USG ZIKA VIRUS MCM RESPONSE

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Resilient People. Healthy Communities. A Nation Prepared.
NIAID resources to support Zika product development

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Ongoing Zika research efforts at NIAID

- Basic research
  - Reagents (mAb panels, rec. proteins, cDNA clones)
  - Structural biology
  - Sequencing and OMICs
  - Animal models of infection and disease
  - Immune responses
  - Viral replication/evolution
  - Vector competence
- Natural history studies (Brazil, Nicaragua)
- Product development
  - Vaccines
  - Diagnostics
  - Therapeutics
  - Vector Control
NIH funding announcements

- Notices highlighting High-Priority Zika virus Research Areas
  - NOT-AI-16-026: Notice of NIAID's Interest to Highlight High-Priority Zika virus (ZIKV) Research Areas
  - NOT-HD-16-004: Notice of NICHD, NINDS, NIDCR and NIAID's Interest to Prioritize Zika Virus (ZIKV) Research Areas

- Funding Opportunity Announcement
  - PAR-16-106: Rapid Assessment of Zika Virus (ZIKV) Complications (R21). Expedited (rapid) funding mechanism for research on Zika virus (ZIKV) and its complications.
NIAID Partnerships Program for Translational Research

FY2017 Request for Applications (RFA):
Partnerships for Countermeasures against Select Pathogens (R01)

- Support for preclinical development of candidate countermeasures and related platform technologies
- Performance-based, milestone-driven funding
- Up to $750K/year (Direct Costs) for up to 5 years
- Supported Zika countermeasures
  - Therapeutics
  - Vaccines
  - Diagnostics

NIH National Institute of Allergy and Infectious Diseases
Pre-clinical Product Development Services

**Therapeutics**

- In Vitro Assessment of Antimicrobial Activity
- Interventional Agents
- Biopharmaceutical Products

**Vaccines**

- Testing
- Manufacturing

**Animal Models**

- [Image of animal models]

- [Image of in vitro assessment of antimicrobial activity]
- [Image of interventional agents]
- [Image of biopharmaceutical products]
- [Image of testing]
- [Image of manufacturing]

**Chemistry, Manufacturing, and Controls (CMC)**

Documentation for IND
NIH’s Network of Vaccine and Treatment Evaluation Units (VTEUs)

- Established in 1962
- Clinical trials for vaccines, therapeutics, and devices
- Access to diverse population types (e.g., pediatric, elderly, infected individuals)
- Expanded scope:
  - International trials
  - Epidemiologic and sample collection studies

Slide Source: A. S. Fauci
Support the advanced development of medical countermeasures for CBRN, pandemic influenza, and emerging infectious disease threats.
BARDA Priorities

BARDA will work with PHEMCE partners to address medical countermeasure needs for the Zika response both domestically and globally.

- **Prevent** Zika virus infection through new vaccines
- **Detect** acute and previous Zika virus infections through new rapid diagnostics
- **Ensure** a blood supply safe from Zika virus through use of screening tests for donated blood and virus inactivation in blood products
- **Activate** our National Medical Countermeasure Response Infrastructure to help medical countermeasure developers
Contact Us

- Request a Tech Watch meeting through [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Contact Jonathan Seals, Director Strategic Science and Technology Division, [jonathan.seals@hhs.gov](mailto:jonathan.seals@hhs.gov)

- BARDA Broad Agency Announcements
  - [BAA-16-100-SOL-00001](http://www.medicalcountermeasures.gov) will support point of care (POC), laboratory based and blood screening assays.
    - Technical Point of Contact: Rodney Wallace; [rodney.wallace@hhs.gov](mailto:rodney.wallace@hhs.gov)
  - [BAA-16-100-SOL-00003](http://www.medicalcountermeasures.gov) will support innovation through development of platform technologies that enhance capabilities for development and manufacturing of MCMs.
    - Technical Point of Contact: Mark Craven; [mark.craven@hhs.gov](mailto:mark.craven@hhs.gov)
FDA Zika Resources

www.fda.gov/medicalcountermeasures

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