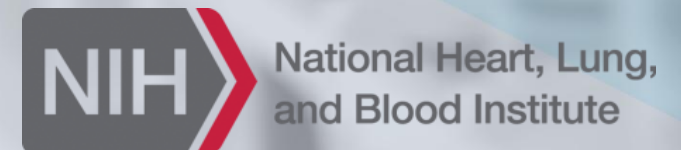




# Catalyze Programs and Funding Opportunities

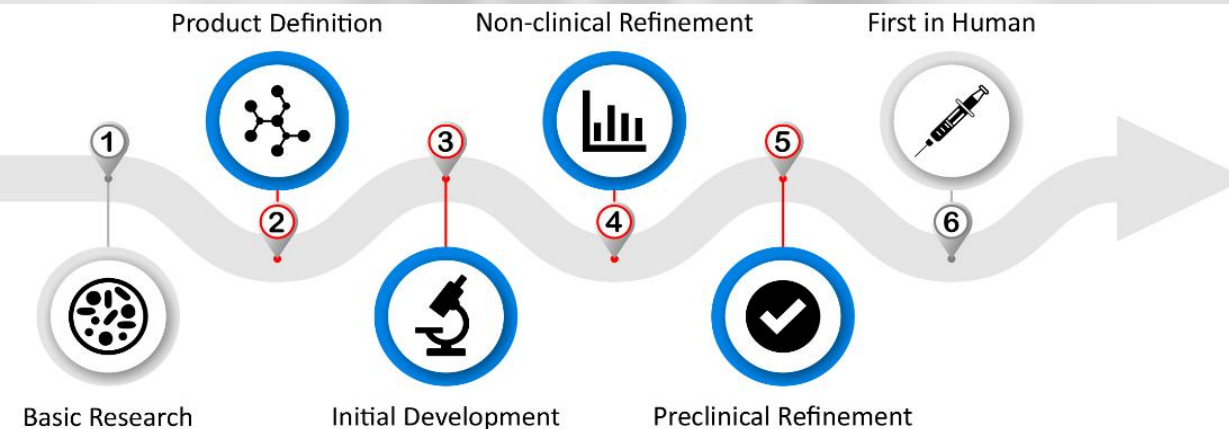
Mike Pieck, Rahul Thakar, Nitin Agrawal, and Tom Hu, NHLBI  
Diana Severynse-Stevens and Sudie Rowshan, RTI

January 9, 2026





## Program Strategy



### **Third-party coordinating center (RTI International) complements and expands awardee's expertise**

Consistent, high-touch support and streamlined access to resources including subject matter experts.

### **Leveraged federal investment with broader impact**

Funding model includes expectation of matching commitments and collaborations with accelerator partners who bring commercialization expertise expanding the reach of each grant dollar spent.

### **Seamless continuum of translational pathways**

Integrates different stages of development into a unified framework, offering a clear and coordinated path through product development from validation to first-in-human trials.

