

Goal 1: MCM Development & Manufacturing / NIH Perspectives

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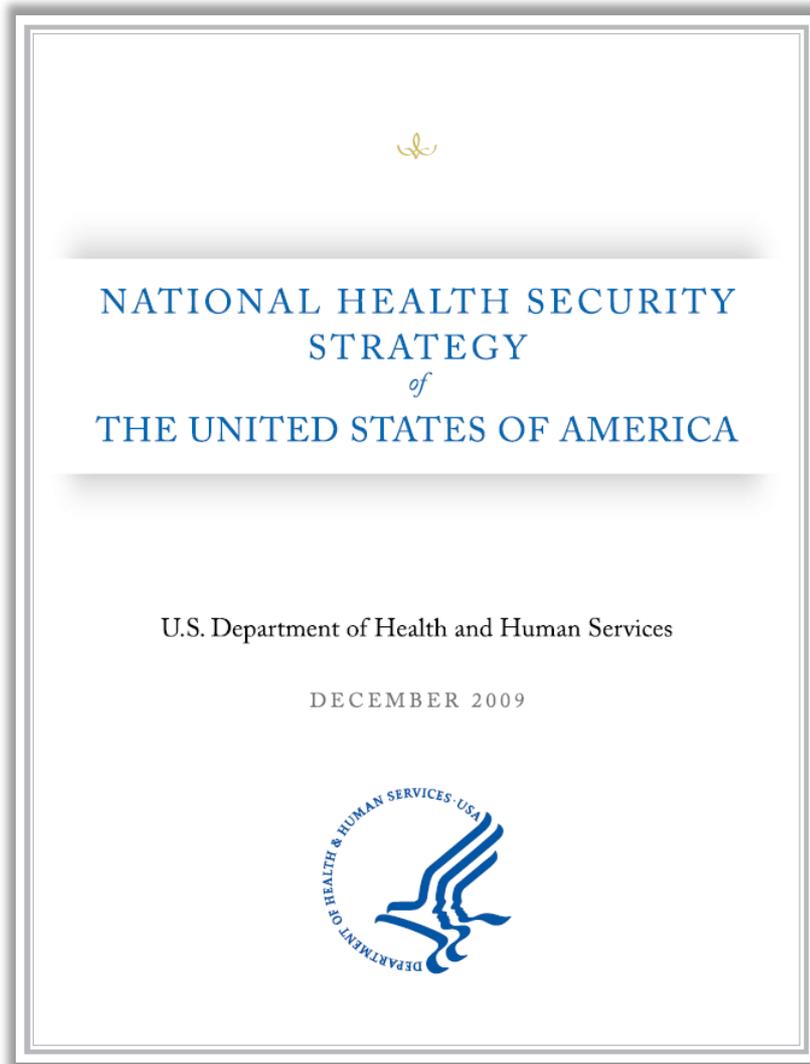
National Institute of Allergy and Infectious Diseases

