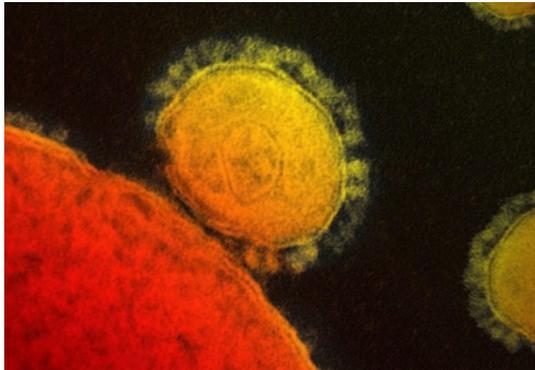




# EMERGING INFECTIOUS DISEASES OVERVIEW



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*Resilient People. Healthy Communities. A Nation Prepared.*

# Emerging Infectious Diseases Program Overview

## Viruses

## Bacteria

## Fungi

- Infinite number of known and unknown emerging infectious diseases (EIDs); most zoonoses and vector-borne diseases remain localized and/or of limited medical impact

- No reliable algorithm/model for predicting which EIDs will result in severe pandemics

- The large number of known and unknown EIDs with pandemic potential and uncertainty inherent in pathogen emergence and evolution makes highly-targeted advanced countermeasure development impractical

Andes  
 Australian bat lyssavirus  
 B19  
 Bagaza  
 Banna  
 Barmah Forest  
 Caliciviruses  
 California encephalitis  
 Cercopithecine herpes  
 Chikungunya  
 Crimean-Congo hemorrhagic fever  
 Dengue  
 Eastern equine encephalitis  
 Ebola sp. (Zaire, Reston)  
 Guama  
 Guanarito  
 Hantaviruses  
 Hendra  
 Hepatitis A  
 Hepatitis B  
 Hepatitis C  
 Hepatitis E  
 Hepatitis G  
 Human astrovirus  
 Human enterovirus A (71)  
 Human enterovirus B  
 Human herpesvirus 1  
 Human herpesvirus 2  
 Human herpesvirus 3  
 Human herpesvirus 5  
 Human herpesvirus 8  
 Human immunodeficiency virus  
 Human immunodeficiency virus 1  
 Human papillomavirus  
 Human T-lymphotropic virus 1  
 Human T-lymphotropic virus 2  
 Influenza (A)  
 Japanese encephalitis  
 Junin  
 Kyasanur Forest disease  
 Lassa fever

LaCrosse  
 Lassa  
 LCM  
 Marburg  
 Measles  
 Menangle  
 Morbilliviruses  
 Murp  
 Murray Valley encephalitis  
 Nipah  
 Norwalk  
 O'nyong-nyong  
 Oropouche  
 Parvoviruses  
 Poliovirus  
 Rabies  
 Rift Valley fever  
 Ross River  
 Rotavirus A  
 Rotavirus B  
 Rotavirus C  
 Sarsa  
 Sandfly fever Naples  
 SARS  
 Sialidase  
 Sin Nombre  
 St Louis encephalitis  
 Tick-borne encephalitis virus  
 Tick-borne virus related poxviruses  
 Venezuelan equine encephalitis  
 Wesselsbron  
 West Nile  
 Western equine encephalitis  
 Yellow fever  
 Zika

*Aeromonas caviae*  
*Bacillus anthracis*  
*B. cereus* (var. *subtilis*)  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis* (*Brucella melitensis*)  
*Brucella abortus*  
*B. mallei*  
*B. pseudomallei*  
*Campylobacter fetus*  
*C. jejuni*  
*Chlamydia psittaci*  
*Clostridium botulinum*  
*C. perfringens*  
*Corynebacterium amycolatum*  
*C. diphtheriae*  
*Coxiella burnetii*  
*Ehrlichia (chaffeensis)*  
*E. coli*  
*Enterobacteriaceae*  
*E. faecium*  
*Escherichia coli* (O157)  
*Francisella tularensis*  
*Legionella pneumophila*  
*M. mageritensis*  
*M. mageritensis*  
*Helicobacter pylori*  
*Klebsiella pneumoniae*  
*Legionella pneumophila*  
*Leptospira interrogans*  
*Listeria monocytogenes*  
*Mycobacterium avium*  
*M. bovis*  
*M. fortuitum*  
*M. haemophilum*  
*M. leprae*