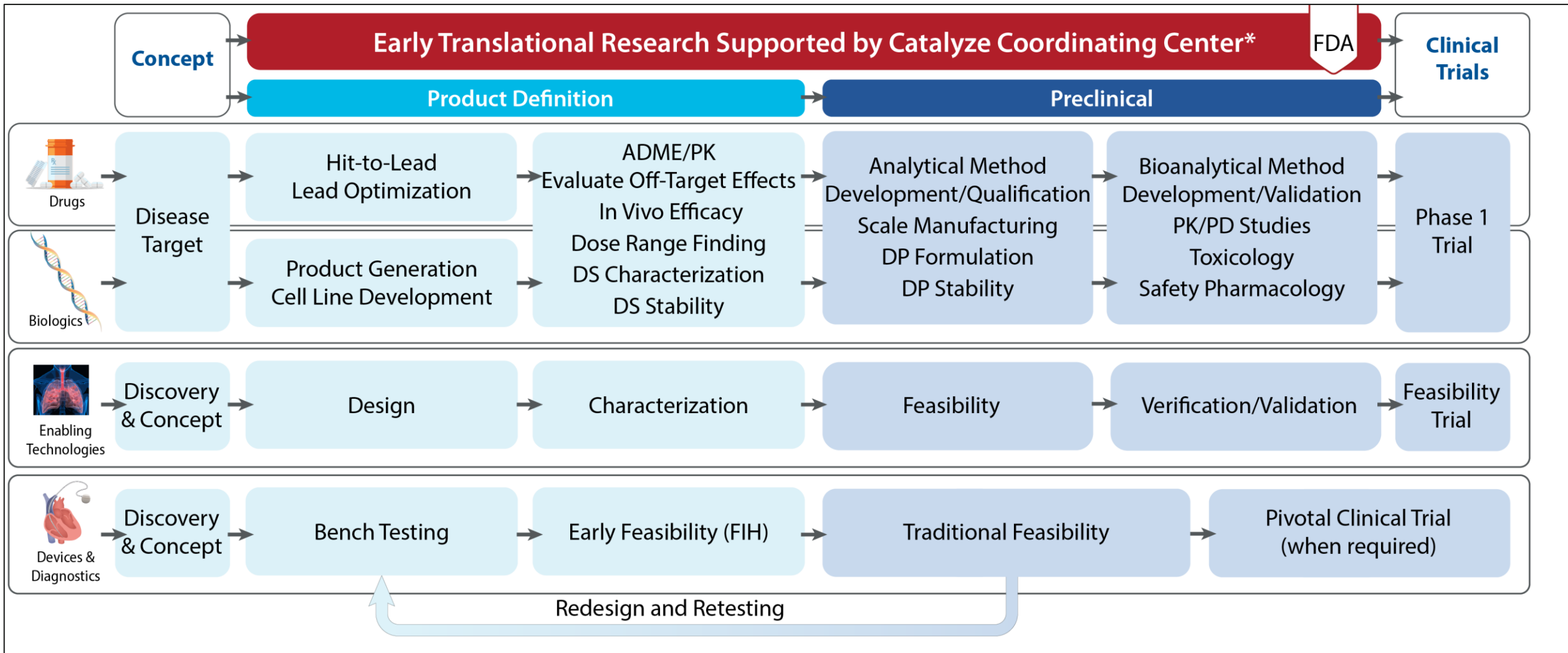
### **Milestone-driven, individualized project management**

Each project benefits from customized, milestone-based planning and active project management tailored to its specific needs, which helps proactively identify risks and pivot support when needed keeping projects on track more effectively.

### **Flexibility and adaptability**

Monitoring trends and challenges across projects allows dynamic adjustment of support strategies. Ability to pivot funding and resources quickly allowing the program to be responsive.

# Components of the Catalyze Program



# 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 2026:** 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)**

## Eligibility: Catalyze vs. SBIR/STTR

	Catalyze	SBIR	STTR
<b>Work Requirement</b>	Outsourcing to contract organizations is allowed/encouraged	Small businesses may outsource: <ul style="list-style-type: none"> <li>• 33% of Phase I research</li> <li>• 50% of Phase II research</li> </ul>	Minimum work requirements: <ul style="list-style-type: none"> <li>• 40% by small business</li> <li>• 30% by research institution partner</li> </ul>
<b>Principal Investigator</b>	Must be employed at a U.S.–based organization	Primary employment (>50%) should be with the small business	Must be employed by either the partnering research institution or the small business
<b>Partnerships</b>	Partnerships are allowed <b>R33 awardees are required</b> to partner with an Accelerator	Research partnerships are allowed	Partnership with a non-profit research institution (e.g., a university) is required
<b>Org. type:</b>	Must be U.S.–based for profit or non-profit organization	U.S.–owned for profit SBC	U.S.–owned for profit SBC

### There are many similarities between a SBIR/STTR Phase I/II application and the Catalyze Product Definition grant funding submission

