Catalyze Regulatory EOI - Version 12 - 2026.11.09

Applicant Last Name: _____

Project Title: _____

Date of Submission: _____

Section 1: Contact Information

Provide contact information for the principal investigator (PI) of this application. If the PI has designated a representative to submit the proposal on their behalf, please enter the designee's contact information as well.

1. Project Title: _____
2. Is this a resubmission of a proposal for a project for which support was previously sought under Catalyze? ☐ Yes ☐ No
3. Principal Investigator (Last Name, First Name): _____
4. Organization: _____
5. Title: _____
6. Department (or Discipline): _____
7. Street Address: _____
8. City: _____
9. State: _____
10. Zip code: _____
11. PI email address: _____
12. PI telephone number: _____
13. Name and contact information for corresponding organizational representative, if not the PI: _____
14. How did you learn about Catalyze? (Select all that apply):

☐ NIH/NHLBI website
☐ NHLBI Catalyze website
☐ NIH Translational Program(s)
☐ Catalyze event
☐ My institution/department
☐ My technology transfer office
☐ Scientific conference or news article
☐ NIH Program Officer
☐ Other (Please specify): _____

Section 2: PI Demographic Profile

Your responses to the following questions allow the Catalyze Coordinating Center to better understand the demographic profile of investigators interested in Catalyze award programs. Your responses to these questions have no influence on proposal selection and will not be shared with reviewers.

15. Position or title: _____
16. Terminal Degree: _____
17. Year of Terminal Degree (or Expected Completion Year): _____

18. Has your professional experience to date been characterized by any of the following? Select all that apply:

- ☐ Been granted a copyright, patent, or trademark
- ☐ A patent has been issued
- ☐ Licensed your technology to another party
- ☐ Applied for funding from a translational research, proof-of-concept, or commercialization support program—other than Catalyze
- ☐ Received funding from a translational research, proof-of-concept, or commercialization support program—other than Catalyze
- ☐ Founded a start-up company

Section 3: Technology Profile

Provide the following information about the project for which Catalyze assistance is sought.

19. Disease area (select all that apply):

- ☐ Blood
- ☐ Cardiovascular/Heart
- ☐ Lung
- ☐ Sleep

20. Technology Type (select one):

- ☐ Biologic
- ☐ Drug
- ☐ Combination product
  - Is the combination product with a device? ☐ Yes ☐ No
- ☐ In vitro diagnostic
- ☐ Health information technology
- ☐ Research tool
- ☐ Gene Therapy
- ☐ Cell Therapy
- ☐ Medical device

If medical device or combination product with device:

- Do you have data supporting feasibility? ☐ Yes ☐ No
- Are you in design lock? ☐ Yes ☐ No
- Does this request involve a device with a modification of a product on the market? ☐ Yes ☐ No
- If yes, does the PI own rights to the data and/or product to be changed? ☐ Yes ☐ No

21. What type of regulatory support are you requesting from the Catalyze Program over the next **6 to 12 months**? Please briefly describe your specific needs, expected outcomes, and how this support will advance your program toward an initial regulatory submission. (50-word limit)

_____

Select up to 3 areas of support.

Please note: The Catalyze Coordinating Center provides strategic input and document review but does not serve as the primary author of regulatory submissions or briefing materials.

- ☐ Regulatory strategy development (through initial submission milestone)
- ☐ Data review and gap analysis for regulatory readiness
- ☐ Review and feedback on FDA briefing materials prepared by the applicant (e.g., pre IND, Q sub, pre-Sub)
- ☐ Preparation for FDA meetings (strategy, materials, rehearsal)
- ☐ Review of IND/IDE/510(k) submission documents and electronic submission to FDA
- ☐ Other (please specify) _____

22. What is the specific technology or product (50-word limit)? _____

23. What is the indication (50-word limit)? _____

24. If the project is for a therapeutic, what is the target (e.g., Kinase, Receptor, Protein, Mechanism of Action) for the product (50-word limit)?

_____

25. In two or three sentences, what is the technical goal of the project (50-word limit)?

_____

26. Indicate the status of intellectual property protection for this technology

- ☐ No invention disclosure filed with technology transfer office (or equivalent)
- ☐ Invention disclosure filed with TTO (or equivalent)
- ☐ A patent application has been submitted
- ☐ A trademark has been registered
- ☐ A copyright has been granted
- ☐ Patent has been issued

For devices (including in vitro diagnostics) and combination products:

Does your device incorporate intellectual property (IP) from another component?

☐ Yes ☐ No ☐ Not Applicable

If yes, do you have the necessary rights or freedom to operate? Please explain.

_____

27. Do you have efficacy data in a relevant animal model by the route of administration to be used in the clinic? Please describe relevant efficacy data in the Project Description below.

☐ Yes ☐ No ☐ Not Applicable ☐ Other (please specify)

28. For device (including in vitro diagnostics), have you confirmed conceptualization and proof of concept via prototyping of all or part of the conceived product with supporting data (i.e., animal or known-sample studies) and documentation? Has a Design History File been created?

☐ Yes ☐ No ☐ Not Applicable ☐ Other (please specify)

29. **Project Description**. In 1,000 words or less, please provide an overall description of your project. Include the project purpose or objective, therapeutic relevance to the NHLBI mission, a description of preliminary studies, a concise description of the studies you are proposing, the unmet market need or innovation to potentially change standard of care, and commercialization path.

_____

30. Explain why support for this project is sought from NHLBI and the Catalyze program as opposed to private sector or other sources of support.

_____

Section 4: Prior Technology Development Support

The following questions request information about the funding and translational program support history for the technology to be developed under the proposed project. Please provide information about NIH and non-NIH support. Please also indicate whether the principal investigator and/or the technology have been supported by any NIH translational programs.

31. Were any earlier translational or product development stages supported by any of the following NIH-sponsored translational programs? (select all that apply):

- ☐ Bioengineering for HLBS
- ☐ CADET II
- ☐ Catalyze - Product Definition
- ☐ Catalyze - Preclinical
- ☐ Catalyze - Regulatory
- ☐ Excellence in Hemoglobinopathies
- ☐ Large Animal Blood Disease Core
- ☐ Molecular Imaging of the Lung
- ☐ NCAI (B-BIC, UC CAI, or NCAI-CC)
- ☐ NIGMS STTR Tech Transfer Hubs (ASCEND, DRIVEN, SHARP Hub, Southeast Xlerator Network)
- ☐ POCTRN (CAPCat)
- ☐ Preclinical GTPR
- ☐ Preclinical SMARTT
- ☐ Pulmonary Vascular-RV Axis
- ☐ REACH 2015 (UofL ExCITE, MN-REACH, or LIBH)
- ☐ REACH 2019 (KYNETIC, MBArC, ROI, CO-SPARK, or WE-REACH)
- ☐ REACH 2023 (CBC HITES, GCC, Mid-South, Rocky Mountain or UM-BILD)
- ☐ SBIR/STTR
- ☐ Thrombotic and Hemostatic Centers
- ☐ tPPG
- ☐ Transformative Platforms
- ☐ VITA
- ☐ None of the above
- ☐ Other (Please provide name of NIH opportunity or program): _____