National Institutes of Health

December 10, 2012

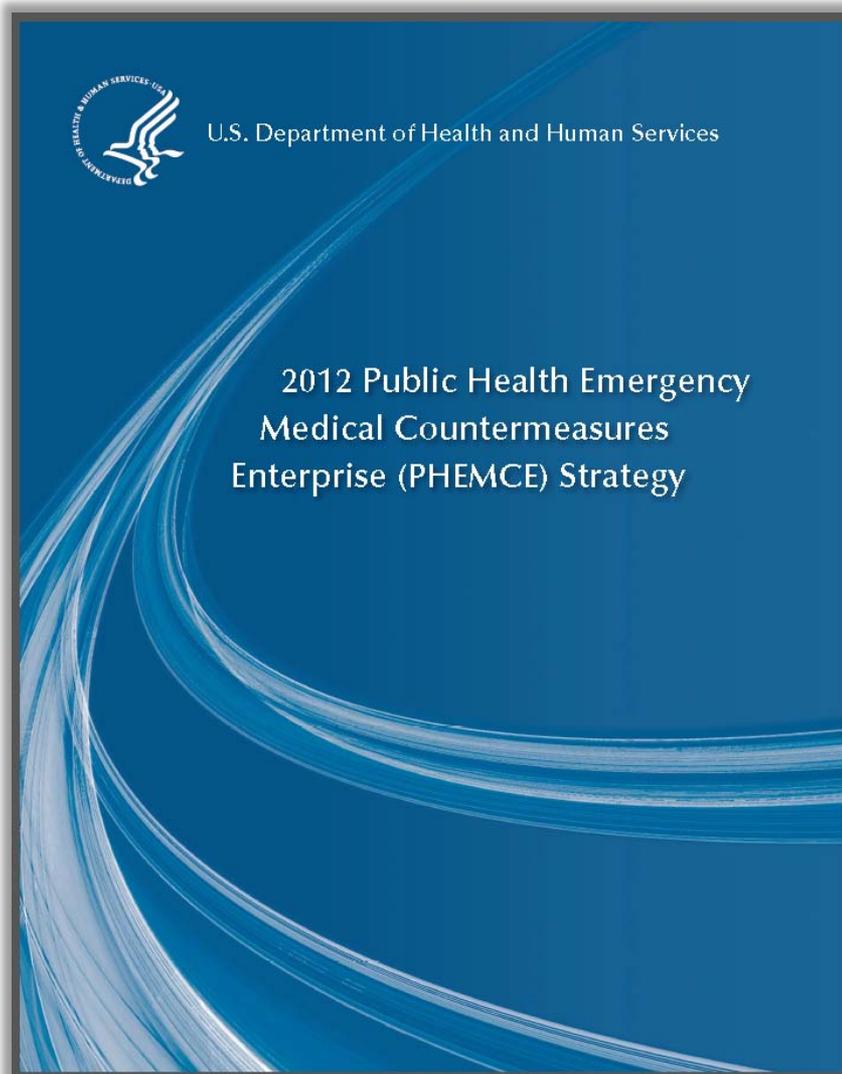


National Strategic Level



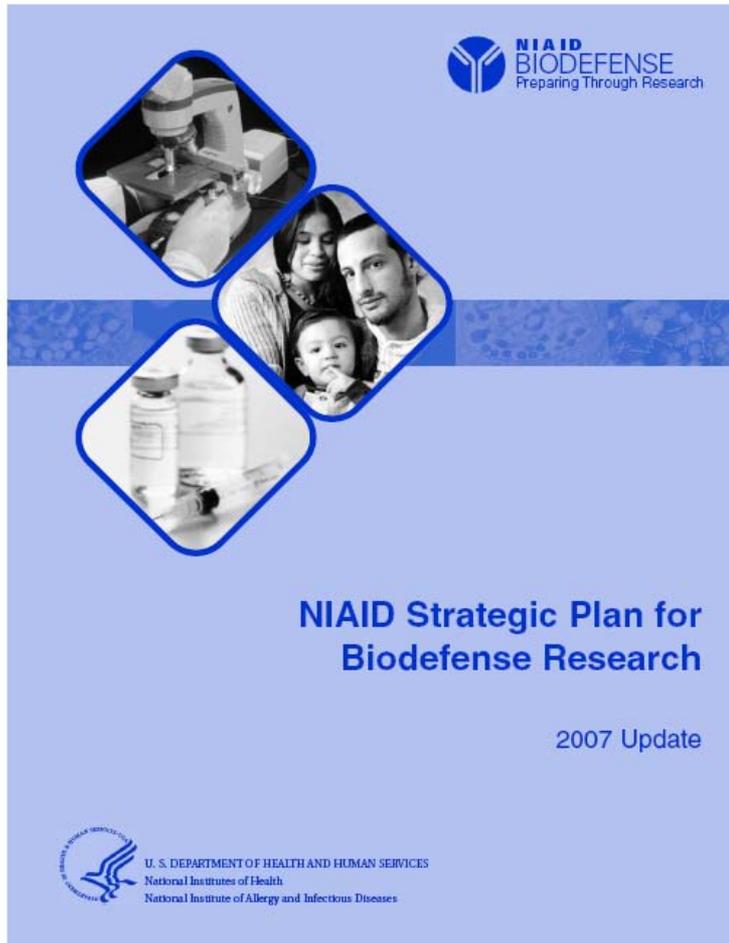
- **Build community resilience**
- **Strengthen and sustain health and emergency response systems**

