and addresses an active need for end-users.



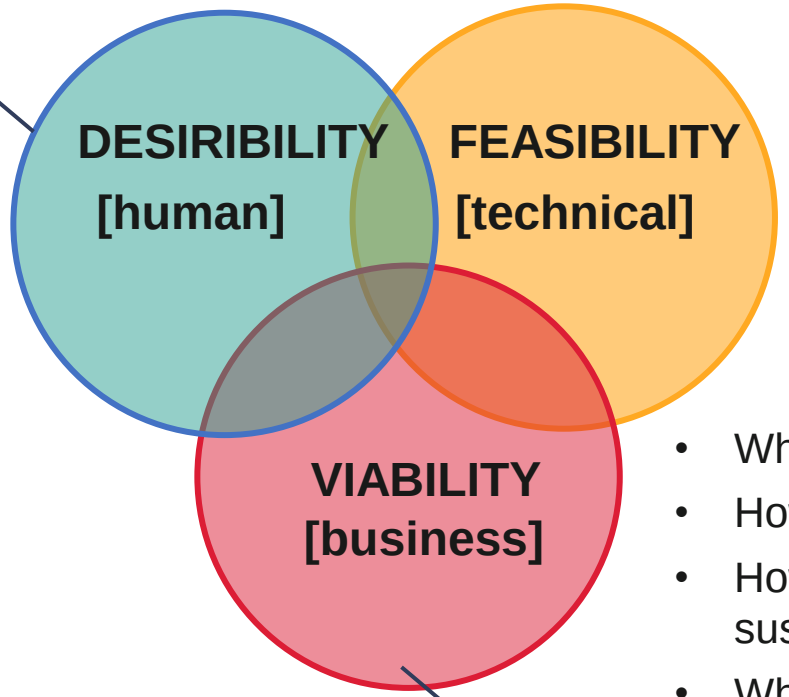
Explores whether your innovation is technically **feasible** given current resources and capabilities.

Determines if your innovation can support a **viable** business model for sustainable growth and is an attractive solution for customers.

RTI Innovation Advisors supports Catalyze PIs by exploring key questions related to a therapy or medical device's desirability and viability.

Examples of Desirability Questions

- What are the perceived and real benefits for the users? For the purchaser?
- What drives adoption and purchase decisions?
- Why would end users choose your product over the competition?
- What concerns or considerations do end users have for the innovation?



- Who is the customer?
- How might the solution benefit them?
- How big is the opportunity? Is the product sustainable?
- What does the value chain look like for the product?

