

# Request for Information

## Partnering Interest for ARPA-H GIVE

NIIMBL RFI 2025.02

RFI Release Date: October 14, 2025

Submission Due: October 23, 2025, 5:00 pm ET



#### 1. Overview

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is dedicated to advancing biopharmaceutical manufacturing innovation, developing standards to enhance manufacturing efficiencies and speed, and cultivating a leading biopharmaceutical manufacturing workforce. NIIMBL's efforts are focused on the BRL4-7 space. However, NIIMBL's community of stakeholders has the capability to address issues across the entire spectrum of BRL1-9.

This Request for Information (RFI) seeks to identify NIIMBL members interested in partnering with other NIIMBL members in response to a recently released ARPA-H Innovative Solutions Opening (i.e. solicitation) for Genetic Medicines and Individualized Manufacturing for Everyone (GIVE). ARPA-H-SOL-25-129, from the ARPA-H Scalable Solutions Office.

According to the solicitation, the GIVE program aims to accelerate biomanufacturing equipment and process innovation, digital transformation, next-generation therapies, and commercial adoption all at once to enable on-demand access to genetic medicines.

## 2. Background and Purpose

NIIMBL is seeking responses and information from NIIMBL Members who may be interested to work collaboratively and synergistically towards a submission. In seeking information, it is recognized that responding organizations may consider submitting proposals separately (on their own or with other teams). NIIMBL has not committed to submitting a proposal and a response to the GIVE solicitation at this time. A response to this NIIMBL RFI is not a commitment to partner by the submitter, nor is the acceptance of the submission a commitment by NIIMBL to submit a proposal to ARPA-H, nor is the acceptance of the submission a commitment by NIIMBL to include the partner on any NIIMBL-associated proposal submitted to ARPA-H.

Rather, this RFI is intended to determine if there are NIIMBL Members willing to collaborate on a proposal by combining a range of expertise and capabilities that would otherwise not be available. In short, to facilitate teaming among NIIMBL Members. Because of the short timeline between the release of this RFI and the due date for an ARPA-H proposal, this RFI is open for a limited period of time.

Interested parties are encouraged to <u>study the ARPA-H GIVE ISO solicitation</u> in detail before responding to this RFI. NIIMBL will acknowledge all submissions and will keep all submitting partners informed of NIIMBL's plans.

## 3. Scope of Interest

NIIMBL invites submissions from interested parties to share information on their interest in participating in a team in response to the GIVE solicitation. Both GIVE technical areas (TA1 and TA2) are under consideration. TA1: Automated RNA Manufacturing. TA2: Integrated Quality Control.

In keeping with the ARPA-H GIVE eligibility requirements, RFI responses from Federally Funded Research and Development Centers (FFRDCs) and Government Entities is not expected and will not be considered by NIIMBL.

Note: This RFI does not constitute a solicitation for funding proposals and is not a commitment to submit a proposal to ARPA-H. The goal is to identify potential partners who might be willing and interested to work together on a proposal.



#### 4. Submission Details

To facilitate consistent and interpretable responses, NIIMBL requests that submissions be organized into the following sections. Respondents may choose to address one, several, or all five Scope of Interest sections. Each section response should be limited as described below.

- Cover Page including Name of submitter, title, organization, and email address (1 page)
- 1. Organizational Type (1 line). Please specify <u>one or more</u> of the following categories for you/your organization that is relevant to the GIVE solicitation:
  - a. Academic research
  - b. Small business
  - c. Analytical Tool/Technique Company
  - d. Vendor and Tool Company
  - e. Contract Manufacturer
  - f. Drug Manufacturer
  - g. Other (describe)
- 2. Your Preference on teaming style (1 line, refer to ISO Section 3.3):
  - a. Traditional subaward
  - b. Multi-Party Team
  - c. Both acceptable / No preference.
- 3. Specify which Technical Area (TA) Goal your organization is willing to contribute to (1 line, refer to ISO Section 2):
  - a. TA1: Automated RNA Manufacturing
  - b. TA2: Integrated Quality Control
  - c. Both TA1 and TA2
- 4. Expertise and Collaboration for TA1. If you indicated an interest in contributing to TA1, then (up to 4 pages total):
  - a. Describe your expertise and capabilities as they relate to TA1. Please address relevant expertise and capabilities as they apply to ISO Sections 1.3, 1.4, 2.1, 2.2.1, and <u>2.2.2</u>. Please indicate what types of RNA production formats your organization has significant expertise with (if any): mRNA, saRNA, transRNA, cirRNA, other (specify).
  - b. Describe any complementary expertise or capability that you feel would be important to have addressed on a team if your organization were participating on the team (e.g. GMP manufacturing experience, analytical technology development, etc.).
- 5. Expertise and Collaboration for TA2. If you indicated an interest in contributing to TA2, then (up to 4 pages total):
  - a. Describe your expertise and capabilities as they relate to TA1. Please address relevant expertise and capabilities as they apply to ISO Sections 1.3, 1.4, 2.1, 2.2.1,



- and <u>2.2.3</u>. Please indicate what types of RNA production formats your organization has significant expertise with (if any): mRNA, saRNA, transRNA, cirRNA, other (specify).
- b. Describe any complementary expertise or capability that you feel would be important to have addressed on a team if your organization were participating on the team (e.g. GMP manufacturing experience, analytical technology development, etc.).
- 6. Optional up to 1 page: Given the three phases of the overall program, what do you perceive as the greatest risks to successful completion of Phase 1 (first 6 months) for TA1 (see ISO Section 2.2.2)?
- 7. Optional up to 1 page: Given the three phases of the overall program, what do you perceive as the greatest risks to successful completion of Phase 1 (first 6 months) for TA2 (see ISO Section 2.2.3)?

#### **Additional Guidance**

- Format: Submissions should be in Word format. Minimum 10 point font.
- **Length:** The maximum submission expected would be: Cover Page + 1 page for Sections 1-3, 4 pages for Section 4, 4 pages for Section 5, 1 page for Optional Section 6, 1 page for Optional Section 7 = 12 pages. However, we anticipate many submissions will be shorter.
- **Confidentiality:** Mark any proprietary or confidential information clearly. Information shared will only be reviewed initially by a small team at NIIMBL with the goal of identifying whether there is critical mass of interest and expertise available to help form a team.

**Note:** This RFI is not a solicitation for proposals for funding, and responses will not result in a contract or formal evaluation.

#### 5. Submission Process and Outcome

Submissions must be sent via the NIIMBL submission hub (<a href="https://niimbl.piestar-rfx.com/opportunities/all/rfp/197">https://niimbl.piestar-rfx.com/opportunities/all/rfp/197</a>) by the due date. As of the date of this RFI posting, Proposer's Day is November 13, 2025 and Solution Summaries are due Dec 19, 2025. NIIMBL intends to make a Go or No-Go decision about a NIIMBL-associated team submission by November 21, 2025.

### 6. Use of Information

The insights and information gathered from this RFI will be used to determine if there is a critical mass of partners and capabilities for a submission.

No information that is submitted as part of this RFI will be shared with any other NIIMBL Members. It will only be reviewed by a subset of NIIMBL staff to help determine if a project team can be assembled.

We recognize that organizations may not be willing to put their most compelling ideas forward in response to this RFI because their organization may be interested to submit a proposal separately. However, we encourage as much information sharing as possible knowing that the ideas will not be shared among the NIIMBL community as part of this RFI process.



## 7. Conclusion

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.

For more information, please contact <a href="mailto:projectcalls@niimbl.org">projectcalls@niimbl.org</a>.