PHEMCE Strategy 2012



- **Focus on high consequence threats**
- **Emphasize multifunctional medical countermeasures**
- **Ensure operational capability is designed in upfront**

Updated BioDefense Strategy (2007)

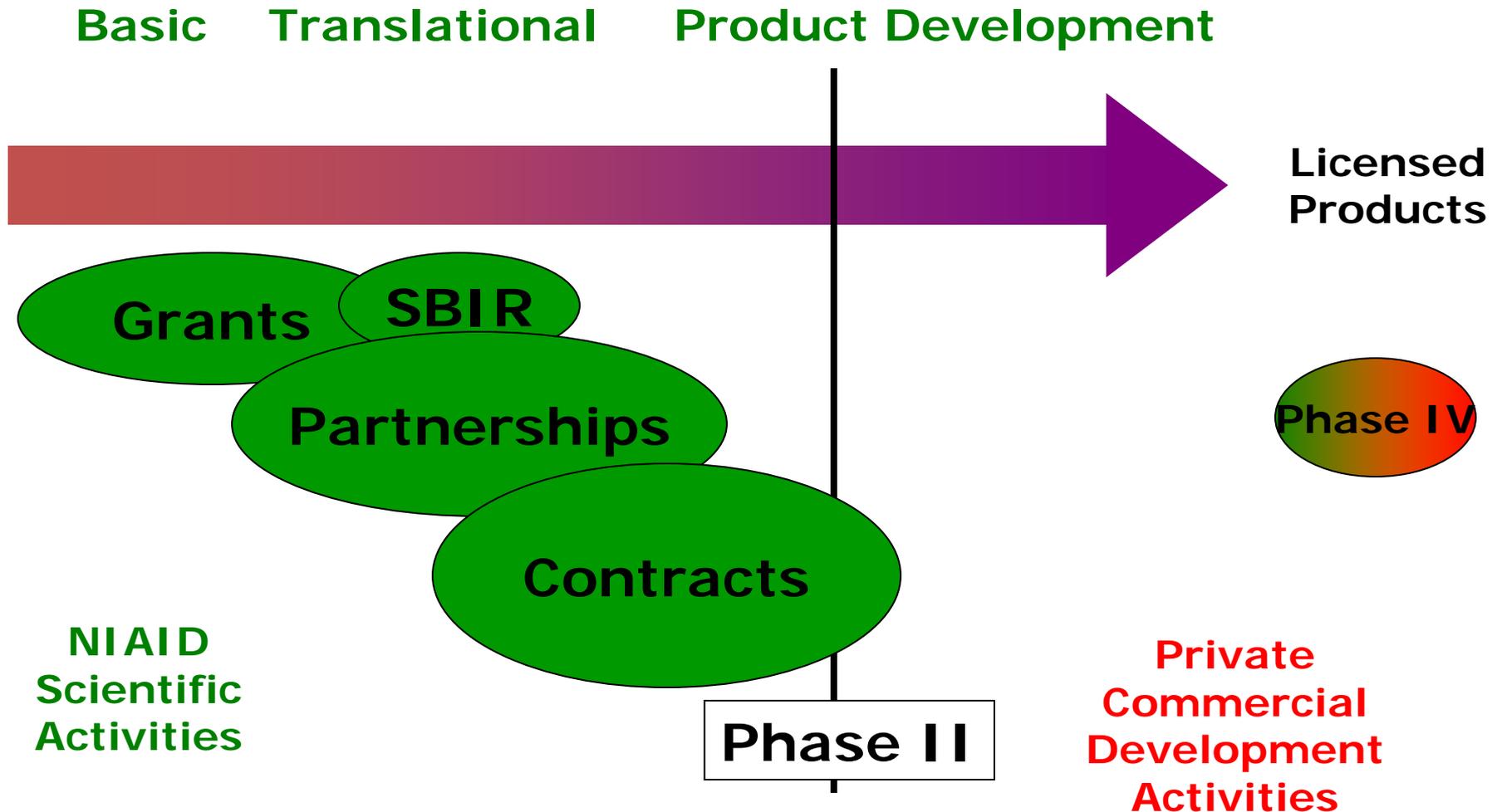


Envisioning the convergence of biodefense and generic public health concerns

Paradigms for new strategic directions

Emphasis on capabilities, rather than specific products

NIAID's Overlapping Funding Mechanisms



Transition partners

- BARDA – advanced development of candidate countermeasures
- FDA – data packages to support new clinical indications for off patent approved products
