Final Responses to Questions

RFI No. HHS-23-BARDA-RFI-mRNA-001

#	Question	Answer
1	Is BARDA interested in domestic vaccine manufacturers (only) for this potential area of interest? Are internationally based vaccine manufacturers eligible to submit a proposal if this indeed the RFI becomes at a later point become a request for proposal?	This RFI is focused on U.S. domestic production capability, regardless of where the company itself is 'based.'
2	Are business models, where the transfer technology from a domestic (US) manufacturer to international large commercial scale facilities and vice versa allowed? This would allow an international company to develop technology but transfer to a CDMO at some point.	See response to Q1.
3	Given that there are only so many technologies that can used to develop a vaccine within 5-6 weeks, can the new technologies and systems be related to RNA or is the RFI only interested in technologies with completely different mechanisms than RNA?	BARDA is interested in any vaccine platform technology (RNA-based or other) that can meet the requirements outlined in the RFI.
4	Is it necessary to have clinical experience and an asset in phase II or later with a vaccine for influenza? Or could we use a clinically validated (phase II) technology that could be applied to influenza?	Requirements for a potential proposal request have not yet been determined. However, as noted in the RFI (**6.0 ATTRIBUTES OF A SUCCESSFUL PARTNERSHIP & RESPONSE CAPABILITY)**, BARDA is looking to support advanced research and development of an influenza vaccine in the future, and there is a strong probability that influenza vaccine data with the platform will be required.
5	Do you envision that equipment could be purchased if an RFP becomes available?	The scope of a potential proposal request has not yet been determined.
6	If international vaccine manufacturers are allowed to participate (in the potential RFP) does BARDA have preference from say, where the manufacturer is located (e.g., low- and middle-income country vs. high-income country)?	See response to Q1.
7	What is the potential size of grant available?	This is a request for information and not a solicitation for proposals, nor is there a guarantee that any solicitation for proposals will be forthcoming.

8	Funding for R&D, procurement of product, and infrastructure are seemingly key to the establishment of a successful partnership with BARDA. Is it anticipated that there would be a single contract mechanism (i.e, an OTA) that would provide the framework for all of these activities? Alternatively, would the anticipated mechanism only fund one of these activities?	The structure and scope of any potential proposal request have not been determined. This RFI seeks input from developers/manufacturers and others on sustainable approaches to address USG needs, which in turn would help inform a potential future solicitation.
9	Establishing domestic infrastructure has not been addressed in this RFI. Is it expected that establishing domestic infrastructure would be funded separately through BioMaC/BioMaP or other initiatives? If infrastructure funding is to come from a separate BioMaC/BioMaP initiative, how does the USG anticipate the two programs collaborating for the intended pandemic readiness aims?	See response to Q8.
10	Is domestic infrastructure a requirement or might the partnership allow for ex-US infrastructure to be utilized?	See response to Q1.
11	The USG is looking for contractors with a willingness to partner with third parties to support development of vaccines for emerging infectious diseases internationally. Is it expected that any contract mechanism with BARDA would cover such activities and liabilities, or that the contractor would establish bilateral agreements with such organizations?	BARDA anticipates that either approach may be necessary, depending on the given situation. BARDA would like to understand from developers the challenges they see in this space under either approach.
12	The RFI states that the USG assessment has determined that mRNA platforms represent the fastest platform at present to go from genetic sequence to cGMP produced vaccine, coupled with proven efficacy. Based on the USG experience and research to-date, beyond improving physical properties of the vaccine, how does it envision accelerating the timeline to an mRNA vaccine to support its objectives?	Some opportunities to accelerate the timeline from identification of genetic sequence to final container product include leveraging known correlates of immune protection, development of a vaccine platform that can be rapidly pivoted to address new threats, as well as having existing infrastructure in place to support full-scale rapid manufacturing capacity. However, BARDA is looking to industry partners to propose any innovative solutions for accelerating platform-based vaccine development.

13	The RFI indicates that with respect to sustainability, it's expected that reliance on a commercial market will provide for a significant portion of sustainment, but that the USG would provide sustainable funding to support pandemic readiness. How does the USG foresee providing such funding (i.e., just for raw materials, etc., or would it also consider purchase of annually produced vaccines to ensure warm-base readiness specific to a pandemic response)?	As part of this RFI, the USG is interested in hearing from developers/manufacturers about which type(s) of sustainment approaches would work in the context of their business models.