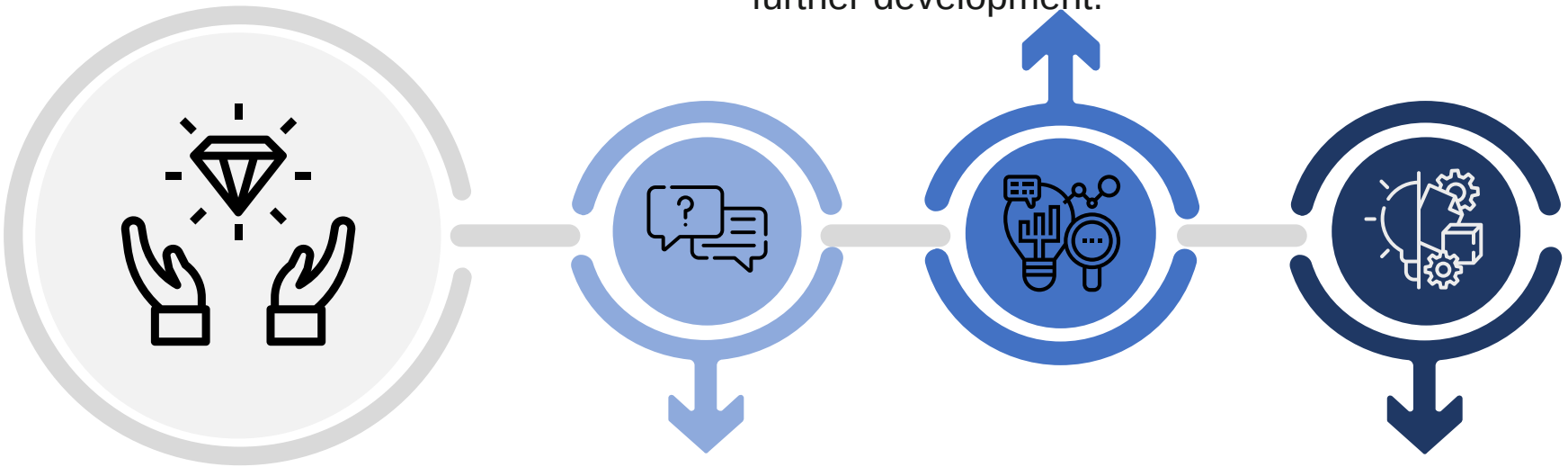
Examples of Viability Questions

Desirability Case Study

Defining perceived value from end users and informing design considerations.

Synthesize

Distilled key insights, opportunities, and barriers for the device to inform further development.



Interview

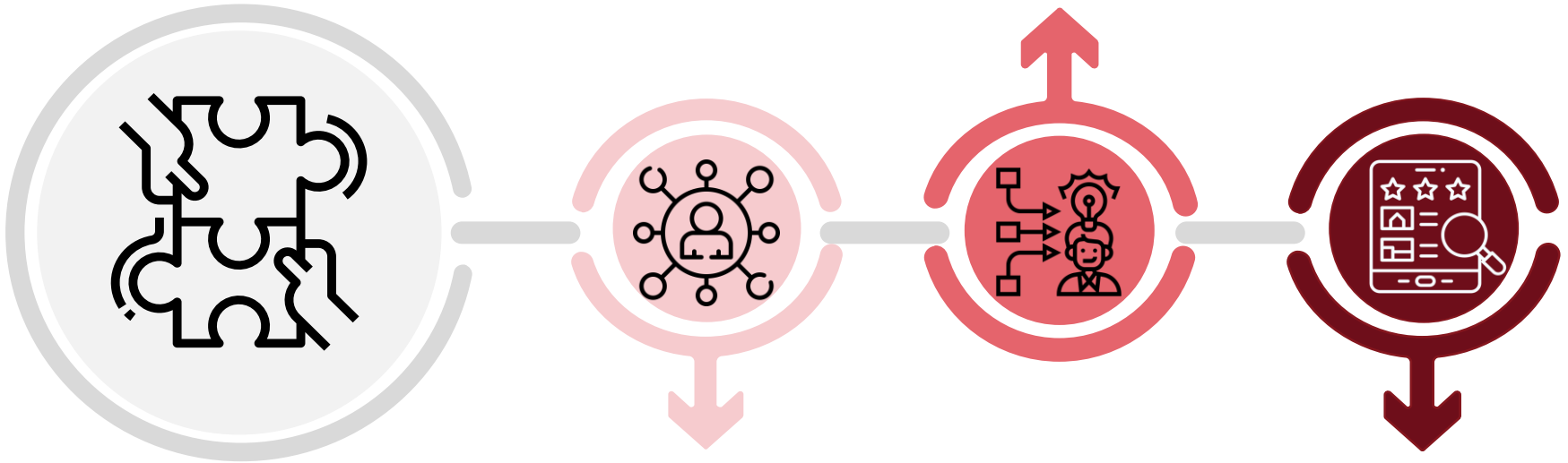
Spoke with 11 end users to understand perceived device benefits, impact on workflow, and barriers for adoption.

Outcomes

Inventor team refined the device value proposition and seeking to hire a design engineer.

Viability Case Study

Understanding and identifying landscape of key ecosystem players and potential partners to inform partnering strategy.



Prioritize

Inventor team identifies prioritization of ecosystem players for further research.

Landscape

Think broadly about stakeholder and partner ecosystem and identified pertinent companies.

Outcomes

Inventor team refined short-term vs. long-term partnering strategies and is beginning to reach out to company contacts provided.

