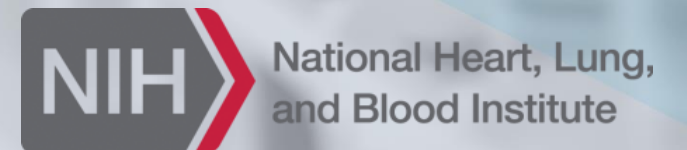




# Catalyze Programs and Funding Opportunities

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Diana Severynse-Stevens, Ph.D., RTI

May 6, 2025



- Overview of Catalyze Funding Mechanisms
- Product Definition Notices of Funding Opportunities (NOFOs)
- Questions/Discussion

# Catalyze offers investigators funding, preclinical services, technical support and training.

**Product Definition grants up to \$1M in direct costs over 3 years**

**Free technical, regulatory, and commercialization support**

**Preclinical Services requests up to \$1M per year**



## **Product Definition**

**Grant mechanism: R61/R33**

**Online submission through: Grants.gov**

### **Three funding opportunities :**

- Therapeutics (drugs, biologics, cell and gene therapies)
- Devices, diagnostics, and tools
- Enabling technologies and transformative platforms

**3 Application Cycles in 2025: February, June and October**

Please see <https://nhlbicatalyze.org/> for more details

**Technology Readiness Level 1–3**

## **Preclinical Services**

**Free services provided by Catalyze**

**Online submission through: Catalyze ([nhlbicatalyze.org](https://nhlbicatalyze.org))**

### **Focus on gap-filling studies:**

- PK/PD, toxicology
- Manufacturing
- Engineering validation/verification
- Regulatory support/submissions

**2 Application Cycles a year**

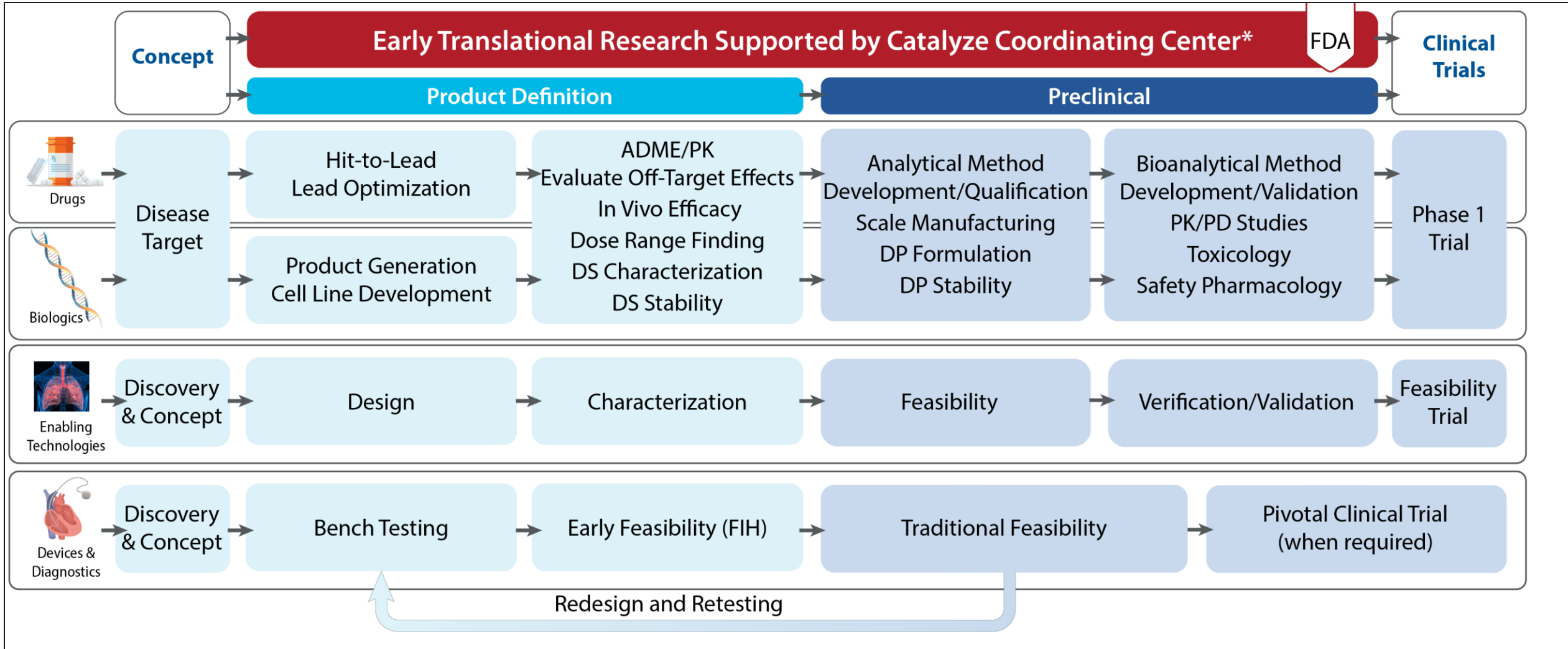
Please see <https://nhlbicatalyze.org/> for more details