*M. marinum*  
*M. tuberculosis* (MDR/XDR)  
*M. tuberculosis*  
*Neisseria gonorrhoeae*  
*N. meningitidis*  
*Psittacosis*  
*Ricin*  
*Rickettsia*  
*Rickettsia sp. (rickettsii)*  
*Salmonella sp. (Salmonella enteritidis)*  
*S. typhi*  
*S. typhimurium*  
*Serratia marcescens*  
*Shigella sp. (dysenteriae)*  
*Staphylococcus aureus*  
*Streptococcus pneumoniae*  
*Streptococcus pneumoniae*  
*S. pneumoniae*  
*Trichinella spiralis*  
*Vibrio cholerae*  
*Vibrio sp. (parahaemolyticus, vulnificus)*  
*Yersinia enterocolitica*  
*Y. Pestis*

*Aspergillus fumigatus*  
*Candida albicans*  
*Candida glabrata*  
*Coccidioides immitis*  
*Coccidioides posadasii*  
*Cryptococcus neoformans*  
*Fusarium moniliforme*  
*F. oxysporum*  
*F. solani*  
*Histoplasma capsulatum*  
*Malassezia pachydermatis*  
*Penicillium marneffei*  
*Pneumocystis carinii*  
*Sporothrix schenckii*  
*Trichosporon beigeli*  
*Encephalitozoon cuniculi*  
*E. hellem*  
*E. intestinalis*  
*Enterocytozoon bieneusi*  
*Nosema connori*  
*Trachipleistophora hominis*  
*Cryptosporidium parvum*  
 genera

## Helminths

*Ascaris lumbricoides*  
*Echinococcus granulosus*  
*Leishmania*  
*Leishmania conjunctus*  
*Onchocerca volvulus*  
*Schistosoma mansoni*  
*Strongyloides stercoralis*  
*Taenia solium*  
*Trichinella spiralis*  
*Wuchereria bancrofti*



# Emerging Infectious Disease: Charge to BARDA

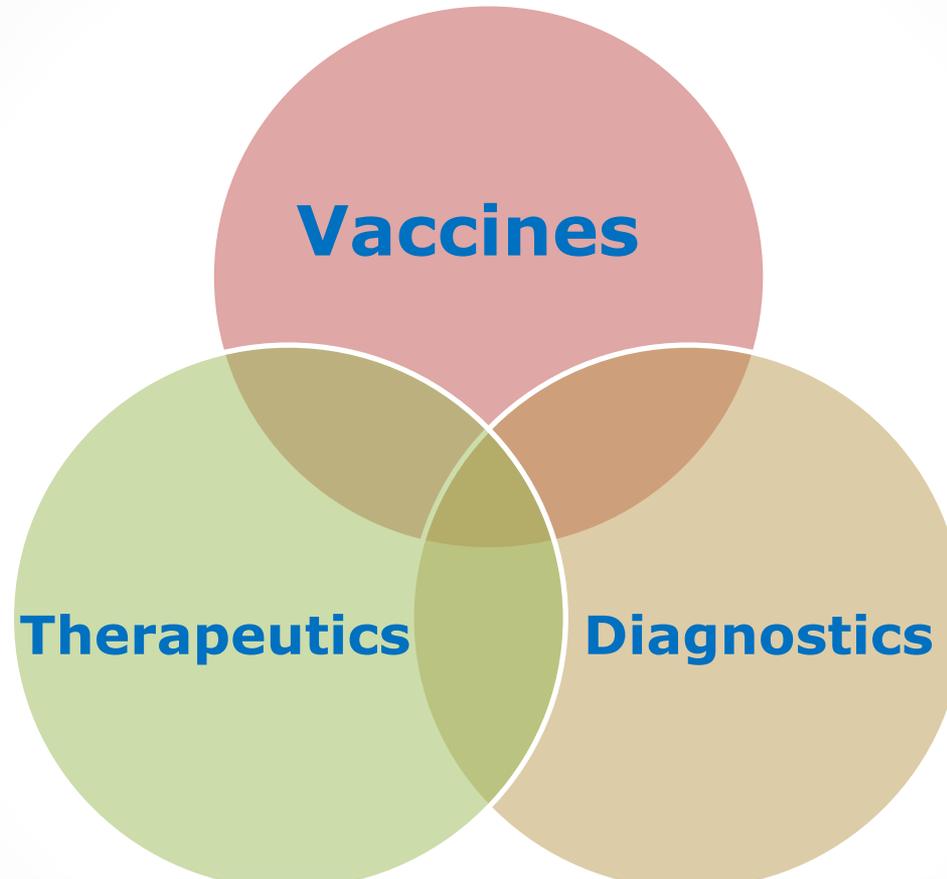
- The Pandemic and All-Hazards Preparedness Act- Title IV, sec. 401 calls for the Secretary to “**integrate ... emerging infectious disease requirements with the advanced research and development strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic and epidemic products**”
- Emerging infectious diseases fall within the charge of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)
- BARDA has assembled the staff, gathered the expertise, and built the program structure for dealing with Pan Flu and CBRN threat preparedness, and is well-positioned to apply this knowledge base to EID threat preparedness

