**Notice ID**

W911QY-21-S-0007

**Related Notice**

**Department/Ind. Agency**

DEPT OF DEFENSE

**Sub-tier**

DEPT OF THE ARMY

**Major Command**

AMC

**Sub Command**

ACC

**Sub Command 2**

ACC-CTRS

**Sub Command 3**

ACC-APG

**Office**

W6QK ACC-APG NATICK

**General Information**

* **Contract Opportunity Type:**Sources Sought (Original)
* **All Dates/Times are:**(UTC-04:00) EASTERN STANDARD TIME, NEW YORK, USA
* **Original Published Date:**Jun 02, 2021 02:35 pm EDT
* **Original Response Date:**Jul 02, 2021 04:00 pm EDT
* **Inactive Policy:**15 days after response date
* **Original Inactive Date:**Jul 17, 2021
* **Initiative:**
	+ None

**Classification**

* **Original Set Aside:**
* **Product Service Code:**AC12 - National Defense R&D Services; Department of Defense - Military; Applied Research
* **NAICS Code:**541715 - Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)
* **Place of Performance:**

**Description**

W911QY-21-S-0007

REQUEST FOR INFORMATION

***Needle-free mRNA Vaccine Delivery System***

**Objective:**This is a Request for Information (RFI) for planning purposes only. It is not to be construed as a commitment by the Government nor will the Government pay for the information solicited.  No solicitation document exists or is guaranteed to be issued as a result of this RFI.

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO CBRND) is seeking information on the capabilities and willingness of private entities (academic, non-profit and commercial) to design, test, manufacture, and serve as regulatory sponsor for an mRNA vaccine delivered by mechanisms other than traditional needle and syringe. Needle-free vaccine delivery technologies for consideration should ideally be easy to manufacture, transport, and store, and should be easy to administer/enable self-administration (example technologies include transdermal microneedle patches, oral formulations, aerosol formulations). A list of potential mRNA vaccine targets that the Government is interested in is provided in **Appendix 1**below**.**The Government is requesting information on the following:

1. Design, development, manufacturing using current Good Manufacturing Practices (cGMP), and lot release and stability testing of alternative non-traditional delivery techniques for mRNA vaccine delivery
2. Formulation and stabilization of an mRNA construct for delivery via vaccine skin patch or alternative delivery techniques
3. Utilization of alternative delivery techniques to elicit protective immune responses with a single dose and/or reduce cold-chain requirements
4. Preclinical efficacy and safety testing of alternative needle-free vaccine delivery methods
5. Regulatory sponsorship and execution of human clinical trials for safety, immunogenicity, and efficacy (if available) testing, and potential FDA Animal Rule development pathway

**Background:**

JPEO CBRND is seeking information on capabilities for the development of a needle-free mRNA vaccine delivery system outlined in the objectives above. Executing this objective may include leveraging existing relationships between industry and academia, leveraging previously FDA-approved mRNA-based vaccine technologies, as well as leveraging any existing partnerships to satisfy FDA regulatory requirements necessary for future human safety and efficacy testing.

**Requirements:**

The purpose of this RFI is to request information on the ability to develop, manufacture, and test a needle-free method for the effective delivery of mRNA vaccines. JPEO CBRND would like to understand industry’s ability to: design and develop a needle-free method for effective immunization; formulate and/or stabilize mRNA vaccines for needle-free delivery; and test the vaccine and needle-free delivery method separately and in combination to demonstrate safe and effective vaccine delivery through preclinical studies and human clinical trials.

**Administration:**The Government will retain comments and information received in response to this RFI. Proprietary information should be identified as Company Proprietary. Do not use Government security classification markings. All written responses must be received by COB on 2 Jul 2021. Responses should be sent by e-mail to:  usarmy.detrick.jpeo-cbd.mbx.mcs-rfi@mail.mil, with Subject Line of Responding Organization and RFI Title. Material that is advertisement only in nature is not desired. If a solicitation is subsequently released based on the responses to this RFI the first choice for an acquisition vehicle, if appropriate, will be the Medical CBRN Defense Consortium (MCDC) Other Transaction Agreement (OTA).    Respondents not already members of the consortium are encouraged to join at www.medcbrn.org.  Respondents may also inquire about the MCDC at mcdc@ati.org.

**Performance Objectives:**Whenresponding to this RFI, please provide responses to the objectives listed limited to 10 pages. Responses submitted should also include answers to all of the following prompts:

1. Design, development, manufacturing, and testing of needle-free vaccine delivery system
	1. Describe  existing capability to design needle-free methods for vaccine delivery
		1. Design considerations and existing or planned testing of needle-free delivery method with/without mRNA vaccine
		2. Vaccine construct(s) tested with the needle-free design
	2. Describe existing or planned capability to manufacture mRNA vaccine delivery needle-free methods suitable for human use. Please address:
		1. Expected throughput and ability to scale up production
		2. Quality control and cGMP manufacturing
2. mRNA vaccine formulation for needle-free delivery
	1. Describe existing capability to formulate and test mRNA vaccines for needle-free delivery. Please address:
		1. Product storage and transport conditions
		2. Product stability (time, temperature and any other requirements)
		3. Product stability testing considerations
	2. Describe experience in manufacturing and releasing sufficient quantities of cGMP material for Phase I-III human clinical trials
	3. Describe any current collaborations/partnerships with entities currently manufacturing clinical lots of mRNA vaccines for use in formulation studies
3. Preclinical testing of vaccine needle-free delivery system safety and efficacy
	1. Describe experience in performing preclinical testing for U.S. regulatory applications
	2. Describe any current collaborations/partnerships with entities experienced in the design and conduct of preclinical studies for U.S. regulatory applications
4. Regulatory sponsorship and execution of human clinical trials for safety and efficacy testing and/or FDA Animal Rule clinical trials where necessary
	1. Describe experience in serving as regulatory sponsor and obtaining FDA product approval(s)

**Appendix 1. Biological Threat List**

The Government interested in potential capabilities to address the following CBRN, pandemic influenza, and emerging infectious disease threats:

**Virus targets**

* Filoviruses
* Pandemic influenza (H5 and H7 specifically)
* Alphaviruses
* Flaviviruses (Zika virus specifically)
* Arenaviruses
* Bunyaviruses

**Bacterial**

* Plague
* Tularemia
* Melioidosis
* Glanders
* Q Fever

**Toxin threats**

* Botulinum toxin
* Ricin
* Conotoxins
* Saxotoxins

**Attachments/Links**

[**Download All Attachments/Links**](https://sam.gov/api/prod/opps/v3/opportunities/31e2f6fdeb094b9eb57a2e6fd654dedf/resources/download/zip?api_key=null&token=)

No attachments or links have been added to this opportunity.

**Contact Information**

**Contracting Office Address**

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* USA

**Primary Point of Contact**

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**Secondary Point of Contact**

**History**

* **Jun 02, 2021 02:35 pm EDT**Sources Sought (Original)