**Technology Readiness Level 3–6**

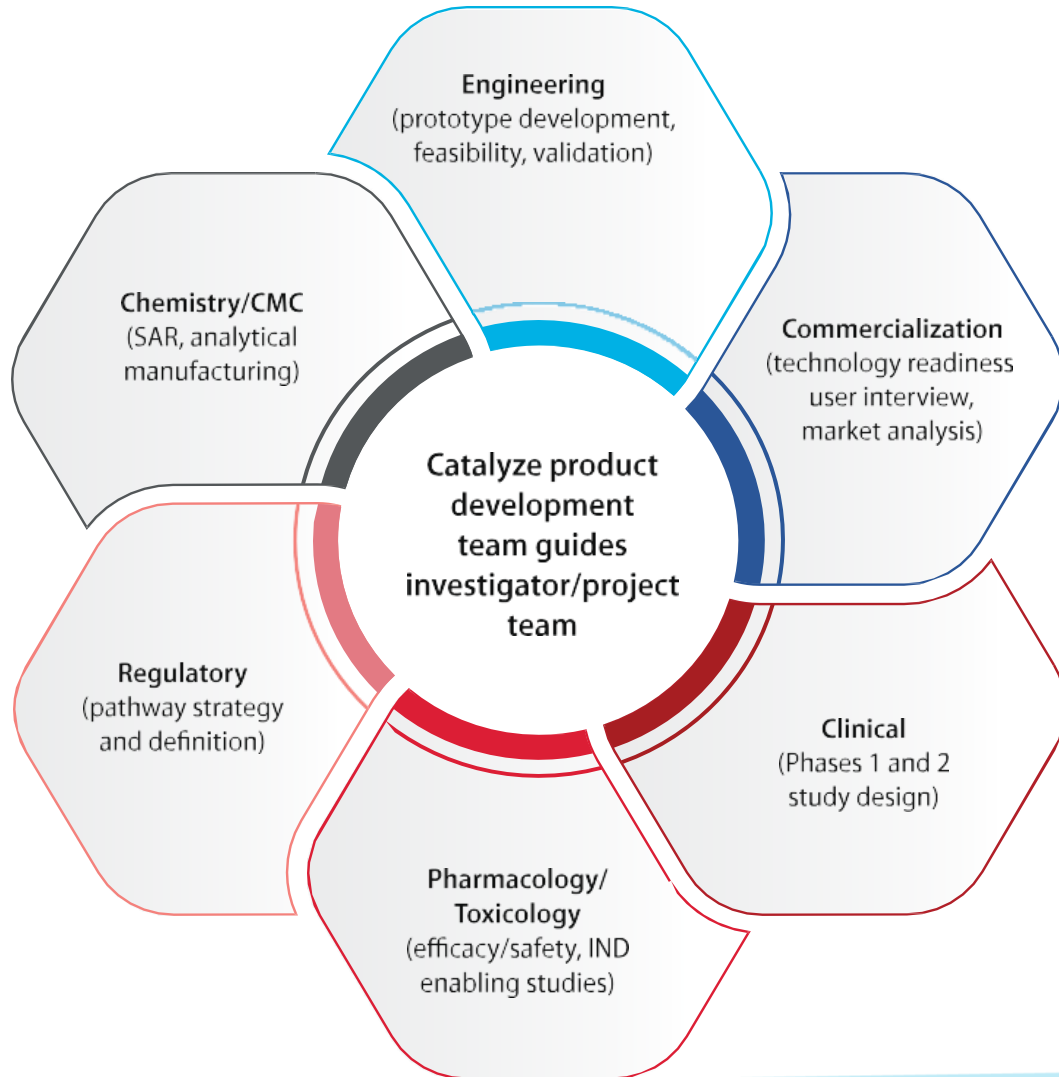


**[nhlbicatalyze.org](https://nhlbicatalyze.org)**

# Catalyze Program Components



# Catalyze provides product development support to PIs with Product Definition grants and Preclinical Service support.



## Therapeutics

Chemistry/CMC  
Pharmacology  
Assay development  
Toxicology

## Devices

Prototype development  
Design verification and validation

## Regulatory Affairs

Strategy development  
FDA meetings and submissions

## Commercialization Support

End-user interviews  
Market analysis  
Commercialization plan



# Where does your project fit in Catalyze?

Have you identified your product and its indication?

No

Yes

## Prerequisite Activities for Product Definition Support

### Device

- Medical device conceptual design initiated

### Therapeutics, cell/gene therapies

- Mechanism of action confirmed
- In vivo proof of concept testing done

## Prerequisite Activities for Preclinical Services Support

### Device

- Prototype lock
- Validation and verification testing
- Q submission meeting before GMP manufacturing
- Development/regulatory plan
- Vendor quotes for services requested

### Therapeutics, cell/gene therapies

- Lead compound/agent or cell characterized
- Demonstration of in vivo efficacy
- Pre-IND meeting before requesting GLP or GMP activities
- Development/regulatory plan
- Vendor quotes for services requested

## Product Definition Grant Activities

### Device Activities

- Prototype design development and testing
- Early feasibility testing
- Animal testing (if applicable)
- Initial validation/verification testing
- Q-submission meeting (if applicable)

### Therapeutics, cell and gene therapies

- Lead optimization studies
- ADME/PK studies
- In vivo efficacy studies
