Question #	Question	Response
1	Could you please clarify whether assays that evaluate host immune responses to infection itself, independent of a vaccine, are considered in scope? Or is the program intended to focus solely on immune responses in the context of vaccine or its development?	BARDA is interested in understanding immune responses developed following natural exposure and infection to pathogens within its mission space, as well as immunity developed from vaccination. Assays that evaluate immune responses to infection and assays that evaluate responses to vaccination would be responsive.
2	If a project aligns with two of the three submission areas, should we submit separate abstracts for each area, or a single abstract that addresses both?	If your project aligns with two of the three submission areas, submit a single abstract that clearly highlights how it addresses both areas. Submitting multiple abstracts for the same project is not necessary.
3	The end goal to have an LDT is clear, but what isn't clear is whether the validation process is to be performed by ASSURE or by the contracted developer of the assay.	The solicitation does not specify a Laboratory Developed Test (LDT). Instead, there is interest in validating assays with clinically relevant samples. The regulatory plan, whether developed for an LDT or a regulated *In Vitro* Diagnostic (IVD), should be part of the proposal This plan for validation and regulatory approach should be proposed by you as developer.
4	My question is whether characterizing immune responses and elucidating mechanisms of protection induced by saRNA vaccines (mRNA in general) be within scope for BARDA?	Characterizing the immune response, regardless of the vaccine modality, or infection that elicited that response, is responsive.
5	Does your white paper submission require all 3 of cell mediated immunity, mucosal immunity, and innate immunity.	All three are not required; however, there is specific interest in developing assays that can measure/assess mucosal and/or cell-mediated immunity.
6	Do you have any requirements on whether these immunity components must be characterized directly, or can they be characterized via functional analogues?	The approach for the immune assay will have to be appropriately justified/explained for how it will be able to provide comprehensive information about an individual's immune response.
7	Are neutralizing antibody measurements in mucosal samples (e.g., respiratory tract fluid, saliva) within scope as a marker of	Mucosal antibodies as well as Peripheral Blood Mononuclear Cells (PBMCs) are in scope.

	mucosal immunity for this program, or is the intent to focus exclusively on non-antibody mucosal immune markers?	
8	For comprehensive immune profiling platforms, would fast, sample-sparing neutralizing antibody assays be considered valuable as one component alongside other immune markers (T cell, innate immunity, etc.), or is BARDA specifically seeking alternatives to neutralization assays in this program?	There are two components to this call. One is for sample sparing technologies/high throughput sampling. The other is for assays that can identify novel measures of protection. Sample-sparing neutralizing antibody assays, if included with other immune markers to build a comprehensive profile of the immune response and if enhanced compared to current commercial neutralizing antibody assays (e.g., high throughput assays with ability to process and analyze large numbers of samples in a shorter amount of time), may be considered.
9	Does BARDA have a preferred or expected cost-sharing ratio for performers?	The RPP does not detail a specific cost-sharing ratio. Performers are encouraged, but not required, to include cost-sharing in their proposals.
10	Is there a cap on indirect cost rates or overhead that proposers should observe?	No. However, proposers should manage their program management related costs in an efficient and prudent manner.
11	Will BARDA accept multiple submissions from the same organization if they address different technical focus areas?	Yes. This is acceptable. Please title the proposals appropriately.
12	Is there a prioritized pathogen list or preferred indication area within BARDA's mission scope (e.g., pandemic influenza, SARS-CoV-2, anthrax)?	BARDA's end goal interest is in evaluating immune responses to PHEMCE priority pathogens listed at https://aspr.hhs.gov/PHEMCE/Pages/Priority-Threats.aspx. However, we understand it may be difficult to get access to these samples. Therefore, using a surrogate pathogen (e.g. influenza) is reasonable as long as it is justified and explained how the assay would be able to translate to measuring protection from other pathogens. Please note that the goal is not to identify biomarkers of protective response for a specific

