The National Institute for Innovation in Manufacturing Biopharmaceuticals

AMERICAN INNOVATION AT WORK

NIIMBL bioLOGIC RFI

Listening Session & Office Hours

August 19, 2025

Logistics

We are recording this webinar to facilitate easy sharing with organizations unable to attend.

Hold questions until the end to facilitate easy recording....but feel free to add questions to the chat for safe-keeping.

Slides and recording will be made available after the webinar.

NIIMBL bioLOGIC | Request for Information (RFI)

To gauge interest and gather insights that will shape the scope of a future Request for Applications (RFA) for NIIMBL bioLOGIC.

Focuses on collecting information, ideas, and suggestions from interested parties without requiring detailed proposals.

Results in a better understanding of available options and informs the development of a more targeted RFA.

NIIMBL bioLOGIC | Program Background

- NIIMBL bioLOGIC is a project-based learning program for high school students developed by NIIMBL that focuses on three pillars:
  - Engagement with advanced technologies
  - Familiarization with the principles of entrepreneurship
  - Exposure to education and career pathways that lead into the advanced manufacturing sector

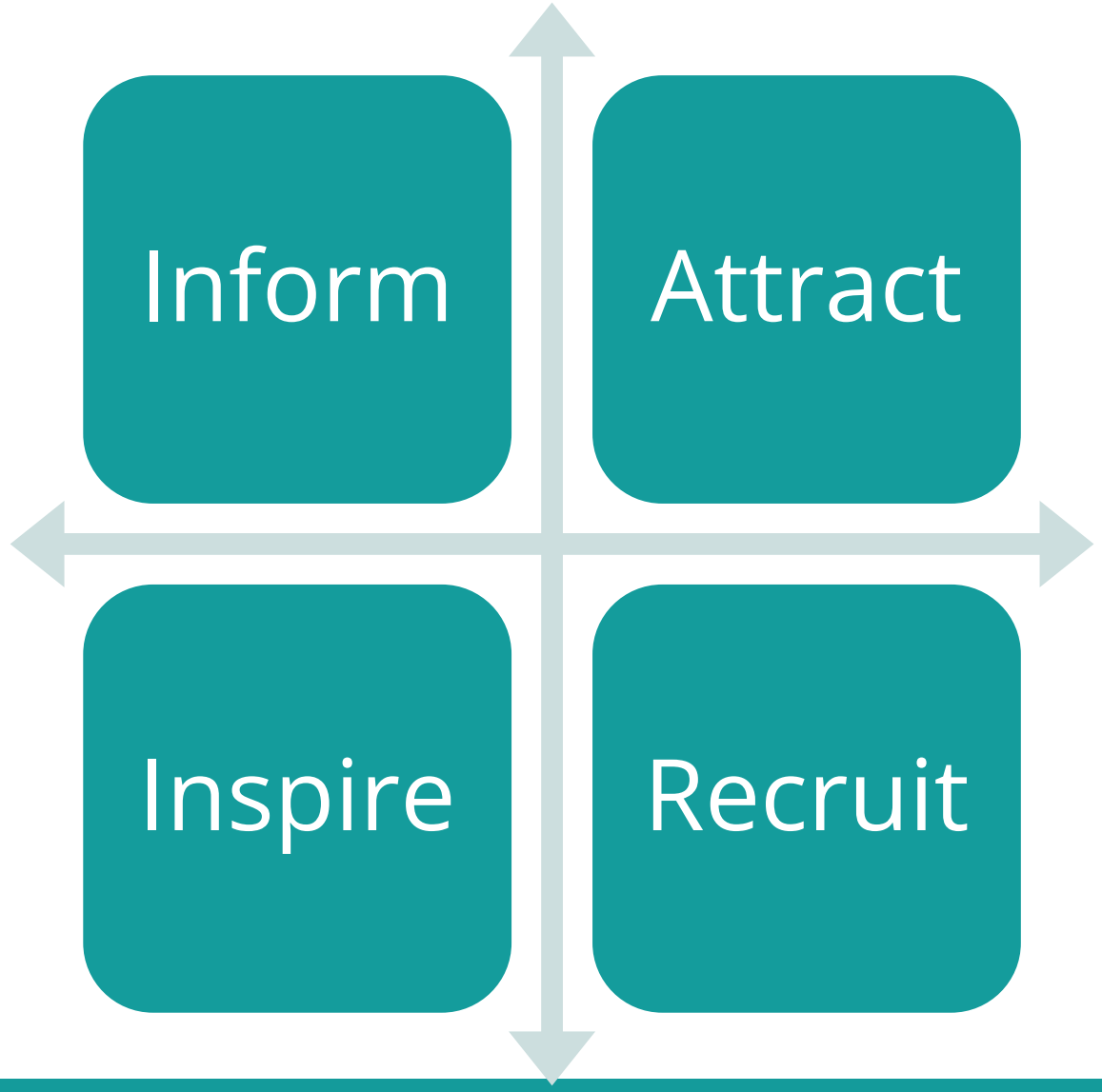
  These focus areas are wrapped around a student-led, design-thinking approach that allows participants to focus on a problem area that holds a real meaning for them and apply what they learned about technology and entrepreneurship to a real-world challenge.
- The purpose of this RFI is to gauge interest and gather insights that will shape the scope of a future Request for Applications (RFA) for the NIIMBL bioLOGIC program.
- NIIMBL invites submissions from interested parties to share information on potential solutions for creating a NIIMBL bioLOGIC implementation.