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Product Definition Funding Opportunities

Application Deadline **July 21, 2022**

Enabling Technologies

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

Small Molecules and Biologics

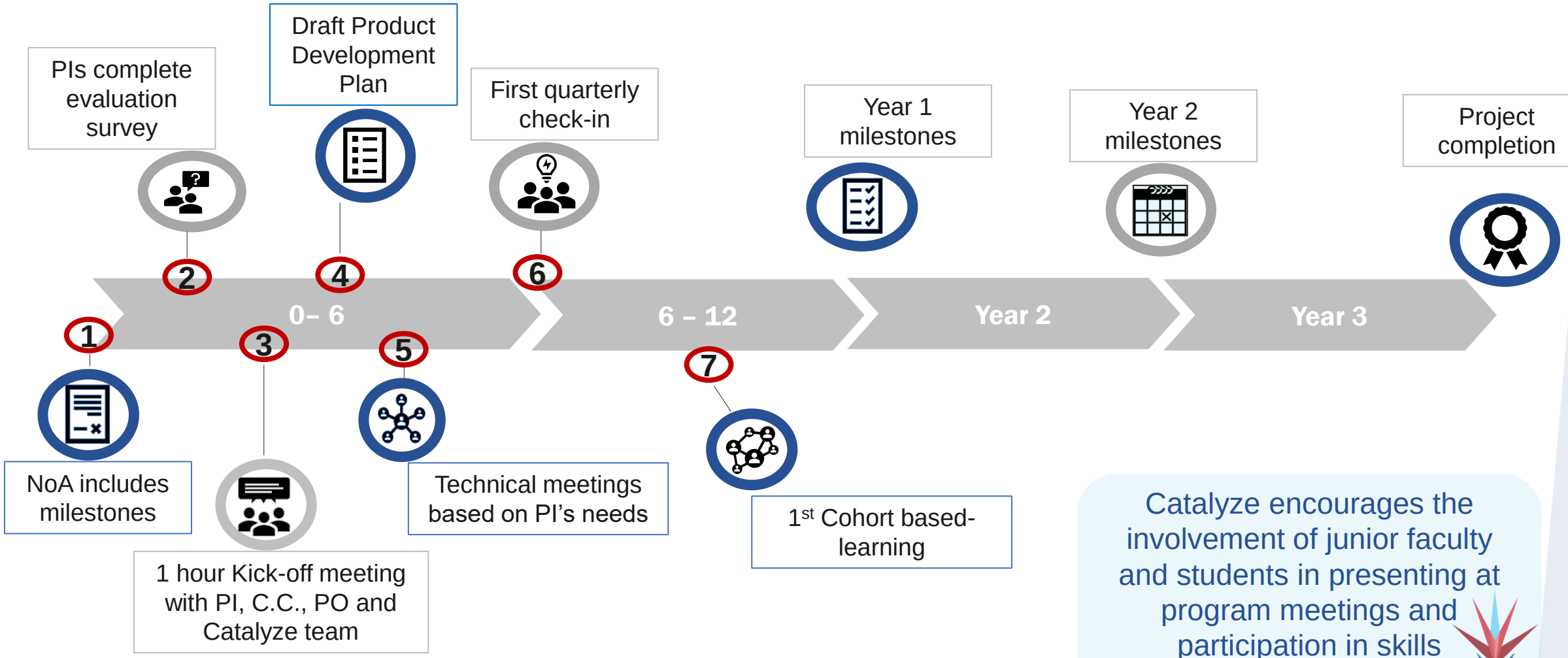
- Target Identification and Validation, Preliminary Product/Lead Series Identification (RFA-HL-23-011)
- Preliminary Product/Lead Series Identification (RFA-HL-23-012)

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

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

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

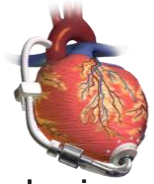
Product Definition

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

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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

- Applicants are required to submit their IP and regulatory strategies in their applications.
- 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.
- 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 Requirements- 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 Requirements- 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 requirements

