



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"> <li>• Are you in or near design lock?<br/><input type="checkbox"/> Yes <input type="checkbox"/> No</li> <li>• Do you have data supporting feasibility? <input type="checkbox"/> Yes <input type="checkbox"/> No</li> <li>• Are there potential issues with IP?<br/><input type="checkbox"/> Yes <input type="checkbox"/> No</li> <li>• Is this activity requiring a modification to an approved product already on the market? <input type="checkbox"/> Yes <input type="checkbox"/> No</li> </ul> |
| <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)?

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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.

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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.

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### 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.*

35. Was the discovery phase or any earlier translational stages supported by NIH? If yes, provide the NIH award number, project title, total amount, and award period for each award. (Note: the format of the NIH funding number is R33HLI56279.)

NIH Award Number	Project Title	Total Award Amount	Award Period



36. 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): \_\_\_\_\_

37. Was the discovery phase or earlier stages of product development supported by any **non-NIH** funders (e.g., other federal agencies, foundations, state/regional programs)? Please provide the funding history. Include the name of the agency (or entity), project title, total award amount, and award period for each source of support.

Agency	Award Number	Project Title	Total Award Amount	Award Period



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- 38. Please provide documentation of all non-federal funds received in the last 12 months and any non-federal investments contingent on Catalyze preclinical support (e.g., redacted bank statement, term sheet, letter of support if funds are contingent on selection in Catalyze).
  
- 39. Has the PI or co-PI ever received support (e.g., funding, coaching) from any translational or entrepreneurship program or service, funded by Federal (NIH or other agencies) or non-Federal sources?

Note: this question asks information about the PI and co-PI in general, not the technology for which support from Catalyze is sought.

Yes

If Yes, please describe (50-word limit):

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No

**Supporting Documentation:** You may provide supporting documents for this section. This is optional. Please limit to only key information (e.g. a figure to support a response).

**Appendix. References Cited**

Please provide a list of citations used (i.e., provide only citations without uploading the articles). If you do not have a citation for an article you would like to include, please upload it (preferably in a PDF format)

## Section 5: Basis for the Project

*Please respond to the following questions. Limit responses to no more than 500 words per question, unless otherwise noted.*

40. **Background:** Describe the scope and nature of the problem the therapeutic, device or diagnostic product will be designed to address and give a brief description of the solution. Ensure detailed technical approach is provided.

- For therapeutics, include any early prototype animal studies (efficacy, PK, toxicology studies) and chemistry, manufacturing and controls (CMC) activities (non-GMP and GMP).
- For devices, include any initial design requirements and early-stage animal testing or prototype development, if applicable.

Please attach supporting figures where applicable, and make sure to reference the figure within your text response.

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41. **Unmet Need:** Clearly state the unmet need being addressed by the technology and provide evidence to support the need from multiple stakeholder perspectives (e.g., patient, clinician, payer). How was the unmet need identified/confirmed (e.g., regulator, voice of customer, stakeholder interviews)? \_\_\_\_\_

42. **Proposed Project/Solution:** Describe the proposed solution, the setting in which it will be utilized (e.g., ICU, in-patient, out-patient, primary care physician, etc.), the primary patient population, and proposed indication for use. Characterize the expected benefit from the technology and how it will enhance standard of care (current or predicted) and/or replace the current standard of care. What is the evidence to support the expected benefit? Provide a brief synopsis of your preliminary data.
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43. **Market Size:** Define the total and addressable market size and approximate target price of the technology. Support your market size and descriptions with evidence about current technologies or approaches to address this indication. Define a specific patient segment of those suffering from the specific targeted disease. What are the market population trends and projections?
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44. **Competitive Landscape:** Define the competition mix (e.g., companies, products, processes, procedures, substitutes) for the proposed technology. Focus on how the disease will be treated when the technology/product gets to market. Is the landscape shifting?
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45. **Differentiation:** Explain how the proposed technology will compete in the marketplace relative to the cost of your product compared to commercialized competitive technologies. Provide data to support this. If no preliminary data is available, describe what data would be needed to justify the differentiation. Describe how the proposed product is superior to current options/technologies, including those currently in clinical trials.

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46. **Regulatory Path (if applicable):** Describe the expected regulatory pathway and identify which FDA Center(s) will regulate the technology. Describe foreseeable regulatory risks or accelerated programs that could impact the technology development. Comment on the clinical trial considerations and how those might impact the regulatory approach. Please also include information on technologies that are currently in development. If a Target Product Profile has been developed, please upload.

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47. **Regulatory Consultation (if applicable):** Have you sought regulatory advice from foreign regulators, the FDA, legal counsel, or consultants for the proposed technology? If there have been any communications with the regulators, please upload.

Yes

If yes, please describe. \_\_\_\_\_

No

48. **Reimbursement (if applicable):** Define similar product(s)/service(s) that is (are) currently being covered for the indication your technology targets and identify relevant CPT/DRG/APC Codes and their reimbursement rates. If no code exists, how will the technology be paid for by the end user? \_\_\_\_\_

49. **Intellectual Property:** Describe how the intellectual property (IP) is connected to the commercialization plan. If applicable, describe your interactions with your technology transfer office. Please upload any supporting documentation. \_\_\_\_\_

**Supporting Documentation:** You may provide supporting documents for this section. This is optional. Please limit to only key information (e.g. a figure to support a response).

**Appendix. References Cited**

Please provide a list of citations used (i.e., provide only citations without uploading the articles). If you do not have a citation for an article you would like to include, please upload it (preferably in a PDF format).