This Request for Information (RFI) is not a funding opportunity solicitation.

NIIMBL bioLOGIC Elements

- A career readiness workshop
- A kickoff and problem identification: Students are oriented to the program and identify a healthcare problem or challenge they want to focus on
- An Industry Day (e.g., tour, classroom visit, virtual visit)
- A College Day (e.g., tour, classroom visit, virtual visit)
- Business Model Creation: Students develop a business model around their healthcare problem
- Pitch Development
- Final Pitch Day: Students present their business model and solution to a panel of industry and academic stakeholders

NIIMBL bioLOGIC | Program Goals



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NIIMBL bioLOGIC | History, Current State, Future

Brief History of Program:

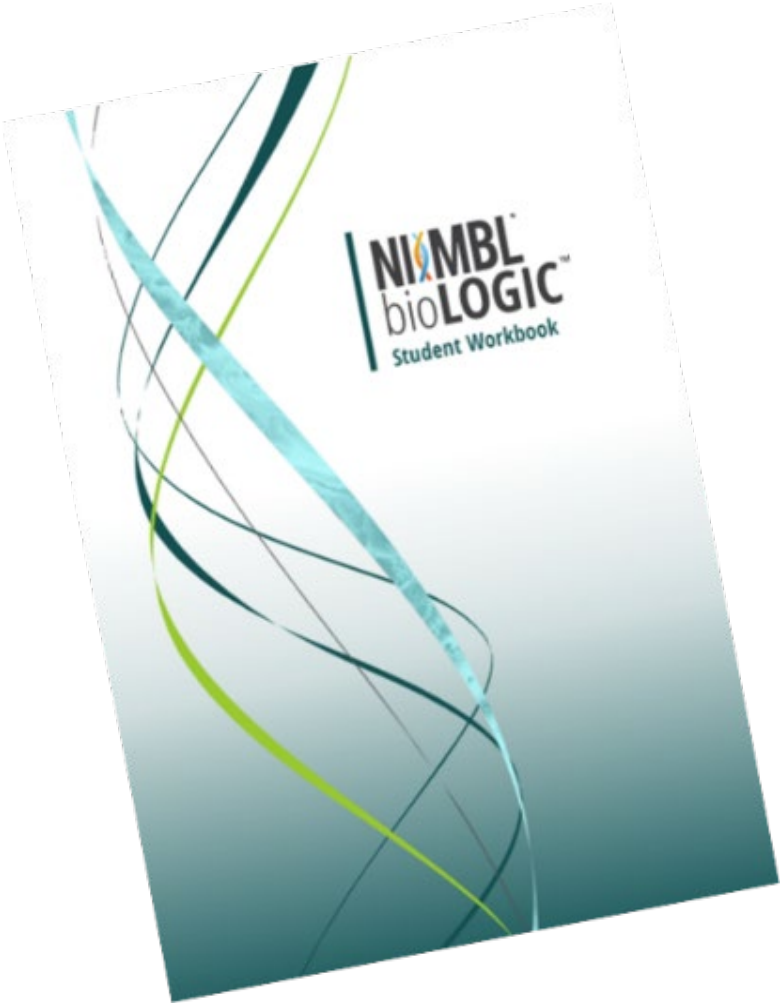
- **NC Biotech**: Several successful pilot classes in NC / continuing implementations of program **(650+ students served / 10+ schools)**
- **NIIMBL**: implemented 2 classes of bioLOGIC in Delaware at Charter School of Wilmington in 2024. **(92 students served)**