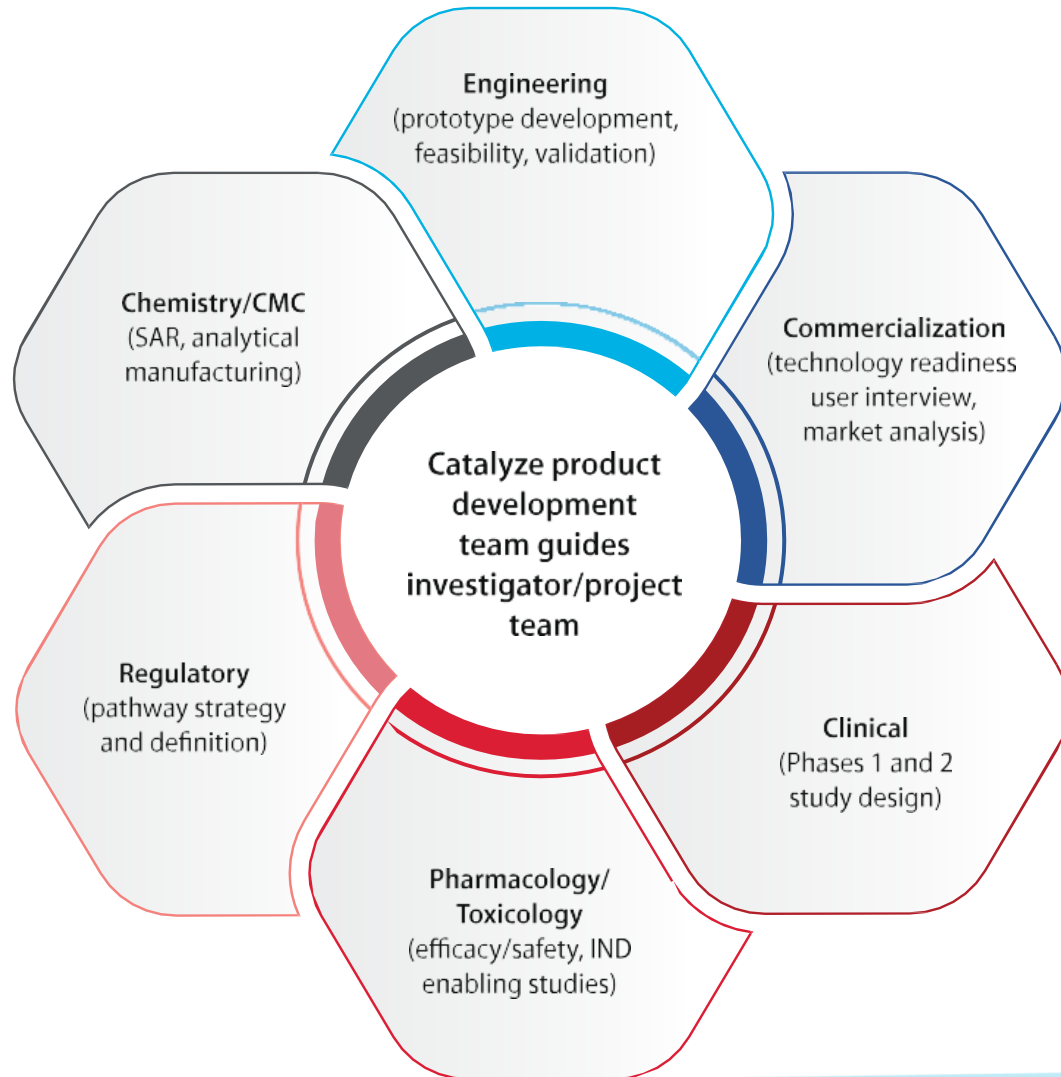
- ▶ Aims focus on validation, feasibility, and generating data aligned with regulatory (FDA) and commercialization vs hypothesis driven research
- ▶ Milestones and clear go/no-go criteria
- ▶ Generation and protection of IP and a commercial exit

#### **Catalyze specific:**

- IP and regulatory strategy required
- Project manager required
- More defined milestones and go/no-go criteria become terms of award
  - ▶ Required to meet quarterly to review progress toward milestones
- Matching funds for more advanced projects are expected
- Separate Commercialization plan not required