# Multi-hazard advanced development strategies

- Approach preparedness against unpredictable disease threats through multi-hazard strategies
- Within multi-hazard strategies, particular focus can be given to pathogens which currently pose a high threat (quantifiable assessment)
- Complements and strengthens current BARDA programs, initiatives, and capabilities

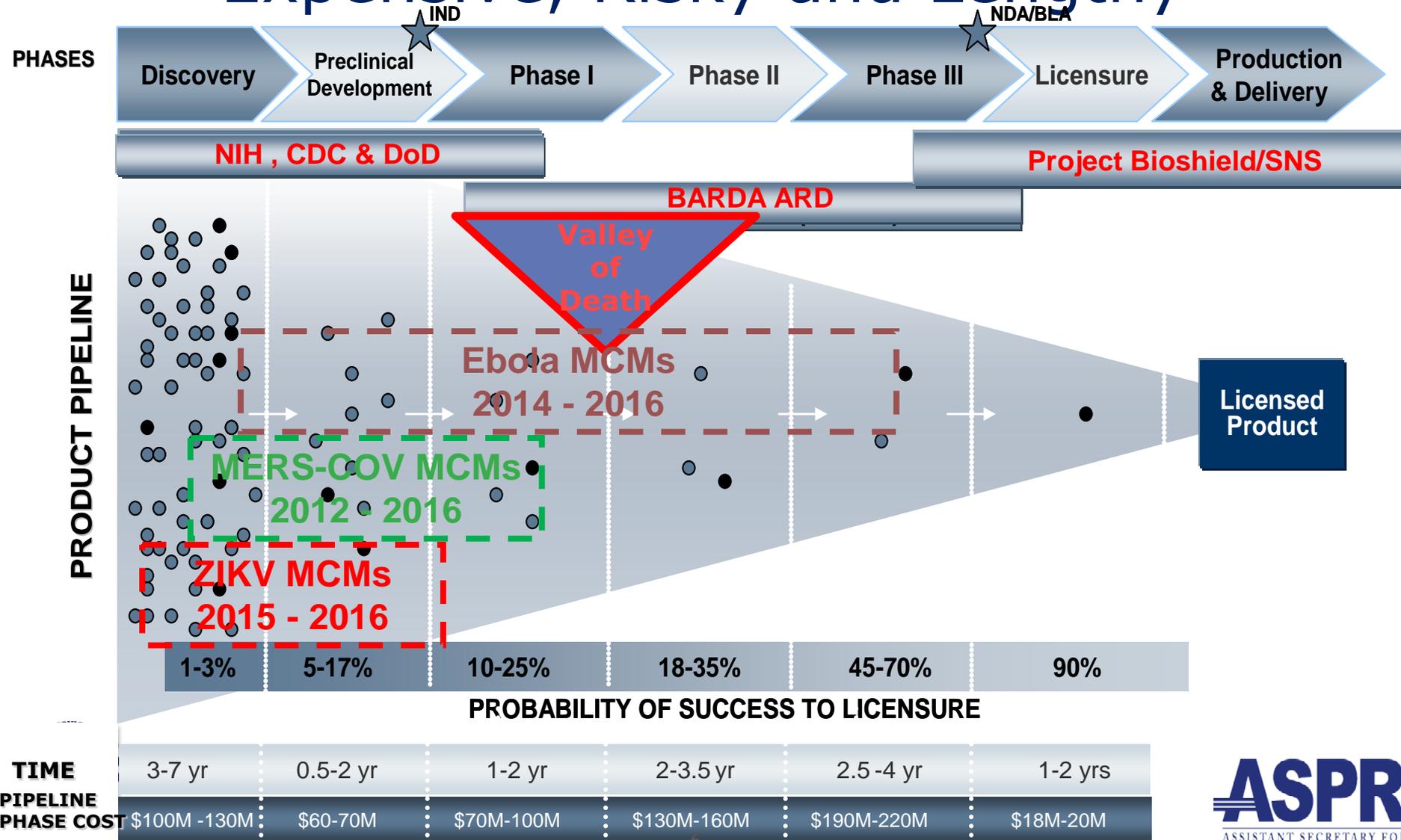


# Emerging Threats Require An Integrated Response



Early Detection → Early Response → Saving Lives

# Vaccine & Drug Development is Expensive, Risky and Lengthy



# BARDA EID Consideration Framework

## Threat-Based Criteria:

Is the pathogen/ pathogen group capable of being a *public health threat* to the U.S.?

- documented threat of emergence
- highly transmissible
- rapid and uncontrollable spread
- high morbidity/mortality rates

Yes

## Countermeasure-Based Criteria:

No or few developed, licensed, and highly effective MCMs already on the market?

Need for additional incentive for Industry to rapidly develop MCMs?

Need for advanced development MCM support (BARDA/CBRN, Global Health NGOs,?)

Yes

CONTINUAL RE-ASSESSMENT OF  
THREATS, COUNTERMEASURES, AND  
STATE OF THE SCIENCE

## Scientific criteria:

Is the level of basic MCM research, proof of concept, and basic development sufficient to progress to advanced development?

Public Health need for BARDA expertise, resources, and capabilities?