- Matching funds are not required 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***"
    - ❑ Milestones
      - Each Specific Aim is specific, measurable, achievable and time-bound and includes at least 1 milestone
- ❑ Project Management
  - Dedicated project manager is identified and budgeted for
- ❑ **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
- ❑ ***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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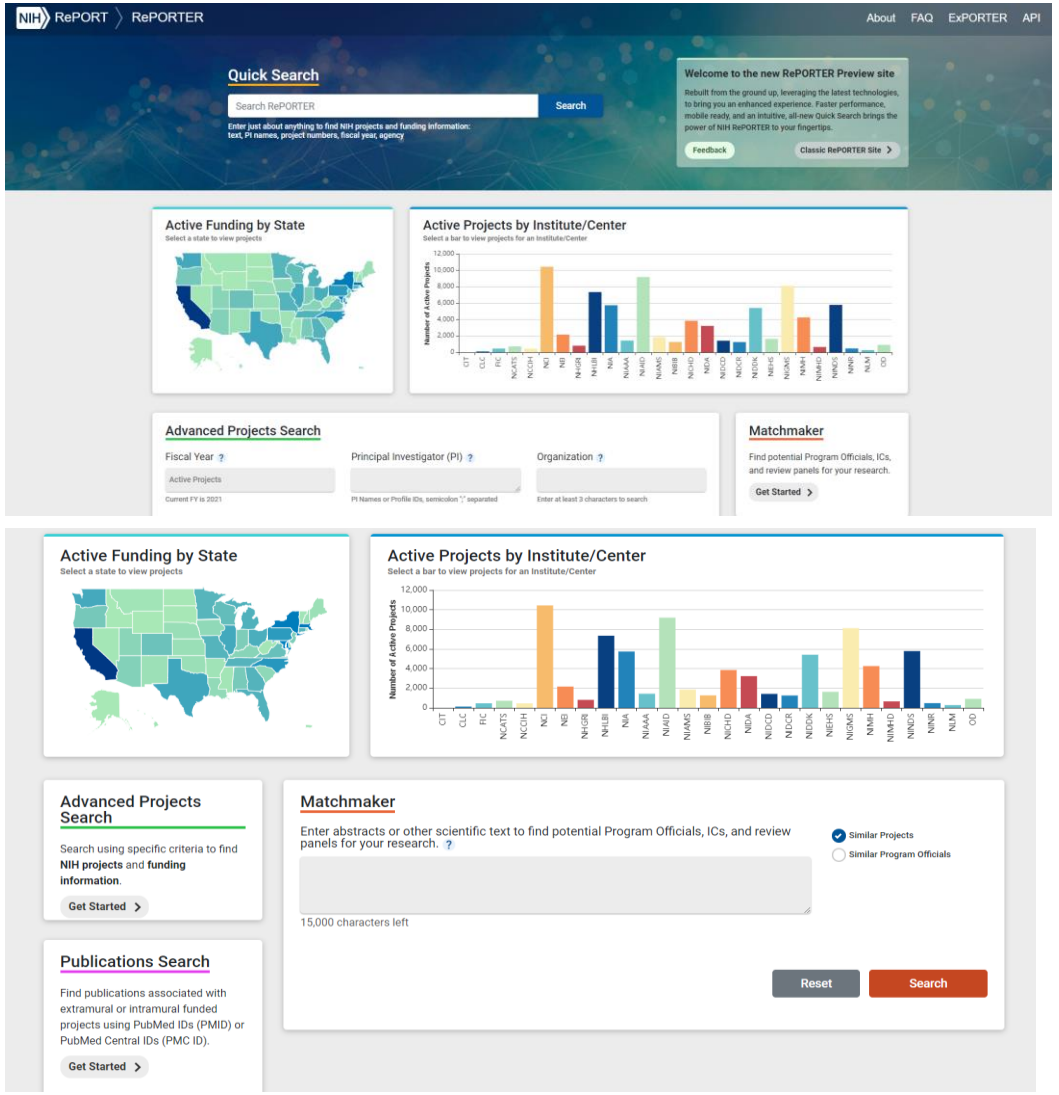
Is my project a good fit for Catalyze?

Reach Out! We want to hear from you.

NHLBI_catalyze@nih.gov

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)
  - Next application due date: **July 21, 2022**
    - Future application due dates:
      - November 21, 2022
      - February 21, 2023
      - July 21, 2023
      - November 21, 2023
      - February 21, 2024
      - July 22, 2024
      - November 21, 2024
  - Eligibility: US academic, non-profit and for-profit institutions
  - NHBLI Catalyze FAQ page

Additional NHLBI Resources

- Office of Translational Alliances and Coordination
  - Expert advisory services
  - Management of SBIR/STTR programs www.sbir.nih.gov/nhlbi
- NIH RePORTER funding database

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Upcoming Events & Reminders

Wednesday July 20th, 12pm ET

How to Source, Vet, and Oversee Medical Product Development Contractors

Presented by Dr. William Salminen & Dr. Gregory Gatto

Register for the Zoom link on our website ***nhlbicatalyze.org/events***

Friday July 21st, 2022, 5pm Local Time

Catalyze Applications Due

Stay up to date with us!

Sign up for our email list at **nhlbicatalyze.org**

- Catalyze newsletter, registration links for upcoming webinars, application resources, and important reminders