

## GLIDE Frequently Asked Questions (FAQ)

### General

#### **1. How can I sign up to be part of a study if I have primary lymphedema?**

For individuals interested in participating in a study, please refer to the specific study's recruitment process or contact the research team directly. The GLIDE program itself does not handle participant recruitment.

The GLIDE program has also implemented a "Discovery Duo" program (ISO section 2.4.1) which requires performers to include a patient or patient ambassador as a key member of the team. We encourage patients to review GLIDE's teaming webpage and reach out to organizations who are seeking patients and patient organizations to incorporate into their proposal.

#### **2. How have you been advertising these programs to make sure you're reaching labs, researchers, and early-stage investigators?**

The programs are primarily advertised via ARPA-H's Vitals newsletter and ARPA-H's official LinkedIn profile. Please encourage your network to sign up for the Vitals newsletter to stay up-to-date on all of ARPA-H's programs and activities.

#### **3. Are there any other things non-profits and advocacy groups could be doing to get involved?**

We encourage non-profits and advocacy groups to sign up on GLIDE's teaming webpage and state that you are interested in working with proposers to the program. GLIDE's solicitation requires proposers to identify and incorporate patients and patient advocates into their proposals to inform their approach and enhance the impact of their novel technologies.

#### **4. Might we be able to have someone from ARPA-H speak about this at our non-profit or advocacy group's scientific symposium?**

If your non-profit or advocacy group is interested in a speaking engagement, please use the ARPA-H Engagement Request Form. The form can be found on the Opportunities to Engage page on the ARPA-H website at [Engage & Transition | ARPA-H](#).

# Proposal and Submission

## **1. Where can I find the solicitation for the GLIDE Program?**

The [GLIDE ISO can be found here on SAM.gov](#). Currently the draft version is posted, and we anticipate the final version will be released in September 2024.

The latest version of the ISO supersedes any information presented in other publications, and sets forth the requirements for Full Proposals, the criteria for the evaluation, and instructions for the submission.

## **2. Where can I find attachments 1, 2, and 3?**

Attachments for the GLIDE program will be provided with the official GLIDE Innovation Solutions Opening (ISO); currently the draft version is posted on SAM.gov as a preview.

We anticipate the final version of the GLIDE ISO will be released in late September 2024. This final ISO will include attachments and instructions for the Pre-award Pitch Presentation.

The latest version of the ISO supersedes any information presented in other publications, and sets forth the requirements for Full Proposals, the criteria for the evaluation, and instructions for the submission.

## **3. Does the GLIDE Program focus primarily on peripheral lymphedema?**

The GLIDE program does not focus primarily on peripheral lymphedema, and is intended to specifically target and modulate the lymphatic system. Demonstration of efficacy across two distinct indications is required, one rare and one chronic disorder. ARPA-H cannot provide guidance on which specific indications to include, and justifications should be made in the submission for the evaluation process.

## **4. Can we receive feedback or guidance on a technology, concept, or idea prior to the submission of the Solution Summary?**

ARPA-H cannot provide a formal approval or feedback on a specific technology, concept or idea prior to the submission of a Solution Summary. Refer to the language in the ISO to determine fitness. Feedback on the fit of specific technology will be provided following solution summary submission.

## **5. When is the Solution Summary due?**

The Solution Summary for GLIDE is due by November 14, 2024, at 2:00 PM ET.

**6. Is there a limit to the number of Solution Summaries an organization can submit?**

Please see Section 2.4 General Requirements in the GLIDE ISO, under 2.4.1 Proposing teams: Proposers may only submit one proposal as the prime proposer.

**7. Who is allowed to submit a Solution Summary or Full Proposal?**

All eligible entities as defined in the GLIDE ISO Section 3.1 may submit Solution Summaries. Only those who submitted a Solution Summary and participated in Pre-award Pitch Presentations may be invited to submit a Full Proposal.

**8. Do you require preliminary data for the application?**

Outside of guidance within the ISO, including Appendices, ARPA-H cannot advise proposers in terms of Solution Summary and/or Full Proposal strategy and content. Solution Summaries will be reviewed, and Full Proposals will be evaluated as described in the ISO Section 5.5. Proposers should prepare submissions accordingly.