Current State of NIIMBL bioLOGIC:

- **Delaware Technical Community College (DTCC)** just completed NIIMBL bioLOGIC as part of their Upward Bound Program summer camp. Served students from across Delaware. **(80 students served/20 schools)**
- **NIIMBL bioLOGIC RFI release**

Future State of NIIMBL bioLOGIC:

- **Continue regional implementation of bioLOGIC in NC & DE**



NIIMBL bioLOGIC | Timeline

2020

- NIIMBL bioLOGIC born

2021

- NIIMBL bioLOGIC pilot begins (NC Biotech—Lead)

2022

- Content finalized in April 2022

2023

- Pilot complete 12/31/23

2024

- NIIMBL bioLOGIC continues in NC
- NIIMBL runs 2 implementations in DE

2025

- NIIMBL takes FY2025 to determine next steps for bioLOGIC
- DTCC runs NIIMBL bioLOGIC as part of Upward Bound Program
- RFI launch

NIIMBL bioLOGIC | Phases

Timeline

CAREER READINESS WORKSHOP

The Career Readiness Workshop will teach you about business communication and etiquette and many other topics that will help you in this project and beyond.

PHASE 1 PROBLEM IDENTIFICATION

KICK-OFF

The Kick-Off is where you'll be introduced to the program and begin brainstorming problem areas.

