Fast Assessment of Solutions, Therapeutics, Pharmaceuticals, and SupplieS (FASTPASS) FAQ - ARPA-H-SOL-26-160

FAQs will be updated on a continual basis through November 3, 2026. Updated content will be highlighted in yellow.

Program Concept

1) Is FASTPASS developing a diagnostic device or clinical tool? What about using clinical data, electronic health records, or sponsor clinical trials?

   No to both. The instruments and systems

   developed by FASTPASS are intended to be used during inspection, sampling and other quality or safety checks outside of a clinical setting. As far as clinical data and health records, because the FASTPASS system will be used on pharmaceutical products and their ingredients, they will not directly interface with patient-facing data, records, systems, or clinical trials.

   There may be secondary uses for the instruments and systems that come from the program, but those may be outside the scope of the program.

2) Is the main use case for this program the site of administration, or the port of entry with large volume shipping situation? What about manufacturing sites? Different scenarios will require different designs.

   The primary use case will be at ports of entry or other locations with large throughput of product. By our estimation, this is the point of greatest need and biggest impact. From there, adapting to other use cases should be easier and would not require the revolutionary development typical of ARPA funding.

Technologies and Program Objectives

3) Will TA1 consider non-spectroscopic sensing approaches, provided they can evaluate pharmaceutical identity, quality, contamination, or degradation through unopened packaging?

   Yes. Any technology that can meet the objectives of the program will be considered.

4) Is there a balance of TA1 and TA2 you are seeking?

   It is expected that the final prototype will incorporate multiple sensor types. It may also require multiple multimodal models. Therefore, there is not a particular balance or ratio of TA1 and TA2 proposals expected at this time.

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5) Is FASTPASS primarily seeking identification and quantification of active pharmaceutical ingredients, detection of degradation products, contaminants, counterfeit formulations, and packaging-related quality failures?

   All of the above, with the slight partial exception of superficial packaging failures. Failures in packaging are only a concern for FASTPASS if they impact the quality of the pharmaceutical. The goal of FASTPASS is to create a system that will be able to add to its own functionality over time as more products and materials are added.

6) Is there a minimum Technology Readiness Level (TRL) that will be considered for FASTPASS?

   No. Projects may submit technologies and processes at a low TRL level if there is sufficient evidence and justification that they believe they can bring them to the point of functional prototypes by the end of the program.

7) How much packaging does FASTPASS aim to scan through? Would it include looking at all the boxes of blister packs or bottles in a carton without having to take out the individual boxes?

   Individual boxes or bottles used in bulk wholesale distribution to pharmacies or commercial retail packaging are the targets for FASTPASS. Technologies that exceed this, such as measuring through all the retail boxes or bottles within a larger shipping box therefore are also of interest.

8) Does FASTPASS aim to be able to detect counterfeit drugs or products that are intentionally obscuring components of the product?

   Yes, analysis of the formulations within the packaging and underneath any coatings will be necessary for the final FASTPASS prototype.

9) How automated is the FASTPASS system expected to be at the final prototype stage?

   Put simply, the FASTPASS system must be able to be used by trained personnel at a port, warehouse or other distribution facility in a manner that allows a sufficient sampling rate to meet the program goals. The system must also be transportable from location to location within a warehouse and between sites with minimal manual setup and calibration. The FASTPASS program is designed so that the final system will integrate components from all the teams to create a system that is reliable and easy to use with high accuracy and precision.

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10) Is it expected that there will be different technology for the different drug types, e.g biologics vs small molecules or finished drugs vs API?

Yes, we know that there are physical limitations to type of sensor, which is why the program emphasizes a system based on multiple sensing technologies. The intent is include sensing modalities that will cover the range of products so that at least two methods can always be used to evaluate each product. That is why we expect multiple sensor modalities to be incorporated into the final prototype.

11) Are there specific primary targets, analytes, quality attributes, or failure modes that the FASTPASS program is particularly interested in detecting?

