PLATFORMS TO FACILITATE EMERGING THREAT RESPONSE

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Resilient People. Healthy Communities. A Nation Prepared.

Platform Technologies

- Some technologies target specific product needs; others support capabilities that may apply to multiple countermeasures and enable improvements in the overall enterprise
- Platforms are technology that can be used, with simple adjustments, to the discovery, development, testing, and manufacturing of multiple countermeasures
- Platform technologies may improve capabilities to prepare for and respond to known and newly emerging threats

Target Characteristics for Threat Response Capability

- Speed
- Probability of Success
- Regulatory Familiarity
- Manufacturing Capability/Capacity
- Cost
- Platform Technologies for development of medical countermeasures are sought to meet these goals

Response Capability Gap

- Countermeasure need: pathogen-specific MCM (vaccines, immunotherapeutics) 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 A

- 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

Innovations Area of Interest B

- 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

BARDA Platform Technology Opportunity

- Support for platform technologies can be sought through BARDA's open solicitation
- Innovative Technologies program: BAA-16-100-SOL-00003
- For more information about BARDA's programs or to request a meeting with BARDA, visit BARDA's web-site, www.medicalcountermeasures.gov
- Platforms may be well established or may be more developmental with potential to improve upon current technologies

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

- Proposals should fully describe all aspects of the platform and supportive technologies
- A real-time demonstration of the platform in a response scenario will be required with a designated pathogen
- The countermeasure produced may consist of the antigen or antibody itself, but viral or genetic delivery vectors will also be considered