PHASE 2 PRODUCT DEVELOPMENT

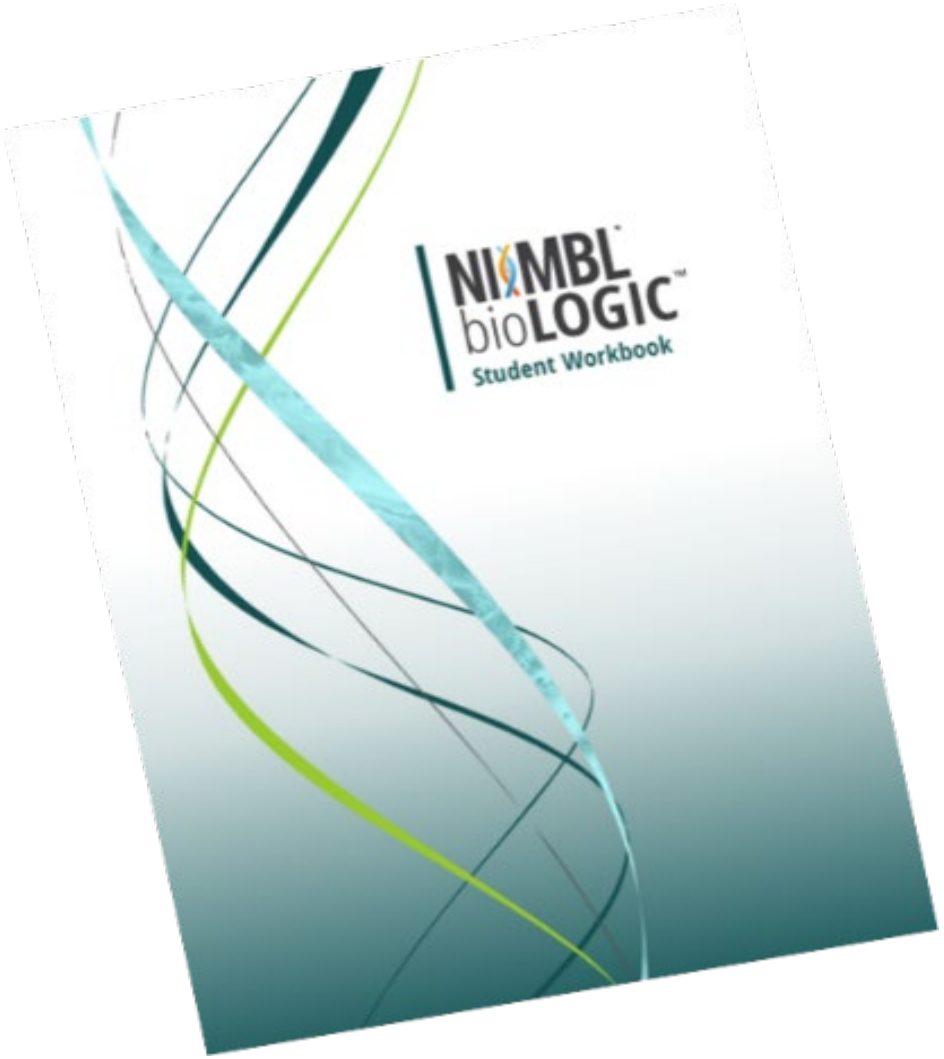
INDUSTRY DAY

FACILITY TOUR

On Industry Day, you'll tour the Industry Partner's facility, learn about careers and meet people working in the field, and become familiar with the products and processes in advanced manufacturing.

PRODUCT DEVELOPMENT WORKSHOP

During the Product Development Workshop, your team will work on your problem and product concept. The Program Manager, High School Instructor, and Industry Advisors provide initial guidance and feedback.



NIIMBL bioLOGIC | Phases

PHASE 3
BUSINESS MODEL CREATION

COLLEGE DAY

CAMPUS TOUR

On College Day, you'll experience a higher education campus firsthand and become familiarized with what it's like to be a student there.

BUSINESS MODEL WORKSHOP

During the Business Model Workshop, your student team will work on creating the business model for your product concept. The Program Manager provides guidance and feedback.

SLIDE DECK WORKSHOP

The Slide Deck Workshop is a working period for teams to create their pitch decks. The Program Manager and High School Instructor will offer feedback on slide content and layout.

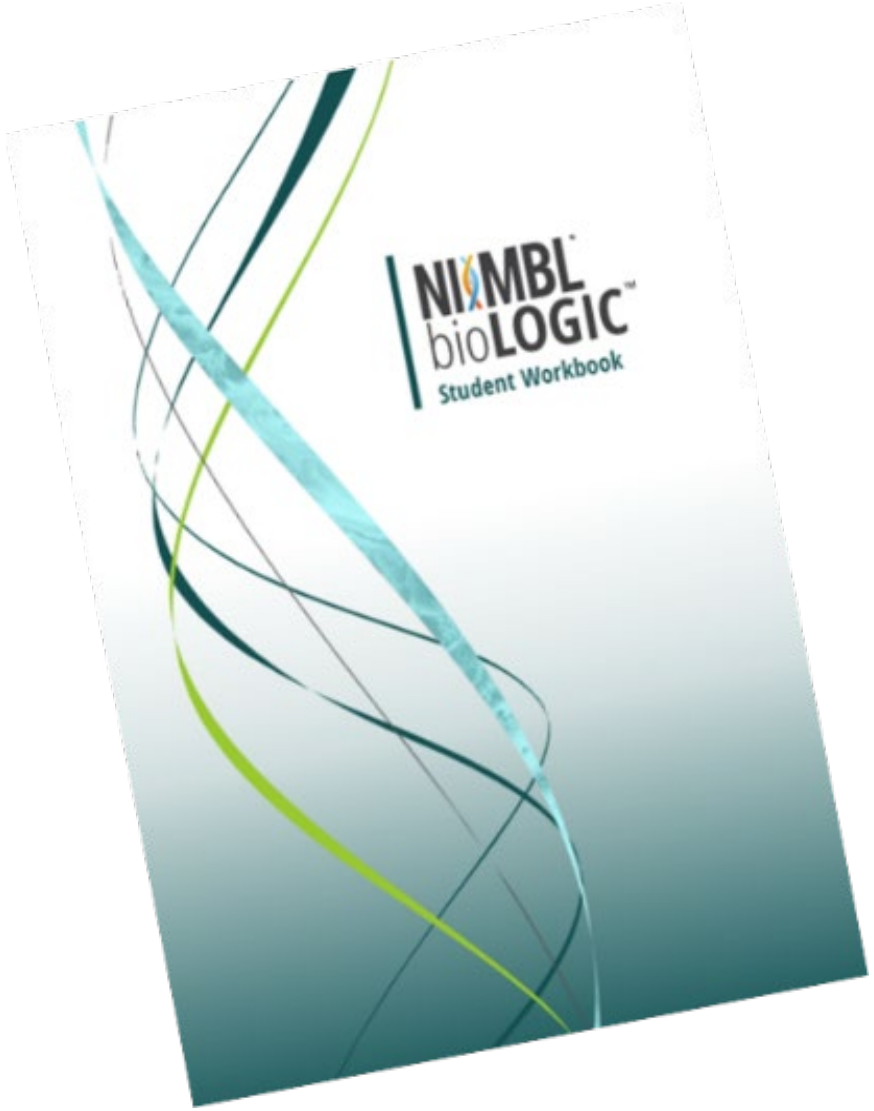
PHASE 4
FINALIZE PITCH AND REHEARSE

FINAL REHEARSAL

The Final Rehearsal is a scheduled class period for your team to run through your final presentations.

