The Role of the National Institute of Allergy and Infectious Diseases in Research Addressing Zika Virus

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NIH Research Response to Emerging Infectious Diseases

- Therapeutics
- Vaccines
- Diagnostics
- Basic Research
- Clinical Research
- Resources for Researchers/Industry to Advance Product Development
Biomedical Research Response: Basic Science

- Molecular Virology: a) elucidate viral structure; b) compare viruses from different outbreaks
- Pathogenesis of disease
- Studies on immune response (innate and adaptive)
- Establish animal models
Biomedical Research Response: Epidemiology and Natural History

- Epidemiology and natural history
  - Symptomatic vs. asymptomatic
  - Frequency of sequelae
  - Cohort studies to determine incidence of adverse pregnancy outcomes in Zika-infected pregnant women

- Pathogenesis of microcephaly
Biomedical Research Response: Diagnostics

- **CDC** – Diagnostic and Reference Laboratory in Arbovirus Diseases Branch

- RT-PCR assay for Zika, Dengue and Chikungunya

- Antibody assay for acute infection that will not cross-react with other flaviviruses
Biomedical Research Response: Countermeasures – Therapeutics

- Developing *in vitro* antiviral screening assay

- Testing compounds with known activity against other flaviviruses

- Broad screening of compounds without known anti-flavivirus activity
Zika Vaccine Development Timeline

2016

- DNA vaccine candidate (NIAID VRC)
  - Preclinical Discovery
  - Phase 1
  - Phase 2/2b

- Whole-particle inactivated virus (NIAID/WRAIR/BARDA and corporate partner)
  - Preclinical Discovery
  - Phase 1
  - Phase 1
  - Phase 2/2b

- Live-attenuated Zika chimer (NIAID intramural/Butantan)
  - Preclinical Discovery
  - Phase 1
  - Phase 2/2b
  - Phase 2
  - Phase 3

2017

- Vesicular Stomatitis Virus vectored vaccine (NIAID extramural)
  - Preclinical Discovery/Tech Transfer
  - Phase 1

2018

- mRNA vaccine candidate (NIAID VRC)
  - Preclinical Discovery
  - Phase 1

Legend:
- Intramural NIAID and partnerships
- Extramural NIAID and partnerships
- Preparation for clinical trials
DNA Vaccine Development Timeline

2016
- Pilot scale manufacturing (NIAID Vaccine Research Center Pilot Plant, Frederick MD)
- Small animal testing
- Non-human primate testing

2017
- Initial safety and immunogenicity data

2018
- Phase 1 US multi-center settings (Zika naïve)
- Phase 2/2b (multiple sites in Southern US, Caribbean, Central and S. America, age range 18-35)
- Long term follow up
- Long term follow up