



BROAD AGENCY ANNOUNCEMENT (BAA)

ADVANCED DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR PANDEMIC INFLUENZA

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October 14, 2015

Overview Information

- Title: Broad Agency Announcement for the Advanced Development of Medical Countermeasures for Pandemic Influenza
- BAA-16-100-SOL-00002 (FBO.GOV)
- Purpose: Identify innovative and promising technologies for advanced development of medical countermeasures for influenza and other emerging infectious diseases.
- Submission interim deadlines:
 - Round 1: 30-Jan-2016
 - Round 2: 30-Apr-2016
 - Round 3: 30-Jul-2016
 - Round 4: 30-Oct-2016
 - Round 5: 30-Jan-2017
 - Round 6: 30-Apr-2017
 - Round 7: 30-Jul-2017
 - Round 8: 30-Oct-2017



Flu BAA History & Success

- History
 - Originally issued June 20, 2011 and renewed in 2012, 2013, 2014, and 2015.
- Success
 - 13 contracts have been awarded across all 5 Flu areas of interest
 - \$443M has been awarded through Oct 2015



Areas of Interest

- Areas of Interest under the 2015 influenza BAA
 1. Personal Protective Equipment (Mask & Respirators) for Influenza Infection and All-Hazards
 2. Full-Featured Continuous Ventilators for Influenza Infection and All-Hazards
 3. Influenza and Emerging Infectious Diseases - Test Systems and Diagnostic Tools
 4. Influenza Therapeutics
 5. Influenza Vaccines
- BARDA will endeavor to prioritize projects that provide benefits to all populations while also allowing for focused development projects or studies for at-risk populations where necessary.
- Special instructions are used to target specific needs
 - Will be released as amendments to the Flu BAA
 - Set "Watch This Opportunity" in FBO.gov to monitor BAA



AoI #4: Influenza Therapeutics

- Technical Point of Contact:
 - Melissa Willis, PhD; Melissa.Willis@hhs.gov
- Priorities:
 - Broadly reactive immunotherapeutics, such as monoclonal antibodies, that will be effective in treating severely ill, hospitalized patients of all ages who are infected with influenza or other emerging infectious diseases. Such therapeutics will demonstrate effectiveness when given later than 48 hours after onset of symptoms.



AoI #4: Influenza Therapeutics

- Data Expectations:
 - *In vitro* studies demonstrating broad-spectrum neutralizing activity across multiple subtypes of influenza A viruses including but not limited to modern strains of H1N1, H3N2, H5N1 and H7N9
 - Pre-clinical animal studies demonstrating efficacy against multiple strains of influenza
 - Data to support a wider therapeutic window (48-96 hours after infection with a preference for 72-96 hours after infection)
 - Data to support combination therapy with other influenza drugs
 - An active US Investigational New Drug (IND) application for an influenza indication, with appropriate pre-clinical GLP data
 - A completed clinical study report documenting Phase 1 dose-escalation
 - Evidence of adequate manufacturing capacity of final product(s)



AoI #5: Influenza Vaccines

- Technical Point of Contact:
 - Armen Donabedian, PhD; Armen.Donabedian@hhs.gov
- Priorities:
 - Vaccines that induce long-lasting and broad (heterotypic and/or heterosubtypic) immunity in all populations compared to currently licensed influenza vaccines
 - Vaccines that induce broad immunity so as to prime the population against newly emerging influenza viruses or other respiratory viruses of pandemic potential



AoI #5: Influenza Vaccines

- Data Expectations:
 - Pre-clinical and clinical studies supporting the ability of your candidate vaccine to elicit cross-reactive immune responses against antigenically diverse influenza A viruses
 - Data to support “Priming Immunity”
 - Pre-clinical and/or clinical data regarding the duration of the immune response
 - Data that demonstrate improvements in immunogenicity/efficacy as compared to existing licensed vaccines
 - Evidence of TRL6 of your proposed candidate or approach, including evidence of an in-effect US IND
 - All communications with the FDA for specific candidate
 - Information on all immunological assays used to evaluate immune responses in clinical trials. Include where assays were performed, qualification/validation state of the assay, and all data that may be used to correlate specific immune responses with clinical benefit



