



*United States Department of*

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



# **Nonclinical Development Network**

BARDA Core Service Overview

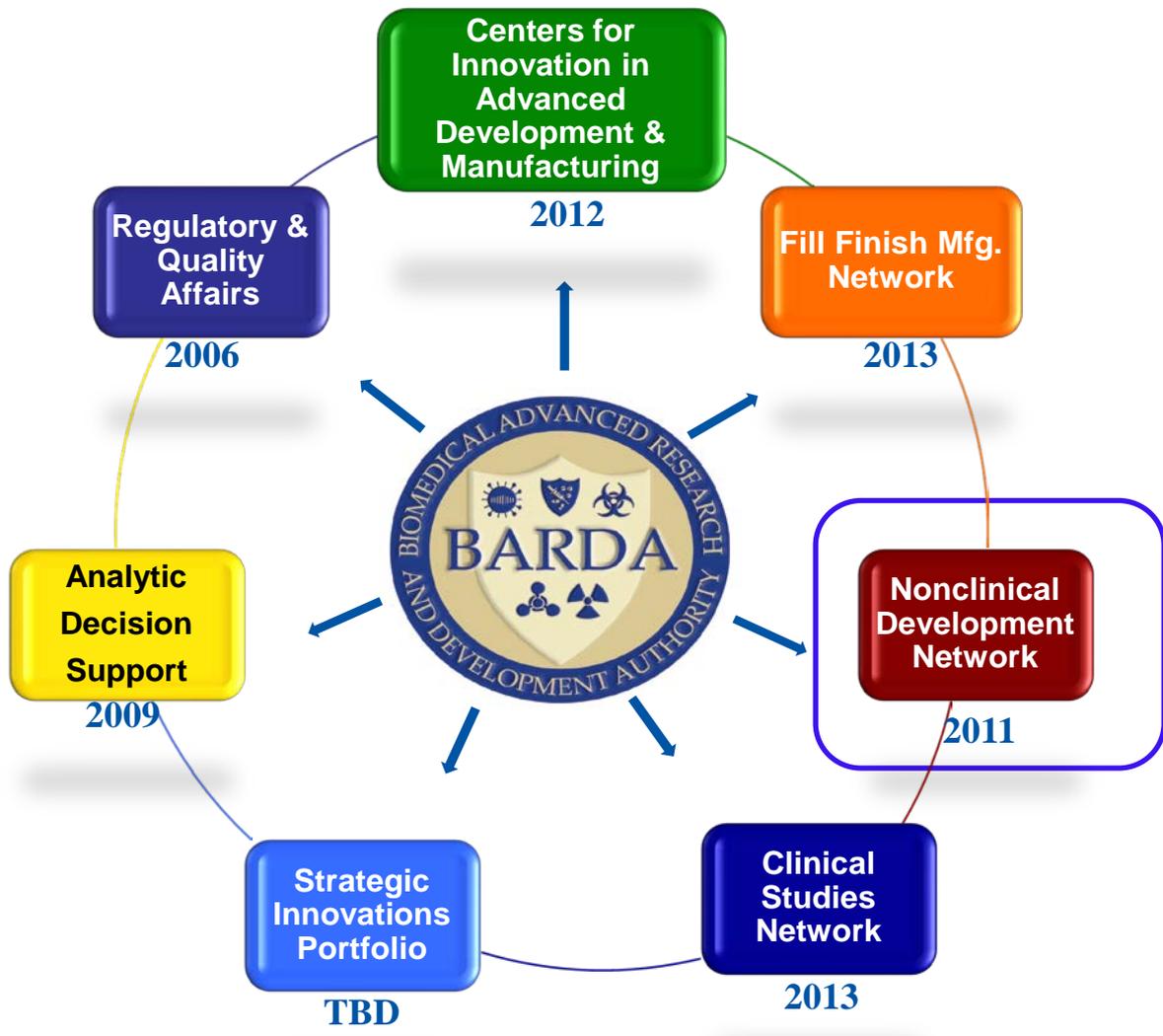
**Adeyinka Reeves, M.S., PMP**

**Acing Chief, Nonclinical Development Network**

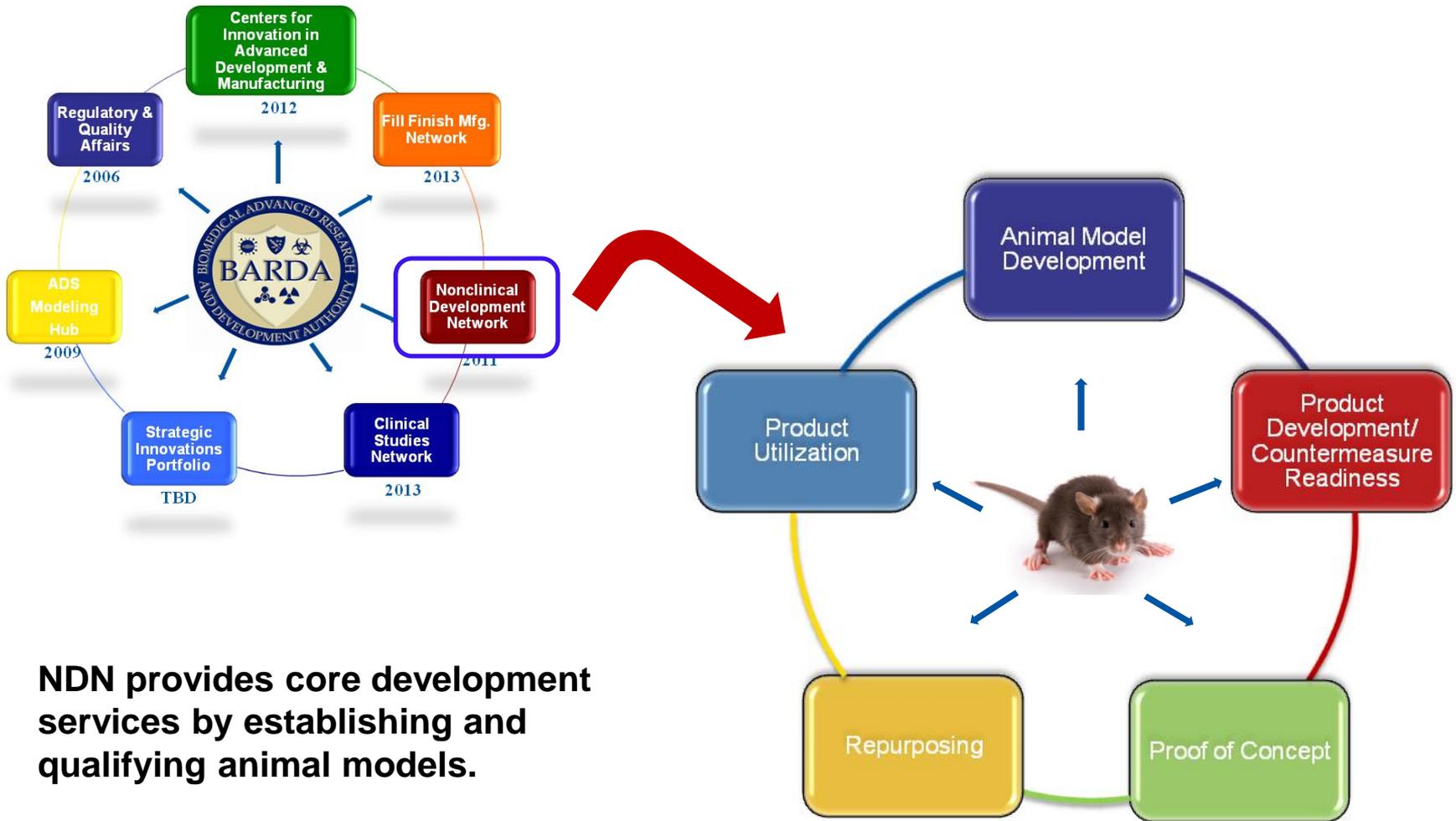
*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*



# The Nonclinical Development Network is a BARDA Core Service.



# Nonclinical Development Network: Capabilities



**NDN provides core development services by establishing and qualifying animal models.**



# Strategic Plan Alignment



## **PHEMCE Goal 1**

Identify, create, develop, manufacture and procure critical medical countermeasures

- Promote effective domestic and international partnerships with developers and manufacturers and support core services

## **ASPR Goal 3**

Promote an effective medical countermeasure enterprise

- Provide core advanced development and manufacturing services to medical innovators

## **BARDA Goal 2**

A capability base to provide enabling core services to medical countermeasure innovators

- Provide core product development services through developing and qualifying animal models.



# Stakeholder Engagement



## PHEMCE Partners

- *Animal Model Interagency Committee Meetings (AMIC)*
- *USG Working Groups*
- *Animal Model Development Qualification and Coordination Working Group (AMDQCWG)*

## NDN Partners

- *Annual Program Meetings*
- *BARDA Industry Day*
- *Study Design Collaboration*

## Product Developers

- *Proof of Concept Studies*
- *MCM Development Studies*
- *Data sharing*



# 2014 Accomplishments



- 35 Task Orders Awarded
- Engaging Our Partners
  - Continued cooperative animal model development efforts with PHEMCE Partners
  - Support of BARDA MCM development portfolio
- Enhancing the Animal Model Knowledge Base
  - Data Sharing
  - Standardized reagents available to scientific community
- Cost Savings
  - >\$14M saved in smallpox antiviral model development (rabbitpox and mousepox models)