- Synthetic optimization and non-GMP manufacturing
- Cell line development
- Dose range finding toxicity
- Pre-IND meeting

Need more data/information

Need regulatory meeting for GLP/GMP services

No

Yes

## Regulatory only services

## Preclinical Services that can be requested

### Device Activities

- Prototype to GMP manufacturing
- Validation and verification testing
- Animal testing (if applicable)
- Observational studies
- IDE/510K support

### Therapeutics, cell/gene therapies

- Dose range finding studies
- GLP toxicology studies
- Non-GMP manufacturing
- Analytical/Bioanalytical studies
- GMP manufacturing
- Pre-IND meeting
- IND support

Submit proposal through the NIH ASSIST system.

Submit online EOI through Catalyze.org website

# New support from Catalyze: Regulatory Services

- Regulatory support can include:
  - Reviewing data and performing a gap analysis
  - Nonclinical or manufacturing development planning
  - Developing a regulatory strategy
  - Preparing for a meeting with the FDA
  - Assembling documents for FDA meetings (Q-sub, pre-IDE, pre-IND)
  - Quality Management System
  - Preparing an IND/IDE/510k application for the FDA
- Applicants cannot apply for Regulatory Services if already in the Catalyze Program (Product Definition grant or Preclinical Services) or have a pending Preclinical EOI or application under review.
- Two step application process: EOI, invitation to submit application
- Applicant must meet the eligibility criteria, which includes:
  - Technology Readiness Level 1-6
  - US-based academic, non-profit institutions, and US-owned for-profit institutions





# Applying for Catalyze Preclinical Services and Regulatory Support



About ▾ FAQ Resources Events ▾ Newsletter [Subscribe](#)

We are accepting stand-alone rolling Regulatory Expression of Interest form submissions.