FINAL PITCH

The Final Pitch is the culminating event of NIIMBL bioLOGIC, where your team will pitch your final presentation to panelists and a general audience. Panelists offer feedback and ask questions after each team pitches.



Phase 1
Problem Identification

Overview

NIIMBL bioLOGIC is a student-led learning project. This means you and your team will be responsible for figuring out how to identify and solve an open-ended, complex problem on your own. This guide is deliberately light on instruction because we believe in your ability to find creative solutions to problems in human health. We have provided reference material to assist with some of the more technical aspects of making a medicine so they do not become barriers to your thinking. At times, a lack of detailed instruction may be frustrating, but the process is more representative of problems you will encounter after you graduate. You will likely become comfortable thinking about and solving complex problems. Through this course, you will develop your critical thinking, creative reasoning, and independent exploration abilities.

During phase one, you will identify, research, quantify, and define a problem that you would like to solve.

A **IDENTIFY THE PROBLEM**

What is the human health problem that needs to be solved?

B **RESEARCH THE PROBLEM**

Review what you already know, and figure out what you still need to learn.

C **QUANTIFY THE PROBLEM**

What is the scope of the problem? How many people need this problem to be solved? Look for relevant data to support the need for a viable solution.

Phase 2

Biopharmaceutical Development

Overview

In Phase One, you identified, researched, and quantified your human health problem so now you will work towards a solution. In Phase Two, you will work through the process of developing a plan to make the biopharmaceutical medicine that addresses your problem. You do not need any prior understanding of how biopharmaceutical manufacturing occurs for this program. You may use your research, reference material provided by your teacher, and logic to develop a manufacturing plan for your medicine.

Biopharmaceutical manufacturing can be quite complex, and you need not worry about the technical details. It will be important to focus on all the different pieces and partners that need to come together to make your medicine commercially available to the patients that need it.

TERMS YOU SHOULD KNOW

Research & Drug Discovery: *Scientists design, make, and test compounds that they think will prevent, treat, or cure a problem in human health*

Process Development: *Scientists and engineers develop a process to make the medicine at a larger scale*

Clinical Trial: *Human studies that test if a medicine is safe and effective, find proper dose, and uncover side effects*

Manufacturing: *Process of making a medicine in large quantities and maintaining quality so that every batch is guaranteed to be safe and effective*

Launch / Distribution: *Process of getting medicine from manufacturing facility to the patients that need it after a medicine has been approved by the United States Food and Drug Administration (FDA)*

Phase 3

Business Model Development

Overview

During this phase of your project, you will develop a business model and analyze the costs involved in bringing your product to market.

Phase 4

Pitch Deck Development

Overview

In this final phase you and your team will create a verbal pitch and supporting pitch deck to deliver your Final Pitch to a panel of representatives and general audience. Your pitch deck will provide the visual background for your presentation, and should reflect your marketing strategy and appeal to your target audience.

Your final pitch should be 3–4 minutes in length, so every word will count. Teams with successful Final Pitches do a good job at identifying the minimum amount of information they need to convey in order to communicate the central themes of their problem areas, product concepts, driving technology, and business models.

We deliberately do not provide you with a sample pitch deck because we want you to use your critical thinking and creative reasoning skills to identify the best way to communicate your ideas and data. If you would like examples, you can search the internet to find sample pitch decks and effective pitches. Good options for creating a pitch deck include Google Slides, PowerPoint, and Prezi, but you can use others if you prefer.

