ZIKA VACCINE DEVELOPMENT AT HHS

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BARDA
NAISS 2017
May 10, 2017

BARDA’s Mission
BARDA’s mission is to protect the American People by developing and making available medical countermeasures to address Chemical, Biological, radiological, and Nuclear (CBRN) threats, Pandemic Influenza, and Emerging, Infectious Diseases.
**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

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**US Zika Vaccine Goals**

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<th>2016-2018</th>
<th>By 2018</th>
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<td><strong>Aim #1</strong>: Evaluate available vaccine candidates to assess safety, efficacy, and immunogenicity and identify protective immune correlates during the time of highest disease incidence</td>
<td><strong>Aim #2</strong>: Deploy an available vaccine under an appropriate regulatory mechanism to US populations at high risk of exposure</td>
<td><strong>Aim #3</strong>: Work with industry partners to commercialize vaccine(s) for broad distribution</td>
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Zika Virus Vaccine Landscape February 2016

Platform | Research & Discovery | Preclinical | Phase 1
--- | --- | --- | ---
Recombinant or Subunit | | | NOVAVAX
Live Attenuated | | | USG Funded
Whole Virus Inactivated | | | 
Nucleic Acid | | | ONA-VRC
Viral Vector | | | 
Other | | | 

Zika Virus Vaccine Landscape April 2017

Platform | Research & Discovery | Preclinical | Phase 1
--- | --- | --- | ---
Recombinant or Subunit | | | ZF-2W, Vir Biotech, Bharat Biotech, Novavax
Live Attenuated | | | 
Whole Virus Inactivated | | | Emergent, Bavarian Nordic, Inovio, Vaxart, Takeda
Nucleic Acid | | | Ono, Moderna, ONA-VRC
Viral Vector | | | VSV with Herpesviral Envelope Protein
Other | | | 

See also the WHO vaccine pipeline tracker for continuing updates:
http://who.int/immunization/research/vaccine_pipeline_tracker/en/
### HHS Zika Vaccines in Development

- **Nucleic Acid Vaccines**
  - DNA – NIAID/VRC, pending partnership
  - mRNA - NIAID/GSK, BARDA – novel vaccine delivery methodologies
  - mRNA – VRC/BARDA/Moderna Therapeutics

- **Whole-particle inactivated vaccines**
  - Based on DoD platform for flavivirus inactivation
  - WRAIR/NIAID/BARDA/SP
  - BARDA/Takeda

- **Live-attenuated dengue/ZIKV chimeric**
  - Based on NIAID dengue vaccine candidate, for non-obstetric population,
    - NIAID/Butantan

- **Vesicular stomatitis virus (VSV)**
  - NIAID/Harvard

### USG ZIKV Trials – Timelines

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- **VRC DNA (NIH)**
  - Phase 1
  - Phase 1
  - Phase 2/2b

- **Moderna mRNA**
  - Phase 1
  - Phase 2
  - Phase 3 Endemic
  - Phase 3 Lot-to-lot

- **WRAIR/NIAID/BARDA PIV**
  - Phase 1
  - Phase 3

- **Sanofi PIV**
  - Phase 1/2
  - Phase 2
  - Phase 3

- **Takeda PIV**
  - Phase 1
  - Phase 2
  - Phase 3
Regulatory Framework to Make Zika Vaccine Available

**Licensure**
- “Traditional” Approval
- Accelerated Approval
- “Animal Rule” Approval

**IND**
Unapproved product with no, or limited, human safety and effectiveness data
Expanded access use options

**EUA**
Unapproved product, or unapproved use of an approved product, in response to a public health emergency

THANK YOU