# 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

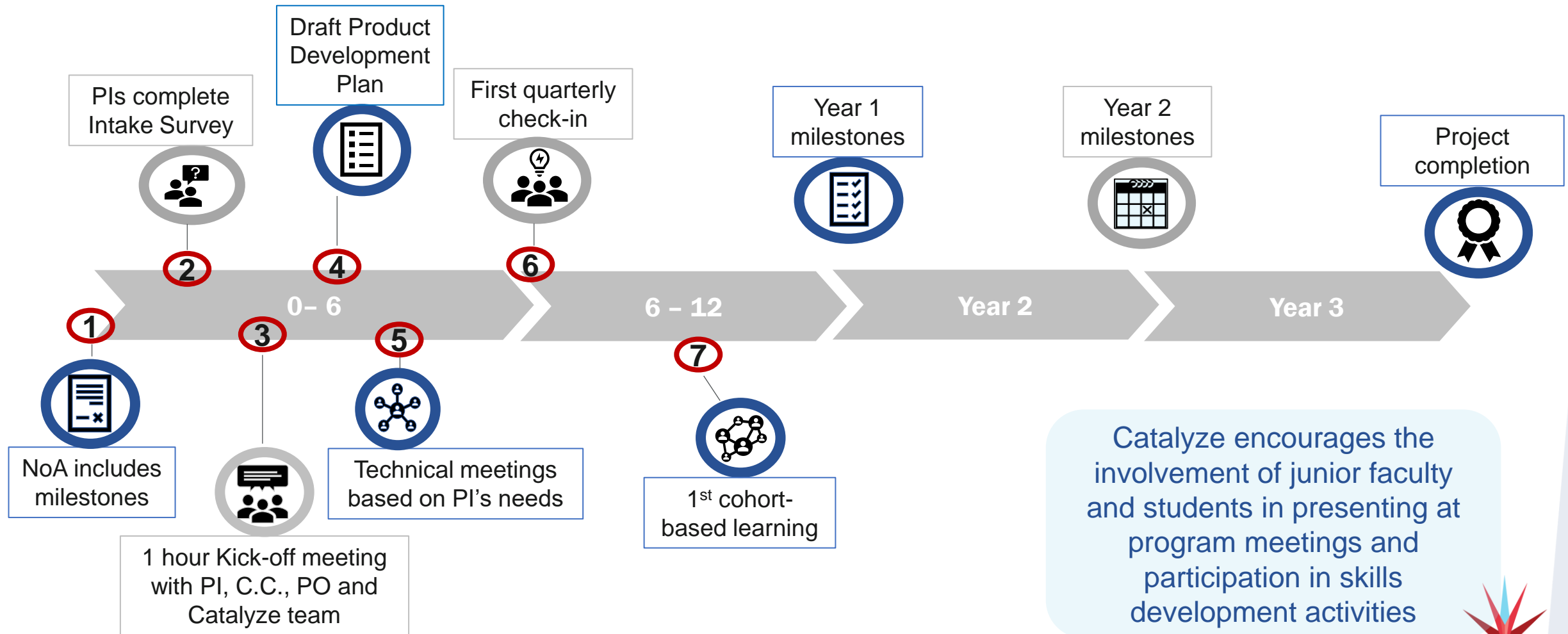
Strategy development  
FDA meetings and submissions

## Commercialization Support

End-user interviews  
Market analysis  
Commercialization plan



# What to Expect as a Catalyze Awardee-Product Definition





# Assessing Your Project's Fit for Catalyze Support

## Where Does Your Project Fit in Catalyze?

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Have you identified your product and its indication?