NIIMBL bioLOGIC | Coordinator Responsibilities

Program Engagement & Outreach

- Collaborate with high schools via events and visits
- Notify NIIMBL of outreach activities
- Use internal staff for consistent messaging

Program Coordination

- Tailor delivery with 7 core components
- Onboarding, training, material delivery determination (school or coordinating organization)
- Organize industry/college days & tours
- Manage joint photo release forms

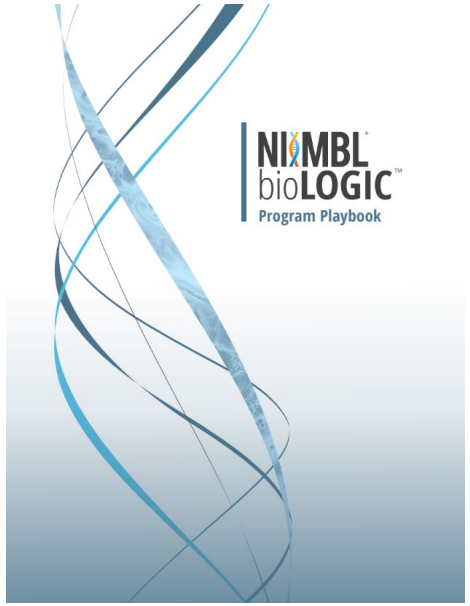
Data Collection & Reporting

- Share data with NIIMBL
  - Include school count, student numbers, classroom type, partners, format, lessons learned, media

NIIMBL bioLOGIC | NIIMBL Support

- **Printed Materials**: NIIMBL will provide student workbooks, teacher workbooks, a program manager guide, and requested forms.

- **Mentoring / connection with other coordinators/teachers** for guidance



NIIMBL bioLOGIC RFI | Submission Details

NIIMBL bioLOGIC was designed for high school students. In addition to implementation focused on high school students, NIIMBL welcomes other innovative adaptations that extend its reach to other audiences. These adaptations should align with the program's core mission of inspiring and preparing the next generation of the biopharmaceutical workforce through a problem-based learning entrepreneurship program.

NIIMBL bioLOGIC Approach

Please provide a brief description of the following:

- Who would you partner with in implementing NIIMBL bioLOGIC in your region (e.g., high schools, colleges, non-profits, industry partners)?
- What would your NIIMBL bioLOGIC implementation look like (high-level program elements, features, industry involvement)? What would be the setting (e.g., classroom, summer camp)?
- When would you ideally run a NIIMBL bioLOGIC (e.g., spring semester, fall semester, summer)?
- Who is your specific target audience. For example, what are the anticipated academic backgrounds and levels? How would participants be identified and/or recruited? In what types of classrooms?
- How many individuals do you anticipate reaching?
- How will you manage logistics (e.g., food, transportation for participants, industry recruitment for final pitches)?

Submission Process

Submissions must be sent via the NIIMBL Submission Hub by **September 11, 2025 (5pm EST).**

Two pages max.

Late submissions will not be considered.

The insights and information gathered from this RFI will be used to inform strategic planning for future solicitations.

NIIMBL bioLOGIC RFI | Submission Details

We provide a number of NIIMBL bioLOGIC documents to support your review and evaluation of the program to support an RFI response. These documents reference multiple additional forms that have not been provided.

Available materials for review (online):

- Program Manager Playbook
- Instructor Guide
- Program Manager Status Tracker

By request: (mailed)*:

- Student workbook

*If requested by September 4, 2025

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NIIMBL bioLOGIC | Submission Details

Organizational Capabilities:

An overview of an organization's capabilities, instrumentation, staffing, and facilities that could support the development and implementation of a NIIMBL bioLOGIC program.

ROM Budget / Cost Estimation:

Rough order magnitude (ROM) budget for the development and implementation of a NIIMBL bioLOGIC program. This estimate will help us understand the potential financial implications and is not binding. This RFI is not a solicitation for proposals for funding.

Encouragement for Broad Participation

We encourage submissions from a wide range of stakeholders, including academic institutions, industry, and non-profit organizations. Whether you can offer comprehensive solutions or insights into specific aspects of the universal connectivity challenge, your input is valuable. Feedback on this RFI's scope, requirements, and objectives is also welcome, as it will help refine our approach to addressing the needs of the biomanufacturing sector.

This RFI is a preliminary step towards identifying innovative solutions and collaborations that can advance the field of biomanufacturing. We look forward to engaging with the community to gather valuable information that will shape future initiatives.

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Submission Details:

- NIIMBL bioLOGIC Approach
- Organizational Capabilities
- Materials available for review
- Cost Estimation