Catalyze application submissions:



**Product Definition**

Apply by: Jun 18, 2025



**Preclinical EOI**

Future Submissions



**Regulatory EOI**

Rolling Submissions

**NHLBI Catalyze Program:** Transforming basic scientific discoveries into viable therapeutics, devices, and diagnostics to treat heart, lung, blood, and sleep diseases and disorders

EOI and full application are available to download at:

[www.nhlbicatalyze.org/preclinical](http://www.nhlbicatalyze.org/preclinical)

[www.nhlbicatalyze.org/regulatory](http://www.nhlbicatalyze.org/regulatory)

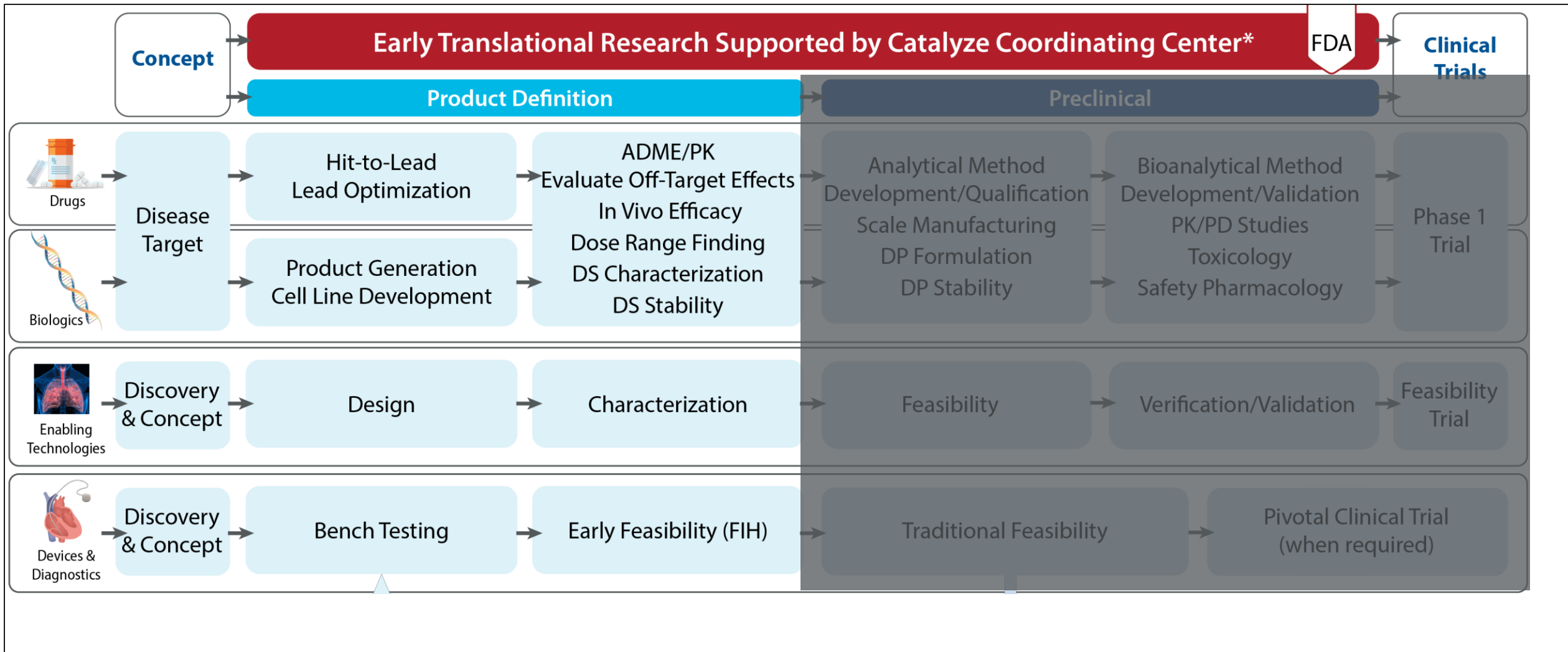
Two step application process:

- Submit online Expression of Interest (EOI)
- Select applicants are invited to submit a full application online





# Catalyze Product Definition Opportunities



# Product Definition Funding Opportunities

>> Next application deadline June 18, 2025

## Enabling Technologies

- ▶ Product Definition for Enabling Technologies & Transformative Platforms for HLBS Research
  - [RFA-HL-26-016](#)
  - R33 (direct to R33)
  - R33 Exploratory/Developmental Grants Phase II

Note: Foreign subawards not allowed:

[NOT-OD-25-104: Updated NIH Policy on Foreign Subawards](#)

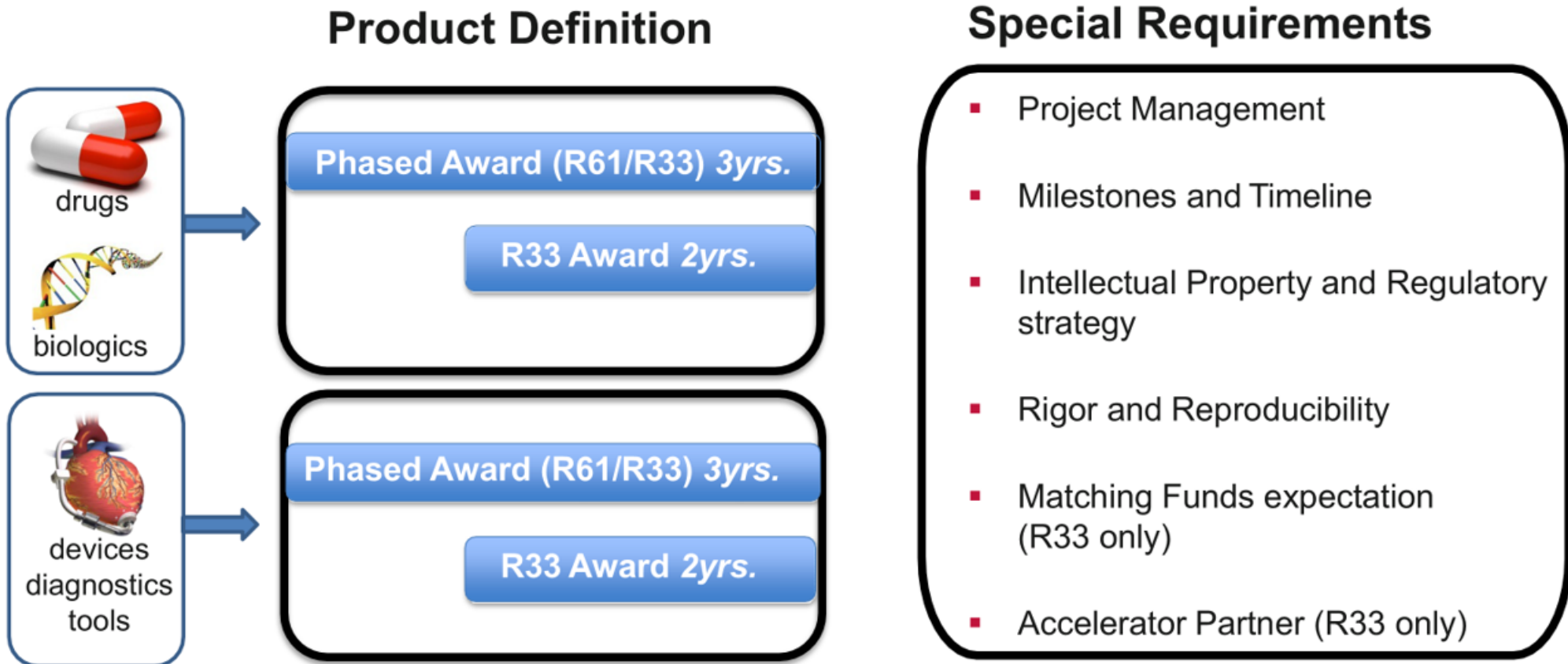
## Small Molecules, Biologics & Combination Products