✓ Yes

✗ No



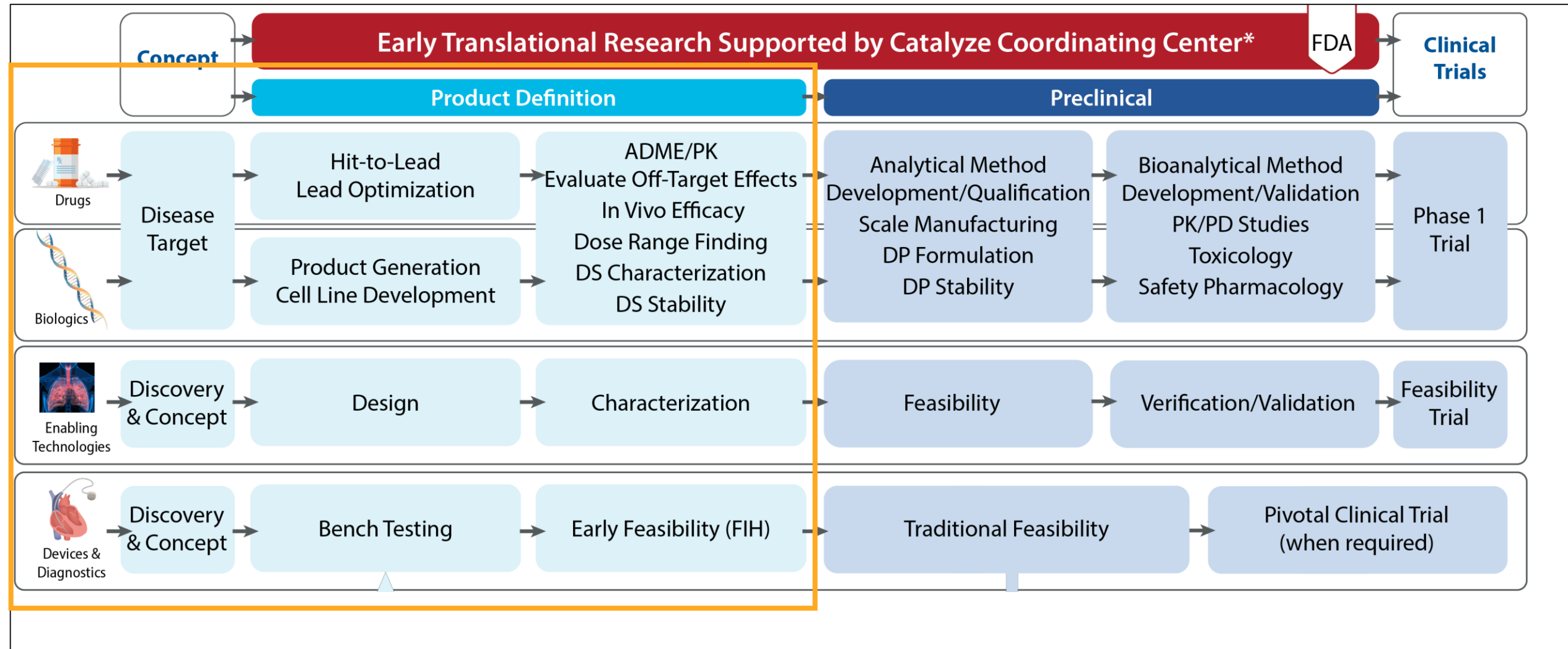
NHLBI\_catalyze@mail.nih.gov  
catalyze\_application@rti.org



nhlbicatalyze.org/helpwithfit  
nhlbicatalyze.org/FAQ



# Catalyze Product Definition Opportunities





# Product Definition Funding Opportunities

## Next application deadline **February 11, 2026**

U.S.-based academic, non-profit institutions & U.S.-owned for-profit institutions are eligible to apply via [grants.gov](https://www.grants.gov).