- CDC – data sets that inform clinical guidelines
- ASPR – data sets that inform utilization policies
- DOD – countermeasures aligned with warfighter requirements
- NGOs – countermeasures with either commercial or public health attributes beyond biodefense

Targeting Chokepoints

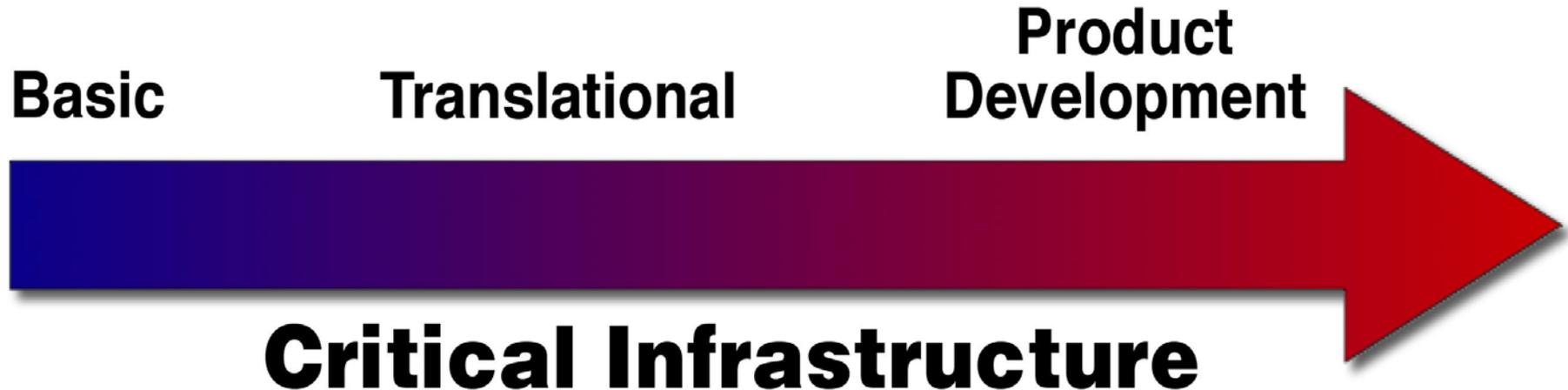


Preclinical & Clinical Infrastructure Support Services:

- *In vitro* assessment
- *In vivo* assessment
- IND enabling activities
- Phase I & II

(Current NIAID resources)

NIAID Services



Specialized

- sequencing, strains, reagents, screening, animal model development, biocontainment, etc.