- ▶ Target Identification & Validation & Preliminary Product/Lead Series Identification
  - [RFA-HL-26-017](#)
  - R61/R33 (phased award)
  - Exploratory/Developmental Phased Award
- ▶ Preliminary Product/Lead Series Identification & Combination Product Prototype
  - [RFA-HL-26-018](#)
  - R33 (direct to R33)
  - R33 Exploratory/Developmental Grants Phase II

## Devices & Diagnostics

- ▶ Medical Device Prototype Design/Testing & Disease Target Identification & Assay Development
  - [RFA-HL-26-019](#)
  - R61/R33 (phased award)
  - Exploratory/Developmental Phased Award
- ▶ Medical Device Prototype Optimization
  - [RFA-HL-26-020](#)
  - R33 (direct to R33)
  - R33 Exploratory/Developmental Grants Phase II

# Product Definition Special Requirements



# Product Definition for **Enabling Technologies & Transformative Platforms**

## Enabling Technologies & Transformative Platforms for HLBS Research

- [RFA-HL-26-016](#)
- **Grant Mechanism:** R33
- **Duration:** 2 years
- **Budget:** \$350,000 direct costs/year
- **Special Requirements:** None

## Funding Opportunity Purpose:

- Develop enabling technologies & transformative platforms to drive next-gen predictive, diagnostic & therapeutic solutions
- Advance early detection, screening, model development, diagnosis, treatment, prevention & epidemiology
- Prior feasibility & a rigorous validation plan to ensure robustness & reproducibility is required
- Projects applying existing technologies where the novelty lies in the biological or clinical target are not eligible



# Product Definition for Small Molecules, Biologics & Combination Products

## Target Identification & Validation & Preliminary Product/Lead Series Identification

- [RFA-HL-26-017](#)
- **Grant Mechanism:** R61/R33
- **Duration:** 3 years
- **Budget:** \$400,000 direct costs/year
- **Special Requirements:**
  - To transition to R33 phase:
    - Accelerator partner
    - At least **0.25:1** non-Federal matching funds

## Preliminary Product/Lead Series Identification & Combination Product Prototype Development

- [RFA-HL-26-018](#)
- **Grant Mechanism:** R33
- **Duration:** 2 years
- **Budget:** \$400,000 direct costs/year
- **Special Requirements:**
  - Accelerator partner
  - At least **0.25:1** non-Federal matching funds



# Product Definition for Medical Devices & Diagnostics

## Prototype Design/Testing & Disease Target Identification & Assay Development

- [RFA-HL-26-019](#)
- **Grant Mechanism:** R61/R33
- **Duration:** 3 years
- **Budget:** \$300,000 direct costs/year
- **Special Requirements:**
  - To transition to R33 phase:
    - Accelerator partner
    - At least **0.25:1** non-Federal matching funds