Yes

CANDIDATE  
EIDs FOR BARDA  
ADVANCED  
DEVELOPMENT

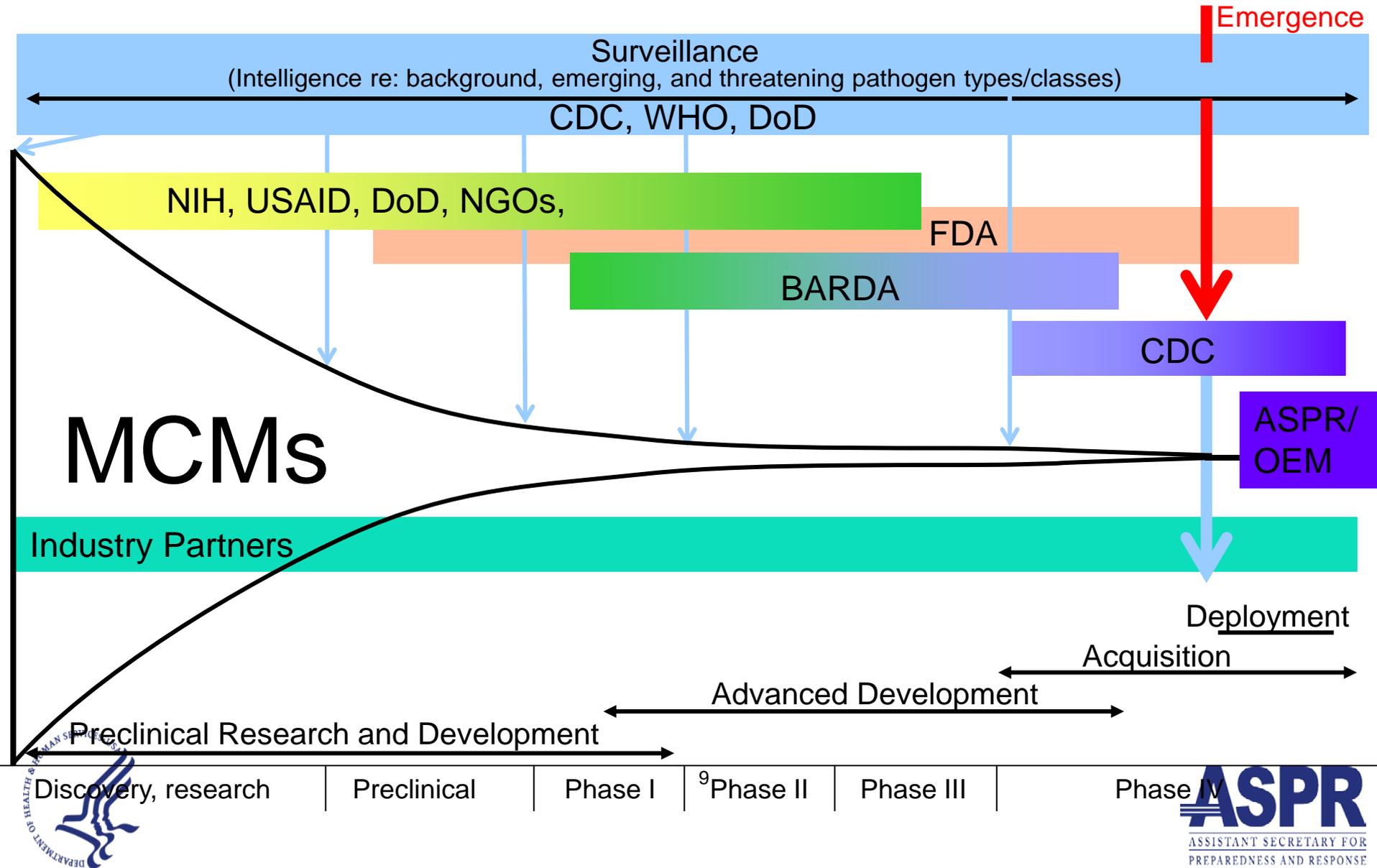


# Emerging Infectious Diseases Program

## Align with Broad BARDA Initiatives

- Build Emerging Disease requirements into solicitations for general, flexible, or adaptive technologies and countermeasures, including:
  - Personal Protective Equipment
  - Broad-spectrum Therapeutics
  - Platform Technologies
    - Vaccines
    - Diagnostics
  - Enhancing Manufacturing Capacity

