Catalyze Regulatory Application Version.8 2025.03.25

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) (e.g., REACH, NCAI, SMARTT, CADET II)
- ☐ 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. Race: What is your race? Please select all that apply

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

19. 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

20. Disability Status: Are you disabled?

- ☐ Disabled
- ☐ Not disabled
- ☐ Prefer not to say

21. 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.

22. Disease area (select all that apply):

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

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

- ☐ Biologic
- ☐ Drug
- ☐ Combination product
- ☐ In vitro diagnostic
- ☐ Health information technology
- ☐ Research tool
- ☐ Gene Therapy
- ☐ Cell Therapy
- ☐ Medical device
  - Are you in or near design lock? ☐ Yes ☐ No
  - Do you have data supporting feasibility? ☐ Yes ☐ No
  - Are there potential issues with IP? ☐ Yes ☐ No
  - Is this activity requiring a modification to an approved product already on the market? ☐ Yes ☐ No

24. What type of Regulatory support is being requested over the next **6 to 12 months** 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:

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

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

27. 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)?

_____

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

_____

29. 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

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.

_____

30. 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)

31. For devices (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)

32. **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.

_____

33. 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.

34. 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

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): _____

36. 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

37. 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).

38. 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):
_____

☐ 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.

39. 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.

    _____

40. **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)?_____

41. **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.

    _____

42. **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?

    _____

43. **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?

    _____

44. **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.

    _____

45. **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.

    _____

46. **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

47. **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? _____

48. **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).