Eventually, FASTPASS aims to measure the quality and safety attributes of any substance or mixture that has a known signature. These signatures will be built up in a priority order determined by ARPA-H in conjunction with FDA and other government partners. Identifying contaminants, degradation products, and counterfeit formulations all fit within this objective.

Ideally, FASTPASS final prototypes will be able to assess quality and safety characteristics of all imported pharmaceutical formulations, APIs, and KSMs. Technologies that are only able to assess a small subset of these or are only able to do so through a small subset of packaging types are likely to have more success when paired with complementary technologies that can fill these gaps. Exceptions may be made for key critical product categories such as certain sterile injectables.

12) Would it be helpful to have drawings of final prototype concepts during the proposal or initial stages of this process?

Since the final prototype must be integrated and function as a unit, it will be useful to understand how each of the components will interact together from an early stage of development. It is best to provide the most information about intended form factors during the initial stages of this process to achieve the outcomes.

13) Are you looking for solutions for bacteria contaminants as well?

Yes. Identifying bacterial contamination is a key need for sterile products

14) Could you please define expected throughput rate for screening?

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Please see the chart on page 11 of Appendix A of the ISO with sample metrics for the program. Overall throughput can be influenced by multiple factors, but must be sufficient to provide a statistically relevant sampling of products.

15) Are proposers required to meet or exceed all the metrics listed in the ISO?

No. The overall goals of the FASTPASS program will remain constant, however individual project metrics will be determined before awards are made. Each technology and process will have its own particular strengths and challenges. All metrics may not apply to a technology or they may not be relevant in a given scenario.

16) Must the proposed system be non-contact, non-destructive, and through-packaging from the beginning of the project, or may these capabilities be achieved through staged development?

The proposal would have to make the case that non-contact, non-destructive, and through-packaging could be achieved in time to succeed at the scheduled demonstrations throughout the program.

17) Can you provide more information on the spatial resolution require or the disposition of packages that will need to be scanned?

Pharmaceutical products can be homogeneous but more often contain inhomogeneities such as when tablets include coatings or capsule contain powders. Spatial resolution is a technology specific metric, proposals leveraging such technology are encouraged to provide it as a metric with evidence supporting the expectation it will be achieved and justification for why that is the appropriate resolution.

18) Are you looking for a fully trained solution (i.e. a solution with libraries or solely a solution that would be trainable)?

The solution must be trainable. During the FASTPASS program performers will train their trainable model on a set of potential pharmaceuticals to develop a small (relative to the variety pharmaceutical imports) library for use in the demonstrations. By the end of the program, the final models should be trained on an agreed upon set of priority products with the ability to be trained on more products in the future.

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19) I have lots of data but don't do R&D, how can I help?

While ARPA-H only funds R&D, your data may be helpful for teams developing TA1 solutions or in the training of the TA2 researcher's models. Feel free to submit a teaming profile or contact others with teaming profiles who align with your data sets.

20) My sensor technology assesses the quality of biologics. Is that in scope?

While biologics account for a very large portion of the industry's revenue, it only accounts for much smaller fraction of prescription and non-prescription use. That being said, technology capable of assessing quality of biologics may also be capable of assessing sterility, biological contamination, or other aspects of generic sterile injectables that often account for shortages and recalls. That will broaden public health impact.

21) Is there a temperature requirement for TA1 sensors, such as 20-25C for small molecule drugs and 2-8C for biologics? What's the typical temperature of the storage at the ports and warehouses?

The final FASTPASS prototype(s) will be required to function in a non-climate-controlled warehouse. The temperatures for which can range higher than 40C and lower than 0C.

Scanning itself should be is expected to be fast enough that drugs which require climate control can be removed, scanned, and returned to climate control within their tolerance for temperature excursions.

22) Will IV&V provide samples and/or data?

Yes, IV&V will provide performers with enough test samples to prepare for and complete the demonstrations for TA1. Data for computational models will also be provided from either real data, augmented/modified data, or simulated data that will enable testing and evaluation of TA2 technologies. There will be extra samples and additional data sets available to all performers but the number of samples and the amount of data that IV&V will provide is not likely to be sufficient to optimize technologies or to train models. Performers should make provisions to acquire enough data or samples to complete their intended development activities.