# Emerging Infectious Disease MCM Continuum



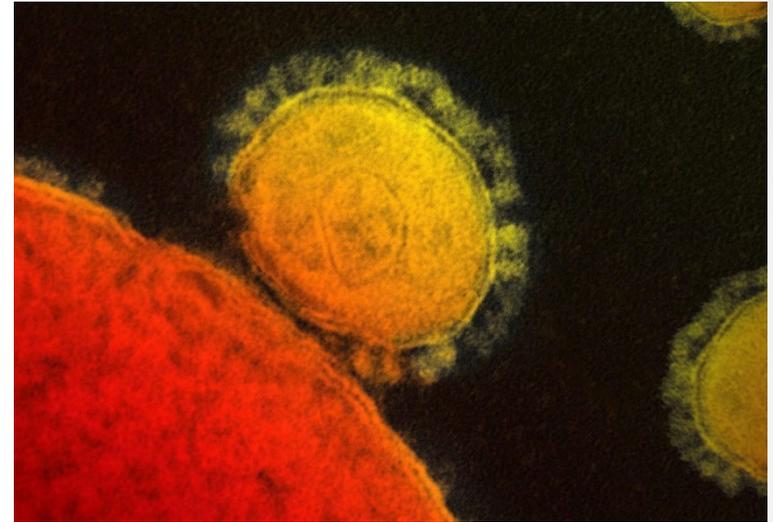
# MERS CORONAVIRUS



# Middle East respiratory syndrome coronavirus (MERS-CoV)

- MERS-CoV belongs to the family Coronaviridae
- Other coronaviruses include:
  - SARS-CoV
  - Human coronavirus 229E & OC43
- Enveloped viruses containing nonsegmented, positive-strand RNA genome
- Two outbreaks of novel coronaviruses causing acute respiratory distress syndrome and high death rates this century

