Goal 1: MCM Development & Manufacturing / NIH Perspectives

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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

- 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

Basic Translational Product Development

Grants
SBIR
Partnerships
Contracts

Phase II

Licensed Products

Phase IV

Private Commercial Development Activities

NIAID Scientific Activities
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

Basic  Translational  Product Development  Early  Advanced

Licensed Products

Preclinical & Clinical Infrastructure Support Services:

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

(Current NIAID resources)
Critical Infrastructure

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

Past

Biodefense and Emerging Infectious Diseases Research Resources Program
Malaria Research & Reference Reagent Resource Center
World Reference Center for Arboviruses
Filariasis Research Resource Center
Animal Models of Human Viral Infection for Evaluation of Experimental Therapeutics

Leprosy/Armadillo Support and Maintenance
Shiga Toxin-Producing E. coli Center
Respiratory Pathogens Reference Laboratory Support
New Animal Models for Post Genomics (TB & IA)

Network on Antimicrobial Resistance in S. aureus (NARSA)
TB Vaccine Testing and Research Materials
In Vitro Antiviral Screening Program

Schistosomiasis Research Reagent Resource Center

Present

BEI Resources Repository (BEI)

In Vitro Assessment for Antimicrobial Activity

Animal Models of Infectious Diseases

Vaccine Manufacturing Services Vaccine Testing Services

Interventional Agent & Biopharmaceutical Product Development Services
Development of a Safer Smallpox Vaccine

Problem: Traditional smallpox vaccine contraindicated for certain populations

Basic Research  Translational  Product Development

Past efforts for a safer smallpox vaccine

Assay and Animal Model Development

Preclinical, Manufacture, & Clinical Trials

Additional Clinical Trial Support

BLA enabling Studies

Delivery to Strategic National Stockpile

FUNDING SOURCE
- NIAID/DMID
- Company/PDP
- Project BioShield
- Other

EFFORT: ♦ Investigator  □ DMID Service Contracts  ○ Company/PDP
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

Basic Translational Product Development

FDA 510(k)

Genomic data

Multiplexed platform

Engineering Evaluation

FUNDING SOURCE
NIAID/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)
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.

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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 to Test Dopamine 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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