



**Simulation-augmented, Real-time Platform
Adaptive Seamless Trials (SURPASS)
ARPA-H-SOL-26-164
Proposer Questions & Answers (Q&A)**

Updated as of October 19th, 2026

Questions for this ISO should be submitted to surpass@arpa-h.gov or through the [Ask A Question](#) form (sign in required). This document will be updated on a continual basis through 01/31/2027. Newest questions will be added to the bottom of each section. Edits to past questions will be *italicized and highlighted in blue*.

General Questions

1. Will SURPASS consider platform trials investigating medical devices or diagnostic arms?

No, SURPASS has a deliberate focus on drugs and biologics. Medical devices and diagnostics follow a separate regulatory pathway with their own requirements and expectations and are out of scope for SURPASS. However, diagnostic technologies, biomarkers, and wearables may be incorporated to support a drug or biologic platform, for example as data sources for in silico models or for participant pre-screening.

2. Can parts of the work be performed outside the United States?

Yes, work may be performed outside of the United States (US). However, ARPA-H has a statutory requirement to prioritize awards to entities who will perform work in the US (see 42 U.S.C. § 290c (n)(1)(A)).

Thus, any work proposed to be accomplished outside of the US should be clearly described and justified in the proposal and must comply with all solicitation requirements, award terms, and applicable requirements for human subjects, data security, privacy, biospecimen handling, and any other relevant controls.

3. For a subperformer that only receives coded specimens and has no access to identifiers, does ARPA-H expect a separate Federalwide Assurance?

Federalwide Assurance: ARPA-H cannot determine in advance whether a specific subperformer arrangement requires a separate Federalwide Assurance. The

proposing team should work with its institutional officials, IRB/human-subjects protections office, and any applicable compliance personnel to determine what assurances and approvals are required based on the role of each organization, the identifiability of specimens/data, and the applicable regulations and award terms.

Drug Selection

1. **Would a regimen of two agents with prior human monotherapy data, were never tested together as a combination, satisfy the requirement for "at least one drug or biologic with no prior human data"?**

No, at least one drug must be truly first-in-human, though that drug need not be the first drug studied in the platform. The goal of SURPASS is to create platform trials that can accommodate first-in-human or first-in-patient drug products on US soil.

2. **For Solution Summaries, what details are needed about potential arms and sponsors?**

Solution Summaries should include as much information and specificity as possible to facilitate the government's review and feedback recommendations.

Team Formation

1. **For Solution Summaries, what details are needed about potential arms and sponsors?**

Yes, the Proposers' Day includes optional teaming profiles, lightning talks, and a poster session to encourage team formation. Teaming profiles submitted at <https://solutions.arpa-h.gov/teaming> will be posted at <https://solutions.arpa-h.gov/teaming/surpass>. Profiles should describe the organization's technical competencies and the partner expertise it is looking for. ARPA-H teaming pages are intended to help interested parties share information and identify potential collaborators; ARPA-H does not recommend or match specific teams or partners.

2. **Can organizations, such as technology providers, be added to a Core Platform Team after the Solution Summary is submitted or after award?**

Proposers are encouraged to identify key team members and partners as early as possible, because the government's review of Solution Summaries and its evaluation of Solution Pitch Packages are dependent on the information provided. The Proposer should describe the proposed team, anticipated capabilities, and any planned process for adding subperformers in accordance

with the solicitation. Teaming changes may be possible later, but may require notification to, or negotiation with, ARPA-H depending on timing and role.

3. What capabilities or types of organizations should a Core Platform Team include? Can ARPA-H recommend specific partners?

ARPA-H is not able to provide guidance on specific organizations, companies, or institutions that a proposer should team with, nor can we advise on a particular partnership strategy. Proposers are responsible for determining the team structure and capabilities needed to best address the solicitation requirements.

That said, we encourage you to review the SURPASS program materials, including the solicitation and any posted FAQs, to identify the technical areas and capabilities most relevant to your proposed approach. You may also use the SURPASS teaming page, where interested parties can share profiles and learn more about other organizations that may be seeking collaborators. This resource is intended to help prospective proposers identify potential partners with complementary expertise.

Solution Summary and Proposal Review

1. Is a Solution Summary required?

Yes. A Solution Summary is required. Only entities that submit a Solution Summary and receive feedback may submit a Solution Pitch package.

2. What are the page limits and formatting requirements for the Solution Summary?

Solution Summaries are limited to 4 pages. The cover page, Rough Order of Magnitude (ROM) with basis of estimate (BOE), and references do not count toward that limit. Use a non-serif font type with a readability like that of Public Sans, Avenir Next LT Pro Light, Arial, or New Century 11-point font. Smaller non-serif fonts may be used for figures, tables, and charts. Margins may be no less than one inch in width. Solution Summaries are limited to 4 pages, exclusive of a cover page, Rough Order of Magnitude including basis of estimate (BOE), and References/Citations. No tables of content shall be provided. The government may not review pages beyond four (4) total; and any Solution Summary submitted that exceeds the 4-page limit will only be reviewed at ARPA-H's discretion.

Proposers' Day

1. Can non-U.S. organizations take part in the webinar and Proposers' Day, including teaming profiles, Lightning Talks, and posters?

Yes. Non-U.S. entities may participate in SURPASS as described in ISO Section 3.1.2. They may register for the webinar and Proposers' Day and take part in the optional teaming activities. The poster session is in person only.

2. Can ARPA-H meet with us or give feedback on whether our technical approach fits SURPASS before we submit a Solution Summary?

At this stage, ARPA-H is not able to provide individualized feedback on the fit of a specific technical approach, advise on proposal strategy, or hold discussions that could provide one proposer with guidance not available to others. We encourage you to review the SURPASS solicitation materials carefully and submit a Solution Summary through the official process if you believe your approach is responsive to the call.

If you have specific clarification questions about the solicitation, please submit them through the official Q&A channel identified in the solicitation so that responses can be made available consistently to the proposer community, as appropriate.