MERS-CoV



South Korea Wedding during the MERS outbreak

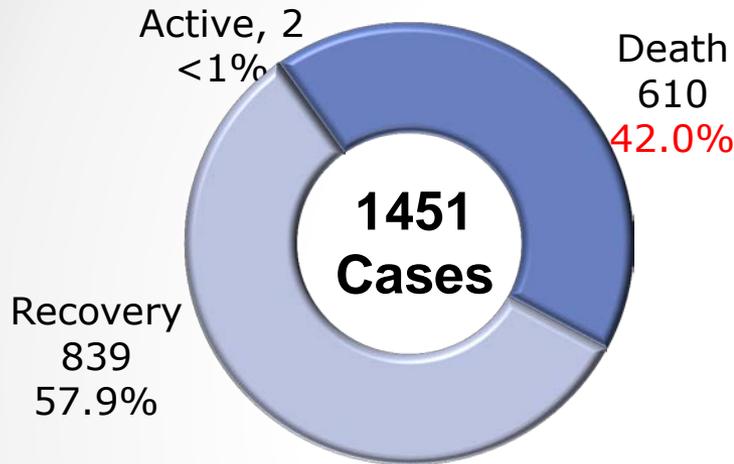


**There are currently no licensed or approved vaccines or treatments for Coronaviruses**

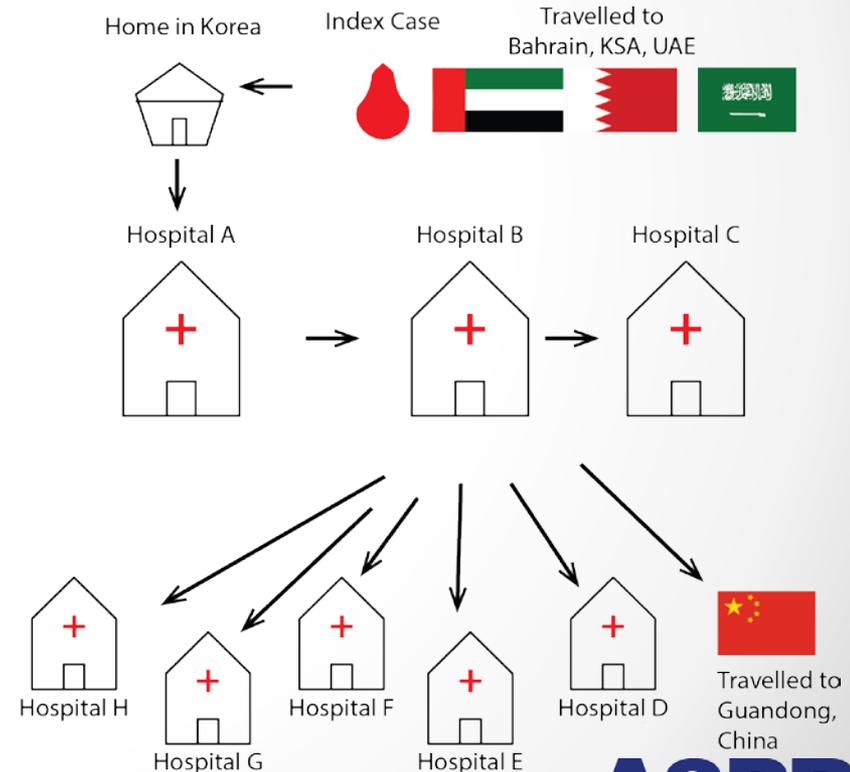


# MERS-CoV outbreaks in Saudi Arabia and South Korea

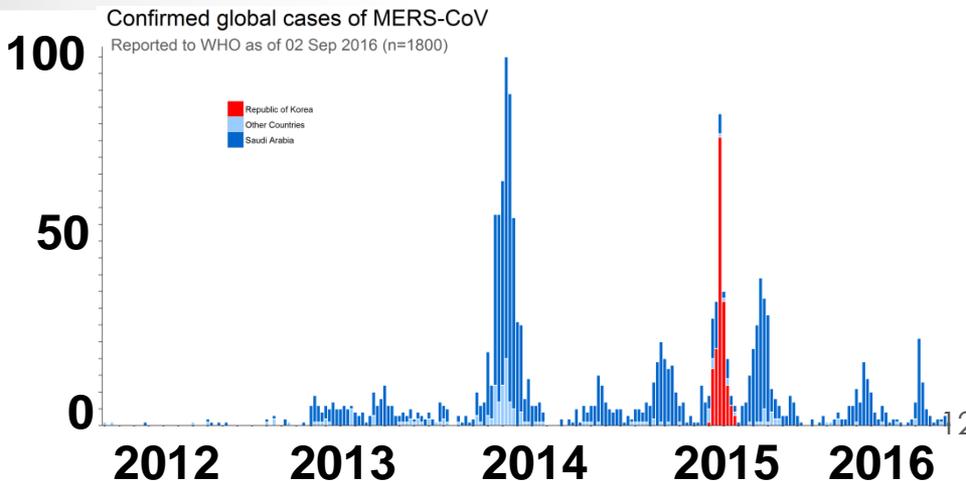
## Saudi Arabia since 2012



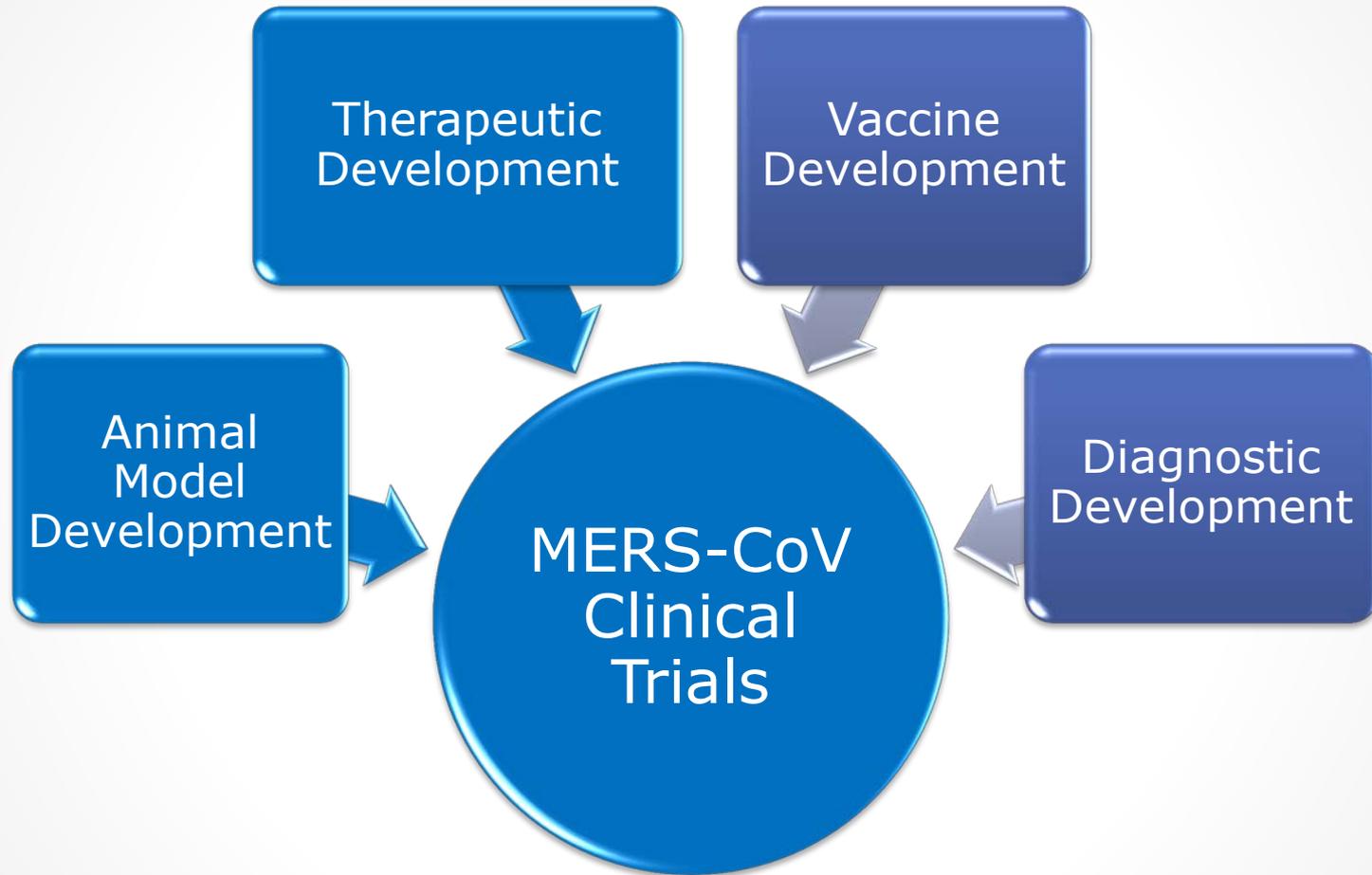
