

Centers for Innovation in Advanced Development and Manufacturing **Request for Proposal**

Frequently Asked Questions

1. What is the primary mission of the proposed Centers?

The primary mission of the Centers is to provide core advanced development and manufacturing services for chemical, biological, radiological and nuclear (CBRN) medical countermeasures through public-private partnerships on a day-to-day basis. HHS/BARDA will coordinate and integrate these ADM core services for CBRN MCMs with those offered by other federal agencies (e.g., clinical studies at NIAID).

2. What are other missions of the proposed Centers?

The other purposes of the proposed Centers are:

(1) increase domestic vaccine and other biologicals manufacturing capacity by building new, or retrofitting existing pharmaceutical facilities for pandemic influenza & other threats in an emergency

(2) provide workforce development programs to foster and advance the next generation of domestic biopharmaceutical manufacturers.

In regard to pandemic influenza vaccines, the requirement for each Center will be to make first doses available within 12 weeks of receipt of the virus reference strain, for a total of 50 million doses of vaccine within four (4) months.

3. Is the development of pandemic influenza vaccines a requirement of these Centers?

No. The USG, through NIAID and BARDA, have other existing contracts in place for the development of vaccines for seasonal and pandemic influenza.

4. In the event of an influenza pandemic requiring vaccine surge capacity, how will pandemic vaccine be assigned to Centers?

Task orders for each MCM needing assistance will be competed among the Centers. If a Center has a cell-, recombinant,- or molecular-based pandemic influenza vaccine available, it will be considered.

5. Are the Centers required to make commercial products?

No, the Centers are NOT required by HHS to make commercial products in these facilities.

Core advanced development and manufacturing services for USG-designated CBRN MCMs are required for at least six (6) months per year; greater consideration will be given to those Offerors who can provide more than the minimum. However, the Centers are required to stay in compliance with all federal and other governmental regulatory guidelines.

6. How will the USG provide for the construction, operation and maintenance costs for the Centers?

Construction costs for the building of new or retrofitting of existing pharmaceutical facilities will be shared between HHS and the Centers with HHS supporting 49% and 75% respectively.

Core Services and Readiness: The costs associated with operation and maintenance of the Centers will be provided by the USG.

7. How will CBRN MCMs entering the Centers for assistance be prioritized & managed?

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is the U.S. government's governance framework for national medical countermeasure requirements, development, acquisition, stockpiling, distribution, and utilization. The PHEMCE is comprised of agencies from HHS, DoD, DHS, and VA. The PHEMCE Product Advisory Committee (PAC) comprised of HHS and DoD agencies reviews routinely the MCM development portfolios across the USG for CBRN threats.

- The PAC will perform a needs assessment of MCMs that could benefit through Center assistance.
- The PAC will recommend a prioritized MCM list to PHEMCE senior leaders for final approval.
- CBRN medical countermeasures will be competitively assigned to the Center having the best fit with that specific medical countermeasure.
- HHS will manage directly the HHS-sponsored Centers and coordinate activities between the pharmaceutical companies and the Centers.
- HHS will provide periodic reports to PHEMCE senior leaders and an outside Advisory Board (TBD) on progress, challenges, and other issues in the construction, operation, and maintenance of the Centers.
- In an emergency, PHEMCE will confer on the best usage of these facilities for the given threat.

8. Can the Centers be located outside of the U.S.?

No. The Centers and their activities must be conducted in the United States.