### 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

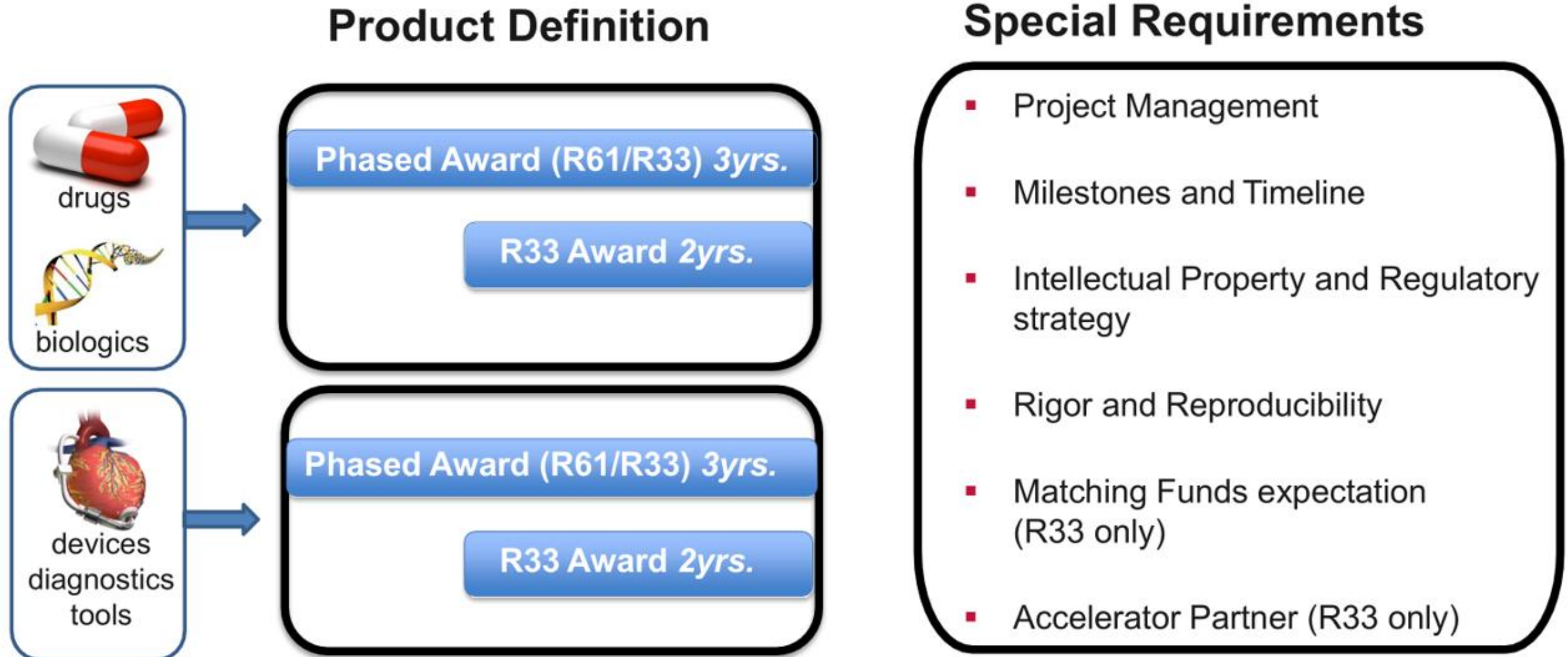
### Small Molecules, Biologics & Combination Products

- ▶ 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

# Special Requirements for Product Definition Awards



# 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:

1. Submit online Expression of Interest (EOI)
  - Next EOI submission window is January 26–February 13
2. Selected applicants are invited to submit a full application online





# Catalyze Preclinical Services

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

- **How the Program Works**

- ▶ Service-based, not grant-based funding
  - Preclinical services are provided by CROs/CDMOs and managed by RTI
  - Funds are not awarded to the applicants
  - Investigators should expect additional commercialization milestones and active project management by RTI

- **Regulatory Requirements**

- ▶ No GLP/GMP work will be supported before a pre-submission meeting
- ▶ You may request regulatory support to prepare for an FDA meeting
- ▶ Preclinical scope must align with your stage of development and regulatory readiness

- **What to Submit**

- ▶ Required for review:
  - Accurate CRO/CDMO quote or cost estimate
    - ▶ If missing, application is deemed unresponsive and will not proceed to peer review
  - Current Certificate of Analysis (for nonclinical work)
  - Stability data (for nonclinical work)

- **Budget Expectations**

- ▶ No formal budget cap, however:
  - In general, projects >\$1M/year are not supported
- ▶ Budget must be:
  - Well-justified
  - Aligned with defined preclinical milestones
  - Supported by CRO/CDMO quote