**9. Is a Solution Summary required?**

Yes, a Solution Summary is required.

**10. Is the “Team Organization and Capabilities” section of the Solution Summaries counted as part of the 3 pages allocated for the proposed work?**

The Team Organization and Capabilities, R&D timeline, and Rough Order of Magnitude (ROM) are not included in the 3 pages, but should adhere to the formatting and length guidelines in Appendix A.

**11. How is the Solution Summary reviewed?**

Solution Summaries will be reviewed within the context of the Full Proposal evaluation criteria, but not to the same extent as Full Proposals, which are evaluated against the criteria as outlined in ISO Section 5.5. Feedback may be limited to 'encourage/discourage' as noted in the ISO.

**12. When would proposals be notified if they are encouraged or discouraged from submitting the Pre-Award Pitch Presentation and in turn, what is the anticipated deadline for submitting this deck and scheduling/completing the oral presentation?**

Responses and decisions will be sent to the email recorded in the submission system once the review process is complete. Additional details and instructions, including due dates for the pitch deck, will be shared at that time. We appreciate your patience.

**13. How is the pitch presentation evaluated?**

Pre-award Pitch Presentations will be evaluated against the criteria as outlined in ISO Section 5.5. Feedback may be limited to 'invite/not invited' for a Full Proposal submission as noted in the ISO.

**14. How will full proposals be evaluated?**

Full Proposals are evaluated against the four criteria in the ISO (see Section 5.5).

**15. How are reviewers selected, and who is reviewing the technical merit of the proposal?**

Pre-award Pitch Presentations and Full Proposals will be evaluated by Government Reviewers who may be ARPA-H PMs or qualified personnel from other Government Organizations and Agencies who are deemed proficient in the pertinent research areas of the solicitation.

**16. Are Letters of Opportunity/Intent required?**

Letters of Opportunity/Intent are not required.

**17. Are the slide pitch slide template slides (GLIDE Attachment 2\_Pitch + Template) strict templates, or general suggestions? For example, are we only allowed to add pictures in the boxes shown on template slides 5 and 6?**

All elements of the pitch slide template must be responded to, but proposers are allowed to make minor modifications to structure or layout, such as the number or location of pictures.

**18. Is there a separate location for ARPA-H Program Manager's Solution Summary feedback, or does the Solution Summary Feedback Letter received via email contain all the feedback (don't want to miss any, if located elsewhere)**

ARPA-H does not intend to provide any additional feedback to proposers prior to the pitch presentation.

**19. Do we need to use text on the slides to answer all the Heilmeier Questions, or can we answer them with pictures and verbally in the pitch?**

The requested Heilmeier questions must be addressed via content on the slide. Text, figures, and/or pictures are acceptable ways to address them.

**20. Are embedded videos allowed in the slide pitch?**

Videos are allowed. Reminder that pitches are allowed up to 20 minutes, maximum.

**21. Are there any example pitch slides we can see?**

ARPA-H does not have example pitch slides to send proposers.

## Proposer's Day

**1. Where is the GLIDE Proposers' Day being held?**

The GLIDE Proposers' Day will be held to support hybrid attendance, virtually and in-person. Registered participants will receive a unique Zoom link to attend the webinar. We are finalizing venue details, please be on a lookout for updates on the [GLIDE Proposers' Day event registration page](#).

**2. How do I register for GLIDE Proposer's Day?**

This registration link for [GLIDE Proposers' Day](#) will be open until September 10, 2024, 5PM ET.

**3. How long is the lightning talk?**

According to the GLIDE Special Notice (SN) posted on SAM.gov, the lightning talks are 5 minutes in length. Please review the SN for complete instructions.

**4. Is a recording of Proposer's Day available?**

The recording of GLIDE's Proposers' Day will be posted to GLIDE's webpage once processed. NOTE: the content in the GLIDE ISO supersedes any information presented in the recording.

## Teaming & Eligibility

### **1. How do I sign up to the Teaming Page to initiate collaboration with others who may be interested in the GLIDE program?**

Please use this [link](#) to submit an update to the teaming profile.