23) Are semi-solid drugs (lotions, gels, cream, etc.) of interest to FASTPASS?

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Yes. All forms of imported pharmaceuticals subject to FDA oversight are of interest to FASTPASS.

24) Does the statement that mass spectrometry is out of scope include methods that sample only exterior package-emitted vapor, require no opening, no physical contact, and no sample preparation?

Yes. Detection of substances on the outside of the container can be heavily influenced by how that packaging has been handled and its exposures. They will have different exposure, degradation, and contaminant profiles than the intact samples within the packaging. Unlike programs development methods to detect the presence of a particular molecule, FASTPASS also aims to evaluate the state of the molecule or formulation.

Proposer Eligibility and Teaming

25) Do proposers have to submit their solution summary before the September 10th Proposers' Day?

No. Proposers' Day (https://solutions.arpa-h.gov/events) is intended to give another organized opportunity for teaming and additional information that potential proposers may need to finalize their solution summary presentations.

26) Will individual small businesses be eligible to lead proposals, or is ARPA-H likely to favor multidisciplinary teams combining sensor developers and artificial intelligence or machine-learning groups?

Individual small businesses are eligible and encouraged to both lead proposals and to be part of teams. Beyond Phase I (18months), all performers will be required to share data, either in teams or as collaborators, to ensure that the systems developed through FASTPASS are fully interoperable. Therefore, teaming is encouraged but not required to submit a proposal. ARPA-H facilitates teaming via a Proposer's Day event Sept 10th (https://solutions.arpa-h.gov/events), and the ARPA-H Teaming Website (https://solutions.arpa-h.gov/teaming/FASTPASS)

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27) Are non-US research organizations eligible to participate and receive funding, and are there restrictions on their roles, data access, or intellectual property?

Yes. Please see the ISO and it's appendices for details.

28) Our organization having difficulty finding the right partners

ARPA-H provides a Teaming Website (https://solutions.arpa-h.gov/teaming/FASTPASS) to assist companies in locating collaborators and team members. The Hybrid Proposers' Day on September 10th (https://solutions.arpa-h.gov/events) will provide several opportunities for in-person attendees to network and team. There are also several consortia and public private partnerships dedicated to advanced manufacturing, advanced technologies, and pharmaceutical quality, which may be able to assist groups in finding the right partners.

29) Is each team expected to provide all these technologies?

No. Initial proposals should have strong sensing or modeling technologies with ambitious objectives that will meet the FASTPASS goals. Teaming to incorporate multiple sensing technologies or more robust models will likely increase the achievable metrics for a project, but they are not required. However, by the beginning of Phase 2 (18 Months), teaming will be required between TA1 sensing technologies and between TA1 and TA2 performers to ensure that the FASTPASS system is fully integrated. Only a few teams which incorporate the most promising technologies will be permitted to proceed to Phase 2 and beyond.

30) Should we complete our teaming before the Solution Summary deadline, or can we continue working on teaming until the full proposal deadline?

Teaming does not need to be complete before the Solution Summary deadline. All full proposals are expected to include all capabilities necessary to complete the work proposed. However, at the time of proposal submission, the proposed work does not have to provide a complete solution to the expected final FASTPASS prototype (For example, a proposal could include only the development of a particularly promising TA1 sensor). In those cases, teaming efforts for that performer must continue over the first 18 months of the program to build or join a team which provides a complete solution to all FASTPASS goals at program end.

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31) If we are a supporting partner, can we collaborate with multiple teams?

Yes. It is not uncommon for performers to support multiple proposals. If you support more than one funded proposal, you will not be funded for the same work twice but will be expected to collaborate with each team joined.

32) Can we submit a proposal where we are the prime and be part of a proposal where we are a sub?

Yes, but as above, APRA-H will not fund for the same work twice.