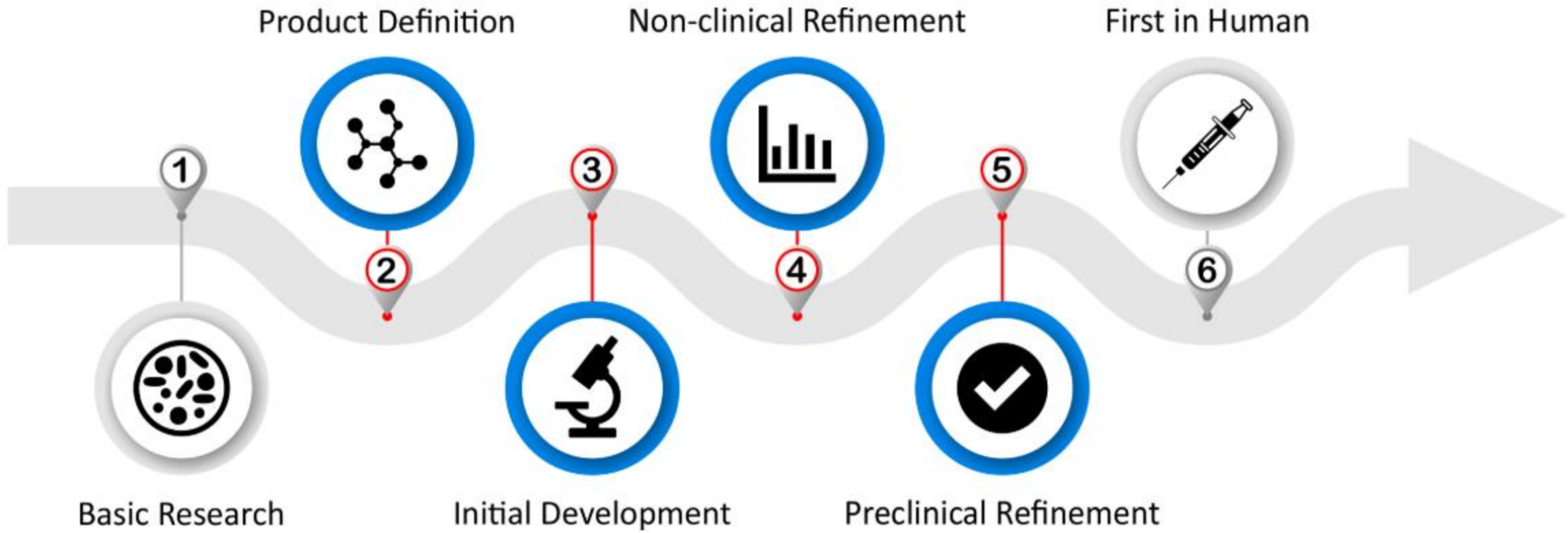
## Medical Device Prototype Optimization

- [RFA-HL-26-020](#)
- **Grant Mechanism:** R33
- **Duration:** 2 years
- **Budget:** \$300,000 direct costs/year
- **Special Requirements:**
  - Accelerator partner
  - At least **0.25:1** non-Federal matching funds





# Product Definition in the Development Process



# Examples of Funded Catalyze Projects

Product Type	Grant Type/ Year Funded	Grant Number	Title
Therapeutics	R61/R33 2024	1 R61 HL171786-01	Adeno-associated virus-mediated SGPL1 gene therapy as a first-in-class treatment for idiopathic pulmonary fibrosis that acts by reducing sphingosine-1-phosphate and downstream profibrotic signaling
Therapeutics	R33 2022	1R33HL163718-01	The genetically engineered pig heart as a bridge to allotransplantation in infants
Device	R61/R33 2021	4 R33 HL156508-02	Rapid platelet dysfunction detection in whole blood samples using machine learning powered micro-clot imaging
Device	R33 2024	1 R33 HL171782-01	Continued Clinical Development of a Novel Pleural and Tracheal Sealant
Enabling Technology	R33 2025	1R33HL173898-01A1	Development of platform technology to measure kinetics and equilibrium concentration of sickle hemoglobin polymerization in single RBCs for drug potency assessment and patient risk stratification
Enabling Technology	R33 2021	1R33HL154123-01	Development of a next-generation glycomics platform to enable glycan structure analyses for precision medicine

For information on additional funded projects visit:  
[www.nhlbicatalyze.org/faq/product-definition/funded-projects](http://www.nhlbicatalyze.org/faq/product-definition/funded-projects)



## Questions Submitted:

1. Can you provide information about this program versus a traditional NIH R01 or and SBIR, with regards to requirements, review process, funds and accelerator partners?
2. Should the Grant application be submitted through an academic institute or a startup?
3. Our last grant application was not funded; how can we submit a better application next time?
4. Can a private company be an accelerator partner? What counts towards matched support?
5. Can start-up companies or small businesses apply?
6. Is it ok to submit a Catalyze grant and an SBIR Phase II application in the same cycle?
7. If an SBIR grant was awarded a PI within a small business, is it possible for the same PI to apply for a Catalyze grant?
8. What can the Catalyze program do to help get a product through final design and engineering?
9. How do you identify accelerator partners, and what type of IP arrangements are typical?