AoI #1: Personal Protective Equipment (Mask & Respirators) for Influenza Infection and All-Hazard

- Technical Point of Contact:
 - Rodney Wallace; Rodney.Wallace@hhs.gov
- Priorities:
 - Support improved respiratory protective devices with improved features over currently available products
 - Essential attributes (functionality, usability, comfort, decontamination and re-use, **cost efficiency**, **manufacturing efficiency**, and durability)
 - Applicable for all ages (pediatric through adult)
- Data Expectations:
 - Proposed benefit and supporting data
 - Commercialization, regulatory, & manufacturing plans



AoI #2: Full-Featured Continuous Ventilators for Influenza Infection and All-Hazards

- Technical Point of Contact:
 - Rodney Wallace; Rodney.Wallace@hhs.gov
- Priorities:
 - Support advanced development of new or improved ventilator to provide respiratory support in clinical care, transport, and emergency use settings
 - Key considerations include portable support neonate ($\geq 2.5\text{kg}$) to adult populations, ease of operation, use of universal components, ease of stockpiling/maintenance, provide accessories, low cost, domestic surge production
- Data Expectations
 - Data to support TRL 6
 - Prototype / preliminary performance data, commercialization plan, regulatory & manufacturing plans



AoI #3: Influenza and Emerging Infectious Diseases - Test Systems and Diagnostic Tools

- Technical Point of Contact:
 - Rodney Wallace; Rodney.Wallace@hhs.gov
- Priorities:
 - Consumer and patient-oriented diagnostic products for point of care, pharmacy, and home testing
 - New technologies: simpler/easier to use sequencing platforms for clinical labs, pandemic + seasonal strain ID & subtype
 - Clinical value studies
 - Novel Marker Identification – symptomatic & pre-symptomatic
- Data Expectations:
 - TRL 6 (most sub-areas)
 - Prototype / preliminary assay data, design history file, commercialization plan, regulatory & manufacturing plans



Overall BAA Process

- Stage 1: Submit Quad Chart/White Paper describing effort in sufficient detail for evaluation. If invited to submit a Full Proposal → go to Stage 2.
 - If not invited to submit a Full proposal → White Paper Submission
- Stage 2: Submit Full Proposal (includes Technical & Cost Proposals) in accordance to instructions provided in the letter of invite for evaluation.
 - If “Acceptable” → Acceptance Notification → Negotiation → Contract Award
 - If “Not Acceptable” → Not Accepted Notification → White Paper Submission



General Guidance

- Potential partners are encouraged to contact appropriate technical point of contact at BARDA prior to submission of White Paper.
 - Consider utilization of the BARDA TechWatch Program (www.medicalcountermeasures.gov)
- After formal submission, all communications related to that submission must be through the Office of Acquisitions Management, Contracts, and Grants (AMCG).
- All submissions and administrative inquiries regarding this BAA should be addressed to FLU-BAA@hhs.gov.
 - Specify "BAA-16-100-SOL-00002 QUAD CHART & WHITE PAPER for Development Area # ___" in the subject line.
- Assess maturity of technology using the appropriate Technology Readiness Level (TRL) criteria
 - Data needs to be provided to support completion of all activities at a given TRL level
 - If technology is insufficiently mature, NIH and DoD solicitations may be more applicable.
- White Papers will not be debriefed.



Website: <https://www.medicalcountermeasures.gov/>

- Information on open influenza BAAs and RFPs
- Information on setting up a TechWatch meeting with BARDA to discuss your technology



The image features a red square logo on the left with a white diamond containing four icons: a biohazard symbol, a radiation symbol, a globe, and a flask. Below the diamond, the text "Medical Countermeasures" is written in white and red. To the right is a photograph of several glass vials with blue caps. Below the photograph, the text "Now Open: Broad Agency Announcements" is displayed in white, followed by "Broad Agency Announcements for Advanced Research and Development of Medical Countermeasures for Pandemic Influenza and Chemical, Biological, Radiological and Nuclear Threats..." in a smaller font.