

Centers of Excellence for Vaccine Innovation and Development

The Concept: The nation requires protection against emerging pandemic and endemic threats both known and unknown. We can achieve this goal by creating a sustainable infrastructure that supports “warp speed” invention and development of vaccine platform technologies that not only provide robust protection and prevent transmission of disease, but also can efficiently and affordably be produced at commercial scale, stored, distributed, and administered worldwide. Establishing and funding a network of six Centers of Excellence (CoEs) with formulation expertise, antigen development experience, and manufacturing capabilities to support vaccine innovation and development will ensure our nation’s ability to rapidly respond to emerging infectious disease threats for public health and military preparedness in a cost-effective manner.

Innovation and development of vaccine platform technologies will focus on:

- Optimal vaccine compositions and combinations that protect against infection and to prevent transmission of disease, including for vulnerable populations such as the elderly, immunocompromised, and young children, by eliciting immune responses that are sufficiently:
 - **Broad**, for protection against future variants and/or related viruses;
 - **Durable**, to reduce the number of boosters needed for protection; and
 - **Robust**, to protect against early infection and potentially prevent transmission by enabling a mucosal immune response.
- Technology characteristics that enable *practical and affordable access* to vaccines:
 - **Temperature stability**, for shelf-life and ease of distribution and a simplified supply chain;
 - **Alternative (needle-free) routes of administration**, to ease administration and increase uptake;
 - **Sustainable raw materials**, for cost-efficient and reliable sourcing of component materials;
 - **Simple, scalable manufacturing processes** that enable the transfer of vaccine manufacturing technology to prepare reliable partners for rapid (on-demand) commercial-scale, globally distributed manufacture of approved vaccines.

The Goal: The network of CoEs will create a library of safe and effective vaccine candidates and critical vaccine components validated through Phase 1 clinical trials, while simultaneously working with commercial partners to ensure rapid scalability. The nation would have a sufficient supply of critical vaccine components to support advanced clinical trials for efficient regulatory approval of vaccines with a clear path to commercial manufacturing and distribution.

The Funding Ask: Ensure the nation is capable of responding to the next disease threat by making a sustained investment in vaccine innovation and development, providing annual funding of \$20 million to each CoE, to establish vaccine platforms for building broad, durable, robust vaccines that are easily administered and ready for commercial scale manufacture.

The Ask of the Vaccine Community: AAHI seeks input from experts in the vaccine industry to refine the proposal, express support, and communicate the need for the establishment of such a network.