INNOVATIONS BAA
BAA-16-100-SOL-00003

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Resilient People. Healthy Communities. A Nation Prepared.

Innovations Program Strategy & Goals

- The Pandemic and All Hazards Preparedness Act directs BARDA to assess and promote technologies that save time and cost in developing MCM for public health emergencies
- BARDA seeks, identifies, and supports technological solutions that improve preparedness capabilities by providing new tools and approaches to MCM development and manufacturing
- Innovations Areas of Interest are intended to find the best match between countermeasure need and technological opportunity, and are revised as that landscape evolves
- A point of emphasis is to identify new approaches and capabilities that elevate preparedness against multiple threats by serving as technological platforms
- The Innovations portfolio is opportunistic and does not have a single countermeasure or threat focus

Past Innovations Areas of Interest

- More efficient manufacturing technologies
- Tools for streamlined product testing and evaluation
- Product formulations to improve efficacy and stability
- More sensitive, rapid, and cost-effective diagnostic test platforms
- Host-directed and immuno-therapeutics
- Improved MCM delivery systems

Innovations Area of Interest BAA-16-100-SOL-00003

- Countermeasure need: pathogen-specific MCM (vaccines, immuno-therapeutics) that may be urgently needed in response to the emergence of a newly emerging pathogen typically take 2-5 years to develop
- Technological opportunity: new technologies have the potential to enable rapid and reliable development and manufacturing of vaccines and monoclonal antibodies to known and novel infectious diseases for preparedness and response

Innovations Area of Interest BAA-16-100-SOL-00003

- Development and demonstration of vaccine "plug and play" platform technologies using selected genes encoding immuno-protective proteins from infectious disease pathogens of interest
  - Cloning of genes into expression systems or vectors
  - Pre-clinical development in challenge or immunogenicity models
  - Toxicology studies
  - Master and working cell or vector banks, as appropriate
  - Validation of manufacturing process at pilot and commercial scale
  - Validation of release tests
  - Manufacturing of clinical lots
  - Validation of clinical assays
  - Dose-ranging Phase 1 safety study in healthy adults

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- Discovery, development, and demonstration of monoclonal antibody platform technologies using immunoprotective proteins from infectious disease pathogens of interest
  - Immunization and selection of candidate mAbs from infected animals or survivors of infection
  - Development of humanized antibodies against pathogen targets
  - Pre-clinical development in appropriate challenge models
  - Toxicology and tissue reactivity studies
  - Qualification of master and working cell banks
  - Validation of manufacturing process at pilot and commercial scale
  - Manufacturing of clinical lots
  - Validation of clinical neutralization or equivalent tests
  - PK/PD Phase 1 safety study in healthy adults

Innovations Area of Interest BAA-16-100-SOL-00003

- Proposals should fully describe all aspects of the platform and supportive technologies
- The countermeasure produced may consist of the antigen or antibody itself, but viral or genetic delivery vectors will also be considered
- Manufacturing process should be suitable for delivery of the product at commercial scale
- Clinical and Regulatory considerations for the platform should be addressed
- A real-time demonstration of the platform in a response scenario will be required with a designated pathogen