## South Korea, 2015



## Global cases per week

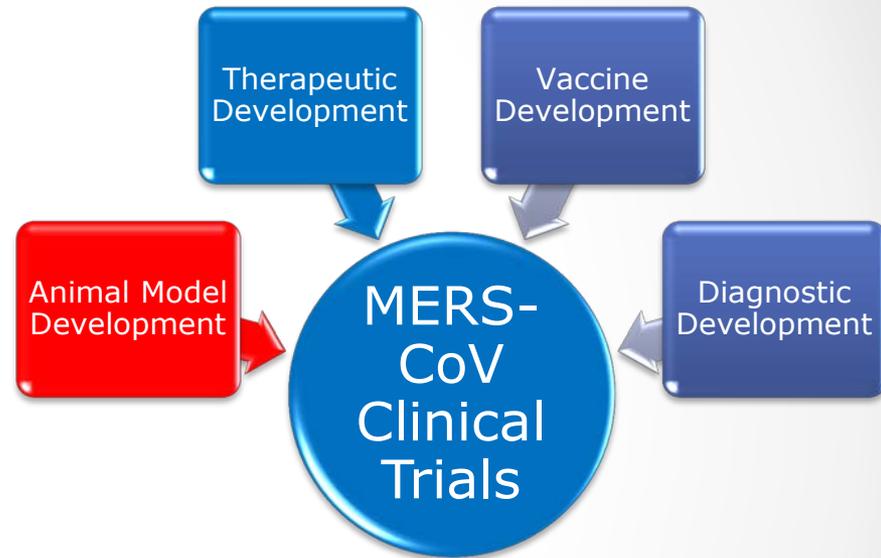


# BARDA Priorities



# Priorities: Animal Model Development

- Mouse studies at University of Maryland School of Medicine
- NHP studies at NIAID Rocky Mountain Laboratories
- Utilize the BARDA Nonclinical Development Network to standardize models
- NIH MERS Animal Model Standardization Workshop



# Priorities: Therapeutic Development

- Funnel all early stage drugs through the mouse models established at U. Maryland in Dr. Matt Frieman's lab
- If there is POC efficacy in the mouse, then test the drug in the NHP model established by Drs. Heinz Feldmann and Emmie DeWit at Rocky Mountain Labs
- Positive data from the NHP is the trigger for advancement into Phase 1