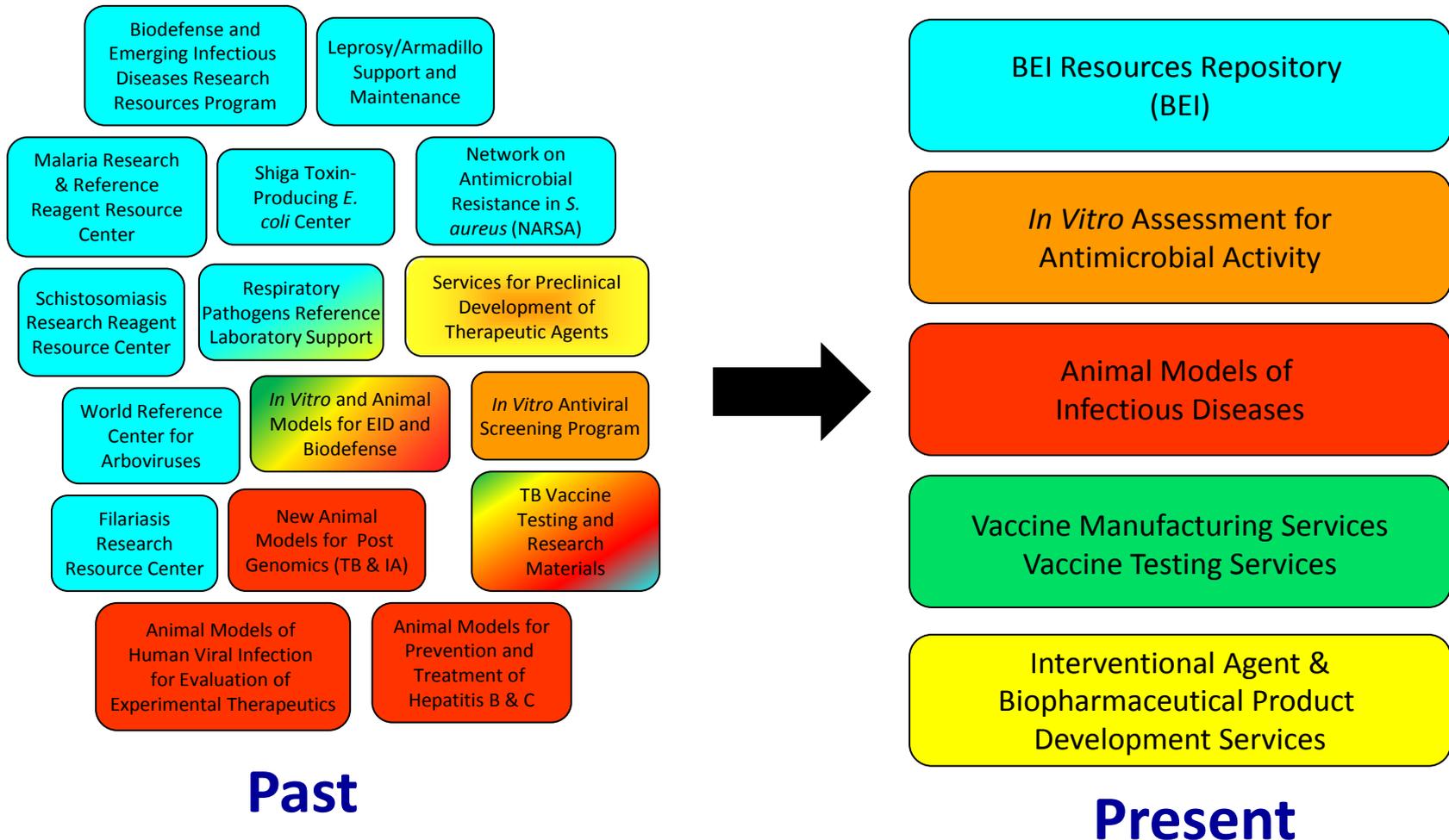
Product Related

- preclinical and clinical drug & vaccine development activities; animal testing

Clinical

- vaccine and drug trial units; Phase I & II with Phase III potential

Resource Evolution & Integration



Development of a Safer Smallpox Vaccine

Problem: Traditional smallpox vaccine contraindicated for certain populations

Basic Research

Translational

Product Development

FDA
Licensure

Past efforts for
a safer
smallpox
vaccine

Preclinical,
Manufacture, & Clinical
Trials

BLA enabling
Studies

Assay and
Animal Model
Development

Additional
Clinical Trial
Support

Delivery to
Strategic
National
Stockpile

FUNDING SOURCE

Other

NIAID/DMID

Company

Project BioShield

EFFORT:  Investigator  DMID Service Contracts  Company/PDP

THE WALL STREET JOURNAL

April 27, 2012

FDA Clears J&J Antibiotic For Treatment Of Plague

- **Levofloxacin approved to treat and prevent pneumonic plague**
- **Represents 10-year collaborative effort of NIAID, FDA, DoD, and Janssen Pharmaceuticals**
- **First product approved under the FDA Animal Rule**
- **FDA decision on ciprofloxacin pending**



Development of Rapid Diagnostic for Respiratory Viruses

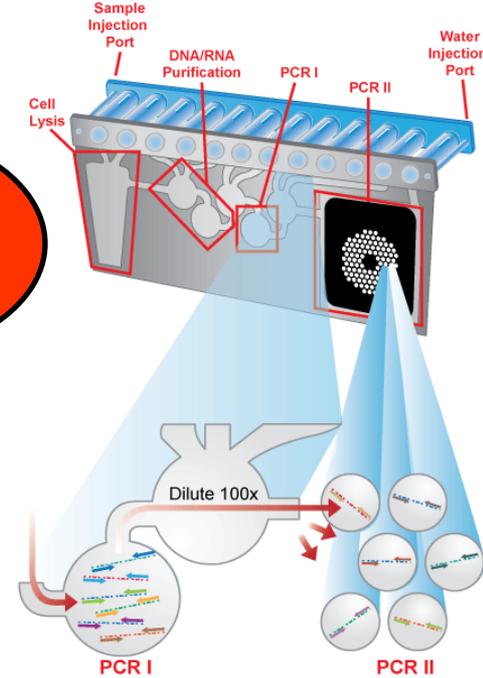
Problem: No rapid, POC diagnostics for respiratory pathogens



Genomic data

Engineering

Evaluation



Multiplexed platform

FUNDING SOURCE

NIAD/DMID
Company/Other

EFFORT: Academic DMID Service Contracts Company/PPP

NIH Focus & Capabilities

- Basic research