### **2. Can there be two or more PIs on the proposal?**

Each proposal must designate a single lead PI from the prime organization. The team may include other Investigators collaborating with the lead PI. All personnel and justification of their contribution to the proposal needs to be clearly stated for budget transparency. Proposers must submit an integrated proposal led by a single Principal Investigator (PI), capable of performing the activities outlined in the solicitation draft.

### **3. Are there qualifications for becoming a PI?**

There is not a minimum number of years post-PhD for the PI role and ARPA-H does not offer any specific guidelines. We encourage you to review section 5.5.2 of the GLIDE ISO draft for how ARPA-H will assess the fit and capabilities of the proposing team.

### **4. Can proposers be part of multiple proposals either as the lead or sub-proposers?**

An entity can only submit one Full Proposal as the prime proposer. Entities may propose within multiple teams as sub-proposers.

### **5. What is the maximum number of teams and/or people for each proposal?**

There is no maximum number. Proposers are responsible for proposing a team capable of meeting the proposed Statement of Work, recognizing the Government is evaluating team capability as well as price reasonableness.

### **6. Are international performers eligible to submit proposals for consideration?**

Yes, non-U.S. entities are allowed to submit proposals for consideration. Non-U.S. entities are encouraged to collaborate with domestic U.S. entities. See GLIDE ISO Section 3.1.2.

### **7. Is a non-U.S. company eligible to apply for the GLIDE program?**

Non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. However, non-U.S. entities are encouraged to collaborate with domestic U.S. entities. See ISO Section 3.1.2 for more details.

**8. How could clinical institutions potentially get involved or provide support within the scope of the GLIDE program?**

Collaborations with clinical institutions can be included in the proposal as part of the performing team. The specific role and involvement should be clearly outlined in the proposal, whether as a prime or subcontractor.

**9. Does ARPA-H assign Discovery Duos?**

No. Each Performer Team must form their own Discovery Duo as outlined in Section 2.4.1 of the ISO.

**10. What is considered an “Early Investigator” for participation as part of the Discovery Duo?**

In Section 2.4.1 under the Discovery Duo Program requirements, it states the early-stage investigator "is within the first 10 years of receiving their advanced research degree."

**11. Does a budget need to be assigned for the Discovery Duo?**

Yes, project budgets must include the minimum stipend for the Discovery Duo support outlined in Section 2.4.1 of the ISO.

**12. How much interaction, or collaboration, will performer teams have with each other?**

The GLIDE Program is based on collaboration within and between Performers/Performer teams. See ISO Section 2.4.2 for more details.

**13. Can performers have international partners?**

Yes, international partners are allowed. See ISO Section 3.1.2.

**14. When do members of the performing team need to be named/selected?**

Key members of the Proposer's team should be identified as early as possible (e.g., Solution Summary). Failure to identify key personnel (e.g., Project Manager) and/or team members (e.g., subawardees) may impact the Government's evaluation. Proposers are encouraged to provide as many specific details as are available at the time of submission, while considering page limitations at each submission stage.

**15. What is needed to demonstrate the unique capability of my program for FFRDC or Government entity participation?**

Documentation should demonstrate that the FFRDC has a unique capability without which their solution is unachievable and that the prime proposer has exhausted all other options. This will be reviewed by ARPA-H to determine if inclusion is necessary. See ISO Section 3.1.1 for more details.

**16. Is it more beneficial to apply as a company or as an academic institution?**

Please refer to section 3 ELIGIBILITY INFORMATION and section 3.1 ELIGIBLE PROPOSERS in GLIDE's INNOVATIVE SOLUTIONS OPENING (ISO).

**17. Is this a new contract or is there an incumbent performing these services?**

This is a new Innovative Solutions Opening (ISO) with no incumbent performer.

**18. What is the breadth of clinical indications in applying?**

Please refer to section 2.2 PROGRAM STRUCTURE, TIMELINE and TECHNICAL APPROACH which describes the breadth of clinical indications requested by each potential performing team.

