



Catalyze Regulatory Application Version.6 2024.10.22

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):

- | | |
|---|--|
| <input type="checkbox"/> NIH/NHLBI website | <input type="checkbox"/> My technology transfer office |
| <input type="checkbox"/> NHLBI Catalyze website | <input type="checkbox"/> Scientific conference or news article |
| <input type="checkbox"/> NIH Translational Program(s) (e.g., REACH, NCAI, SMARTT, CADET II) | <input type="checkbox"/> NIH Program Officer |
| <input type="checkbox"/> Catalyze event | <input type="checkbox"/> Other (Please specify): _____ |
| <input type="checkbox"/> My institution/department | |



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. Gender: Do you describe yourself as a man, a woman, or in some other way?

Man Woman Non-binary Prefer not to say

19. Race: What is your race? Please select all that apply

American Indian or Alaska Native White
 Asian Other
 Black or African American Prefer not to say
 Native Hawaiian or Other Pacific Islander

20. Ethnicity: Do you describe yourself as Hispanic or Latino?

Hispanic or Latino (A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race)
 Not Hispanic or Latino
 Prefer not to say

21. Disability Status: Are you disabled?

Disabled Not disabled Prefer not to say

22. 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.

23. Disease area (select all that apply):

- | | |
|---|--------------------------------|
| <input type="checkbox"/> Blood | <input type="checkbox"/> Lung |
| <input type="checkbox"/> Cardiovascular/Heart | <input type="checkbox"/> Sleep |

24. Technology type (select the product type that best reflects your product):

- | | |
|--|---|
| <input type="checkbox"/> Biologic | <input type="checkbox"/> Medical device <ul style="list-style-type: none"> • Are you in or near design lock?
<input type="checkbox"/> Yes <input type="checkbox"/> No • Do you have data supporting feasibility? <input type="checkbox"/> Yes <input type="checkbox"/> No • Are there potential issues with IP?
<input type="checkbox"/> Yes <input type="checkbox"/> No • Is this activity requiring a modification to an approved product already on the market? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <input type="checkbox"/> Drug | |
| <input type="checkbox"/> Combination product | |
| <input type="checkbox"/> In vitro diagnostic | |
| <input type="checkbox"/> Health information technology | |
| <input type="checkbox"/> Research tool | |
| <input type="checkbox"/> Gene Therapy | |
| <input type="checkbox"/> Cell Therapy | |

25. What type of Regulatory support is being requested from the Catalyze Program? Please describe (50-word limit): _____

Do you need assistance with? Please check all that applies

- | | |
|---|--------|
| Preclinical development planning? | Yes/No |
| Developing a regulatory strategy? | Yes/No |
| Reviewing data and performing a gap analysis? | Yes/No |
| Assembling documents for FDA meetings (Q-sub, pre-IDE, pre-IND) | Yes/No |
| Preparing for a meeting with the FDA? | Yes/No |
| Preparing an IND/IDE/510k application for the FDA? | Yes/No |
| Manufacturing development planning? | Yes/No |
| Quality Management System? | Yes/No |
| Other? | Yes/No |

If yes, please describe:

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

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

28. 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)?



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

30. 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
- A patent has been issued

31. 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)

32. For device and 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)

33. **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.

34. 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.



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

- NCAI (B-BIC, UC CAI, or NCAI-CC)
- REACH 2015 (UofL ExCITE, MN-REACH, or LIBH)
- REACH 2019 (KYNETIC, MBarC, ROI, CO-SPARK, or WE-REACH)
- NIGMS STTR Tech Transfer Hubs (ASCEND, DRIVEN, SHARP Hub, Southeast Xlerator Network)
- tPPG
- POCTRN (CAPCat)
- VITA
- CADET II
- Excellence in Hemoglobinopathies
- Molecular Imaging of the Lung
- Thrombotic and Hemostatic Centers
- Pulmonary Vascular-RV Axis
- Preclinical GTRP
- Preclinical PACT
- Preclinical SMARTT
- Transformative Platforms
- Bioengineering for HLBS
- Large Animal Blood Disease Core
- None of the above
- Other (Please provide name of NIH opportunity or program): _____