- Countermeasure concept identification and development (CAP)
- Discovery & early stage product development
- Product development support (in vitro / in vivo testing, etc.)
- Necessary regulatory science (in partnership with FDA)



National Institute of Allergy and Infectious Diseases

Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases.

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NIAID Labs

Resources for Researchers

Technology Development

Find NIAID Researchers

Scientific jobs, fellowships, and training

Clinical Trials Networks

Preventing and Treating Hepatitis

In the United States, about 80,000 are infected with hepatitis every year. NIAID supports and conducts research on new therapeutics and vaccines for the five hepatitis viruses.

Read More ▶



Health and Research Topics A to Z

- ▶ Antimicrobial (Drug) Resistance
- ▶ Biodefense and Related Programs
- ▶ Food Allergy
- ▶ Global Research
- ▶ HIV/AIDS
- ▶ Influenza (Flu)
- ▶ Immune System
- ▶ Malaria
- ▶ Sexually Transmitted Diseases
- ▶ Tuberculosis

▶ [View all A to Z Topics](#)

News & Events

NIH and D.C. Department of Health Work Together to Find New Approaches to Deter HIV/AIDS—July 25, 2012

NIH to Test Dapivirine Vaginal Ring for HIV Prevention in Women—July 24, 2012

Q&A: The ASPIRE HIV Prevention Study—July 24, 2012

NIH Scientists Identify Likely Predictors of Hepatitis C Severity—July 23, 2012

At AIDS 2012, Fauci Delivers Opening Plenary on Ending the HIV/AIDS Pandemic—July 23, 2012

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