Website: [www.nhlbicatalyze.org](http://www.nhlbicatalyze.org)

## NHLBI Catalyze Information

- Email: [NHLBI\\_catalyze@mail.nih.gov](mailto:NHLBI_catalyze@mail.nih.gov)
- Catalyze Product Definition funding announcements [Catalyze - FAQ](#)
  - ▶ Application Deadlines: Feb 11, June 18, Oct 21
  - ▶ Eligibility: US academic, non-profit and for-profit institutions
  - ▶ [NHLBI Catalyze FAQ page](#)



### In This Issue:

- [Missed a recent webinar? Catch up on our website.](#)
- [NHLBI Catalyze: Did you know?](#)
- [Welcoming New Catalyze Product Definition Awardees](#)
- [Catalyze Team Spotlight](#)
- [Biotech Blueprint - Strategies for Entity Formation and Founder Agreements Webinar](#)
- [Apply for Catalyze Support: July 22nd Product Definition Receipt Date](#)

### Missed a recent webinar? Catch up on our website.

The Art of Market Sizing: Defining your Technology's Opportunity, presented by Emily Vernon, MMB and Brailey Fatts, MSc

#### Link to Recording

Medical product innovators whose goal is to see their product reach the market require a comprehensive understanding of the technology's potential to be adopted, which includes getting the technology's opportunity through market sizing. This goal if this webinar was to explain the importance of market sizing, when to perform during development, different methods as well as resources for conducting market sizing.

Don't Wait Until It's Too Late: Target Product Profiles and Avoiding

### NHLBI Catalyze: Did you know?

As of June 2024, the Catalyze Coordinating Center hosted 603 meetings with funded investigators and their teams:

**68**  
Projects

- 59 Product Definition  
- 9 Preclinical

**178**  
Technical Meetings

- 27 Chemistry/CMC  
- 99 Regulatory  
- 41 Nonclinical  
- 51 Business Development/ commercialization

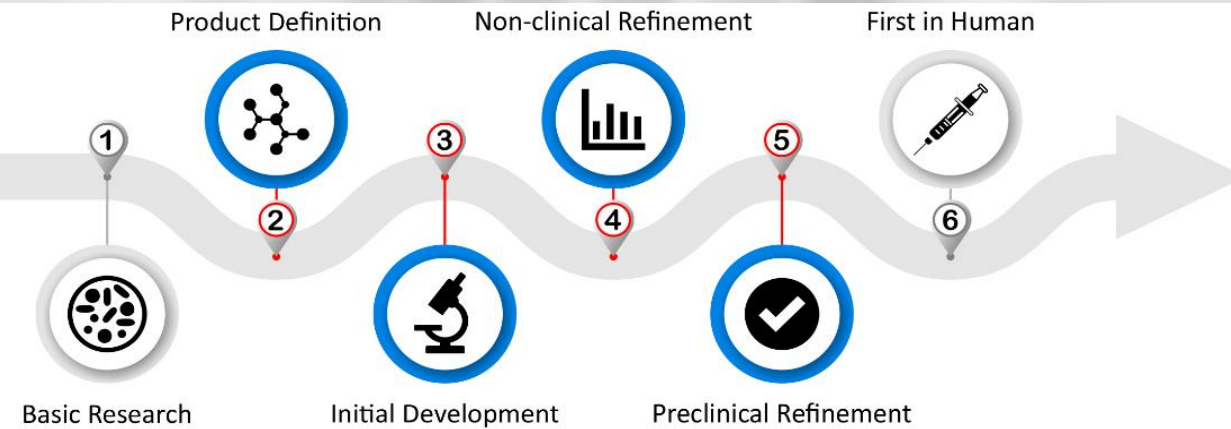
# Q&A







## Strategy



### Funding:

Leverage NHLBI investment with matching commitments and flexibility

### Coordinated approach:

Seamless continuum of programs from product definition to first-in-human trials

### Individualized support:

Milestone-driven project management and support to mitigate technical risk

### Program flexibility:

Early identification of trends and challenges across the program (pivot) and disseminate lessons-learned