## Technical & Science Questions

**1. Which technical area should I apply to?**

ARPA-H cannot advise as to strategy and/or content of Solution Summaries and Full Proposals. Proposers must use the guidance in the ISO as well as their professional expertise when preparing submissions.

**2. Which technical area should I apply to, TA1 or TA2?**

Submissions should only be made to one of the technical areas, either TA1 or TA2. Even for combination therapy solutions, proposers need to determine if the “primary mode of action” applies to either TA1: Physical Intervention or TA2: Pharmacologic, Gene and Cell Therapies.

**3. Do you intend to hold us to the metrics in the R&D Solicitation?**

Unless indicated otherwise in the ISO (i.e., written as suggested), Program metrics in the ISO are requirements for Proposers. Proposals that do not propose to meet the metrics will be evaluated accordingly. Proposers are expected to define success metrics appropriate for respective proposal and technology, to be captured in the target product profile

submission, and are accountable to these agreed upon final metrics after negotiation and approval with the PM. Please refer to the ISO section 2.3, as shown below.

#### TECHNICAL AREA METRICS AND OBJECTIVES:

*Achievement of all metrics as agreed to by ARPA-H is part of the basis for initiation of moving to the next phase. Key overall program metrics and milestones are listed in this section below. Performers may propose quantitative metrics and milestones for the PM to consider that may be better suited for their specific technology. However, the performers must provide a justification for these additions to the metrics and milestones as specified in the ISO section 2.3. A full target product profile (TPP) outlining the minimum and ideal functionality of the technology developed in each TA must be included with all submission materials. An example of a TPP can be found in Appendix D of the ISO.*

#### **4. Will ARPA-H provide/facilitate access to relevant healthcare data?**

Proposals should not assume provision of any Government Furnished Information (GFI). The Government may provide GFI, but the specific GFI would be negotiated after a proposal is selected for award negotiations (i.e., a proposal must stand on its own without assumptions and conditions related to GFI).

#### **5. Does the GLIDE program support FDA-approved clinical trial or a new IND application and subsequent human trials?**

The GLIDE program supports both FDA-approved clinical trials and new IND applications. The suitability depends on the specific phase and technical readiness level of the proposed solution.

#### **6. As a part of the "Phase I encompasses platform development, proof-of concept research, and feasibility investigations" (see page 6 of ARPA-H-SOL-24-111, GLIDE) we need to conduct a diagnostic non-invasive clinical study to verify our hypothesis and to investigate a feasibility of our approach. Would you consider such clinical study as a part of the Phase I?**

The program is focused on technology development and advancing therapeutic solutions to the market. If you have a technology that addresses lymphatic dysfunction which requires clinical study investigation to support the technology development, this would need to be justified for evaluation. Please see the GLIDE ISO in Section 2 which discusses the program overview and goals.

## **7. Are improved surgical procedures without innovative technologies for intervention eligible for GLIDE?**

The focus of GLIDE program is to develop innovative therapeutic (i.e. pharmacological, biologics, gene and cell therapies) and physical interventions (i.e. stents, compression, or artificial lymph nodes, surgical or interventional procedures) targeting abnormal lymphatic structure and function that alleviate, repair, and regenerate irregular or dysfunctional lymphatic vasculature. The proposed metrics of efficacy targets under Section 2.3 are intended to demonstrate how the innovative technology directly impacts and modulates the lymphatic system with the intended effect to address an underlying rare and/or chronic disease. Please refer to Section 2.2.1 for qualifying novel innovations.

## **8. Is there any role for AI in the GLIDE program?**

Please see GLIDE's Innovative Solutions Opening (ISO) section 2.2.1 Technical Areas (TAs) which addresses the role of AI in the GLIDE program.

**For further questions, please refer to the [GLIDE ISO](#) or contact [GLIDE@arpa-h.gov](mailto:GLIDE@arpa-h.gov).**

**The FAQ may be updated within 14 days pending received inquiries.**

The latest version of the [GLIDE ISO](#) supersedes any information presented in other publications, and sets forth the requirements for Full Proposals, the criteria for the evaluation, and instructions for the submission.