# 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 or Preclinical Services awardee
  - Preclinical EOI or application under review
- Two step application process:
  1. EOI submission
  2. Invitation to submit application
- Applicants must meet eligibility criteria:
  - Technology Readiness Level 1-6
  - US-based academic, non-profit institutions, and US-owned for-profit institutions





# Examples of Funded Catalyze Product Definition Projects

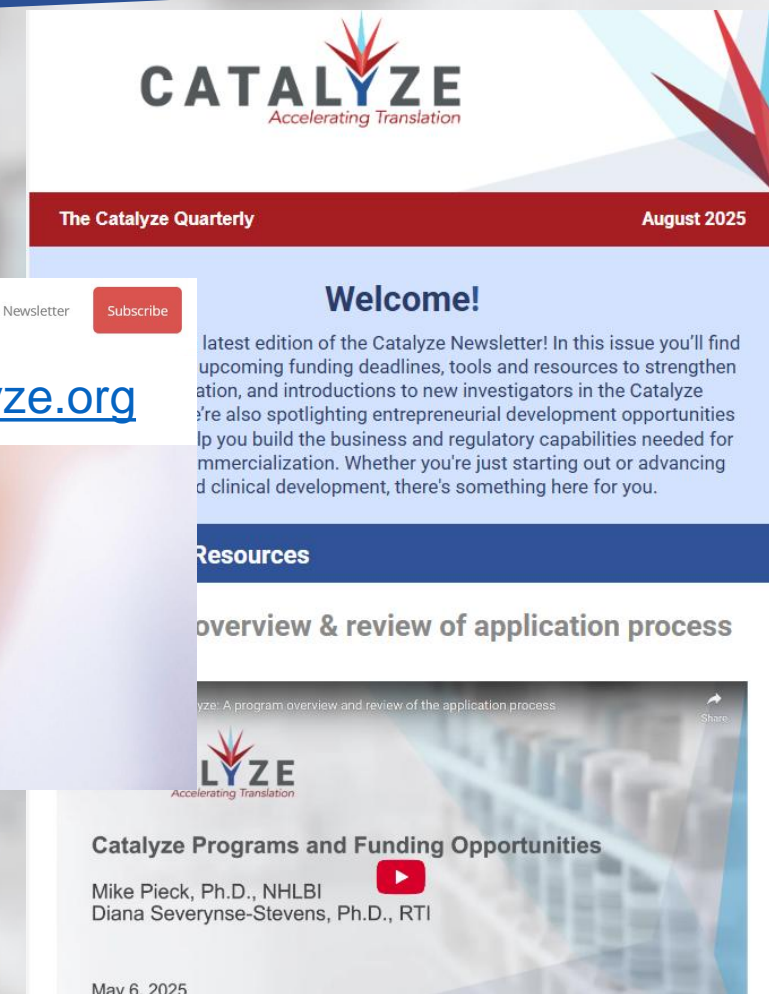
Product Type	Grant Type Year Funded	Grant Number	Title
Therapeutic	R61/R33 2024	1 R61 HL171786-01	Adeno-associated virus-mediated SGPL1 gene therapy as a first-in-class treatment for idiopathic pulmonary fibrosis that acts by reducing sphingosine-1-phosphate and downstream profibrotic signaling
Therapeutic	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: [nhlbicatalyze.org/faq/product-definition/funded-projects](https://nhlbicatalyze.org/faq/product-definition/funded-projects)



# Q&A

- Reach out via email:
  - ▶ [NHLBI\\_catalyze@mail.nih.gov](mailto:NHLBI_catalyze@mail.nih.gov)
  - ▶ [catalyze\\_info@rti.org](mailto:catalyze_info@rti.org)
- 2026 Application Deadlines:
  - ▶ Product definition via **grants.gov**
    - February 11
    - June 18
    - October 21
  - ▶ Preclinical EOIs via **[nhlbicatalyze.org/preclinical](https://nhlbicatalyze.org/preclinical)**
    - January 26–February 13
- Eligibility: U.S. academic, non-profit, and for-profit institutions
- [FAQ page](#)



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# 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

