PLEASE NOTE: Attachments that are not referenced in the application or that use unclear naming conventions will not be reviewed. Please limit your uploads to only essential documents as our reviewers have limited time to review many attachments. Make sure all files are clearly labeled and are properly identified.

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. Principal Investigator (Last Name, First Name): _____
3. Organization: _____
4. Title: _____
5. Department (or Discipline): _____
6. Street Address: _____
7. City: _____
8. State: _____
9. Zip code: _____
10. PI email address: _____
11. PI telephone number: _____
12. Name and contact information for corresponding organizational representative, if not the PI: _____
13. 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.

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

17. 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.

18. What barrier does your concept address (select one):

- ☐ Gaps in translating in vitro models for in vivo outcomes
- ☐ Translating humanized mouse models to human studies
- ☐ Uncertain immune tolerance to foreign therapeutic proteins
- ☐ Niche-specific intercellular crosstalk absent in existing models
- ☐ Other (50-word limit)

19. Type of project (select up to 2):

- ☐ Novel viral platforms
- ☐ Non-viral delivery systems
- ☐ Immune evasion technologies
- ☐ Gene editing systems
- ☐ Targeted Lipid Nanoparticle (LNP) Platforms
- ☐ Translational models or assays
- ☐ Other (50-word limit) _____

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

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21. 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

22. **Project Description**. In 1,000 words or less, please provide an overall description of your project **and how it ties into your response for what barrier your concept addresses** (in question 18).
Include the following:
    - Project purpose or objective
    - Details of any preliminary studies conducted
    - Concise description of the proposed studies
    - Proposed high level milestones

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.

23. 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): _____

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.

24. **Background**: Describe the barrier or challenge your project is addressing. Briefly discuss the scope of this barrier, its significance to advancing the field and how it currently limits progress in *in vivo* gene therapy.

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25. **Proposed Barrier Solution**: Describe the proposed solution to the barrier identified above and the significance of the solution. Explain the scientific or technical approach, how it's expected to overcome the barrier, and the potential impact of the solution on advancing the development and translation of *in vivo* gene therapies. (**Limit responses from 750 to 1000 words.**)

Supporting Documentation: You may provide supporting documents for this section. This is optional. Please limit 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 6: Project Plan

Please respond to the following questions. Limit responses to no more than 500 words per question.

26. Using the milestone table below, list the milestones associated with the Catalyze requested tasks (**only for the next 12-18 months period**). Explain how the requested tasks relate to your project's milestones and go/no-go decision points, and how completion of these activities will advance the project toward achieving its stated objectives.

Milestone	Go Criteria	No-Go Criteria	Deliverable	Comment

27. Provide any additional project plan comments.

_____

28. Do you have other funding sources to support the studies in your program not funded through Catalyze?

_____

29. Define the key risks and uncertainties that may affect the successful development of your technology, including scientific, technical, operations, regulatory, personnel, or other relevant risks. For each risk specify existing and/or proposed mitigation plans to manage these risks.

_____

Section 7: Budget Justifications

Please respond to the following questions and remember to upload the required budget justification file.

30. Provide the budget for the senior/key personnel that will be involved in your project

Name	Suffix Project Role	Base Salary	Calendar Months	Requested Salary	Fringe Benefits	Total Funds Requested

31. Provide the budget for 'Other Personnel' that will be involved in your project (e.g., post-doctoral associates, graduate students, undergraduate students, secretarial/clerical, research assistant).

Name	Project Role	Calendar Months	Requested Salary	Fringe Benefits	Total Funds Requested

32. List the items and dollar amounts for all equipment requested.

Equipment	Total Funds Requested

33. Provide the total costs requested for other direct costs.

Other Direct Costs	Total Funds Requested
Materials and Supplies	
Publication Costs	
Consultant Services	
ADP/Computer Services	
Subawards/Consortium/Contractual Costs	
Equipment or Facility Rental/User Fees	

34. Provide the total in direct and indirect costs requested from above

Total Direct Funds Requested	Total Indirect Funds Requested

35. If using vendors, provide an overview of the activities and costs associated with each vendor. List all tasks in sequential order. Provide the cost and vendor information only for the services you are requesting from the Catalyze Program.
NOTE: The use of Chinese CROs/CMOs (and other countries of concern) are not supported by the Catalyze Program. Applications that include estimates from these CROs/CMOs will not be reviewed. Please also be aware that the use of foreign vendors may incur additional costs due to tariffs and may cause a delay in approval. (Countries of Particular Concern, Special Watch List Countries, Entities of Particular Concern - United States Department of State)

Task	Start Date	End Date	Cost	Vendor

Supporting Documentation:
Please upload a supporting document that provides detailed justification on all requested funds, separated by year. **Include the total direct and indirect costs requested**.

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).