		pathogen but instead to develop assays that can be used to measure immune response across a breadth of pathogens.
13	Are AI/ML-based or computational approaches to immunogenicity analysis considered in-scope when integrated with assay development?	If integrated within a novel assay being proposed, AI/ML-based or computational approaches will be considered. However, solutions solely based on AI/computational approaches are not responsive.
14	For mucosal or cellular assays, are there specific biosafety level (BSL) limitations or expectations regarding sample sources?	The proposer is responsible for determining this based on the samples they access.
15	What level of preliminary data is expected at the abstract stage—proof-of-concept data or early validation results?	Proposers are encouraged to provide as much relevant preliminary data as available and as advanced as available. NOTE: Proposals will be considered "OUT OF SCOPE" if they lack preliminary data to support use of the assay in measuring comprehensive immune response OR use of the new sampling methodology.
16	How will BARDA assess comparability of proposed assays to existing benchmark methods (e.g., ELISpot, ICS, ELISA, or neutralization assays)?	The proposer will need to propose a way to benchmark their new assay. For example, other methods that demonstrate immune protection could constitute candidates for comparators.
17	Will BARDA provide standardized reference materials or panels to support cross-validation of assays?	No; at this stage of the program, the proposer will be responsible for identifying sources of samples for the work proposed. BARDA seeks to develop novel assays to inform on immune responses. Proposers will need to correlate this data with the clinical state of individuals to provide information on clinical relevancy. Proposers will need to consider appropriate benchmarks or comparators for their assays.
18	What level of throughput or scalability should offerors target for large clinical trials (>10,000 participants)?	The offer is responsible for proposing the level of throughput or scalability, with the understanding that this may not be achievable for every assay, and for describing the clinical/research relevance and metrics, and how the assay that you are building is useful.

19	Are there specific metrics BARDA considers critical for determining assay readiness (e.g., time to result, sample volume, sensitivity/specificity thresholds)?	This is highly dependent on the clinical/research use case/indication for the assay and should be proposed. The proposer should explain /justify why the assay/sampling metrics are relevant. High throughput (HTP) assays on large numbers of patient samples is of interest, especially when considering the large-scale clinical studies conducted with P2/P3 studies
20	Does BARDA expect proposers to include an FDA engagement plan (e.g., qualification or pre-submission strategy) within the 24-month period of performance?	Not every assay may need to be regulated, given the intended use. For those that are pursuing an IVD regulated by the FDA, a regulatory approach /plan at the end of the project will be beneficial, although a regulatory strategy should be part of your proposal submission
21	How does BARDA define “unlimited data rights” in this context—does it extend to use, but not ownership, of intellectual property?	Unlimited Rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.
22	Will the Q&A responses posted on the RRPV website include anonymized versions of all questions received?	Yes. All questions and answers posted on the RRPV website will be anonymized and non-attributional.
23	Will the Stage 2 virtual presentations be private (limited to BARDA evaluators) or open to other consortium members?	Stage 2 virtual presentations will be private and limited to BARDA evaluators. They will not be open to other consortium members.
24	Are specific figure or graphic formats preferred for the Abstract or Quad Chart beyond the standard PDF/Word file requirement?	No. Please just ensure readability when converted to PDF
25	If a proposal is placed in the “Basket,” will offerors be notified of potential future interest or award timing?	Placement in the “Basket” indicates that the proposal may be considered for future needs. Offerors will be notified if additional interest arises, but no specific timeline for potential award can be provided.

26	Will BARDA provide any feedback for Stage 1 submissions not selected to proceed to Stage 2?	No. BARDA will not provide formal feedback at the end of stage 1.
27	The recently announced December 8th Teaming Connect event provides a valuable opportunity to explore new partnerships and strengthen potential teaming arrangements. Given that this event will occur only ten days prior to the current abstract submission deadline, is BARDA considering an extension of the submission period to allow concepts to be further matured based on newly formed partnerships?	The submission deadline is extended to January 7, 2026, at 1:00 pm ET.
28	The RPP states that preliminary data must be included in the abstract for the submission to be considered. Could BARDA provide additional clarification on the expected level of preliminary data at this stage? Specifically, if a proposed solution comprises multiple components that have each been individually validated, would component-level data be sufficient, or is data demonstrating performance of the fully integrated solution expected?	Preliminary data can be for components, but that component data must be from components that the proposer clearly plans to integrate.
29	Could BARDA clarify the anticipated Technology Readiness Level (TRL) for the underlying technologies included in the proposed solution? Is there a minimum TRL expected for individual components or for the integrated system at the time of abstract submission?	This may vary based on the assay. However, preliminary data is required to be considered in scope.
30	Section 1.2 of the RPP states that the ASSURE program intends to advance assays that evaluate immune responses beyond standard antibody measurements – such as cell mediated immunity, mucosal immunity, innate immunity – and describes antibody responses in terms of serum concentrations and neutralizing activity. We would appreciate clarification on whether BARDA is also interested in assays that quantify Fc-mediated mucosal antibody functions.	ASSURE aims to develop assays that may contribute to a more holistic and comprehensive understanding of one's immune response in response to vaccination or infection. The program has a specific interest in assays that capture markers of cell-mediated immunity and/or mucosal immunity, which include Fc-mediated mucosal antibody activity. Assays that may help establish new correlates of protection are also of interest to BARDA.