# Enhancing the Animal Model Knowledge Base



## • Publications

- Glanders: An Overview of Infection in Humans and Animals: Accepted to Orphanet Journal of Rare Diseases (Battelle)
- Animal Models for *Francisella tularensis* and *Burkholderia* Species: Scientific and Regulatory Gaps Toward Approval of Antibiotics Under the FDA Animal Rule: Journal of Veterinary Pathology 2013 (BARDA)
- Clinical Definition of Melioidosis: American Journal of Tropical Medicine and Hygiene, March 2013 (PHE)
- An objective approach for *Burkholderia pseudomallei* strain selection as challenge material for medical countermeasures efficacy testing: Fronteries in Cellular and Infection Microbiology (Battelle)
- Genome Sequence of *Burkholderia pseudomallei* NCTC 13392: Genome A (Battelle)
- Comparative *Burkholderia pseudomallei* natural history virulence studies using an aerosol murine model of infection: Scientific Reports 2014 (UTMB)

## • Presentations

- ASM Biodefense 2012(Battelle)
- ASM Biodefense 2014 (Battelle, DSTL)
- World Melioidosis Congress 2013 (Battelle, UTMB)
- American Association for Laboratory Animal Science (AALAS), (Battelle)
- Bacillus ACT Meeting 2013
- Radiation Research Society Annual Meeting 2013 (PNNL, UIC, LBERI)
- Radiation Research Society Annual Meeting 2013 (BARDA)

## • Availability of strains to scientific community

- *Burkholderia pseudomallei* strain panel submitted to Biodefense and Emerging Infections Research Resources Repository (BEI)



# Portfolio Support



## BSA

- *B. pseudomallei* model development
- *B. mallei* model development
- Rabbitpox model development
- Mousepox model development
- *F. tularensis* model development

## Antitoxins and Vaccines

- AVA sample analysis
- *B. anthracis* spore viability

Nonclinical  
Development  
Network

## Chem and RadNuc

- Cyanide ingestion model development
- Mini-pig model development for H-ARS
- Repurposing studies for treatment of ARS
- Cytokine evaluation for treatment of radiation injury
- Proof of Concept studies for treatment of H-ARS
- Supportive care model development

## Diagnostics and Medical Devices

- Anthrax natural history
- Model development for biomarker expression



# What's New in FY14?



FY14 Task Order Awards	Threat	Function
Anthrax Antitoxin Head to Head	Anthrax	Product Utilization
Anthrax Natural History	Anthrax	Animal Model Development
Ketamine Repurposing	Nerve agents	Animal Model Development
Fractionated Irradiation Study in NHPs	Ionizing radiation exposure	Animal Model Development
Entolomid Proof of Concept	H-ARS	Proof of Concept
Multigenerational Irradiation Study in NHPs	Ionizing radiation exposure	Animal Model Development

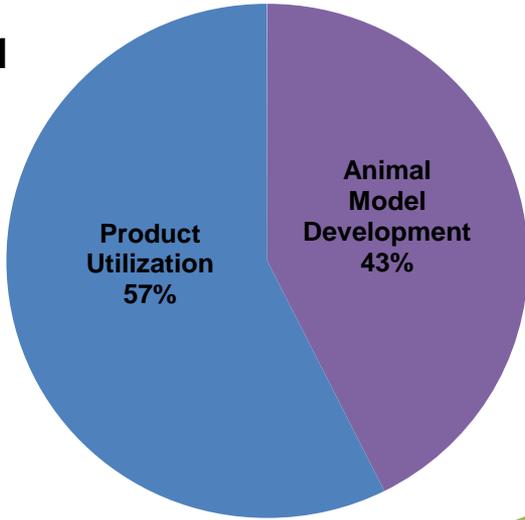
**35 projects initiated since May 2011**



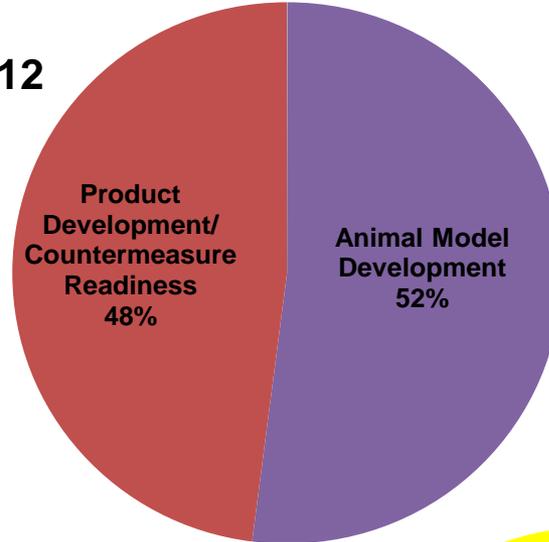
# Functional Area Resource Allocation



**FY11**

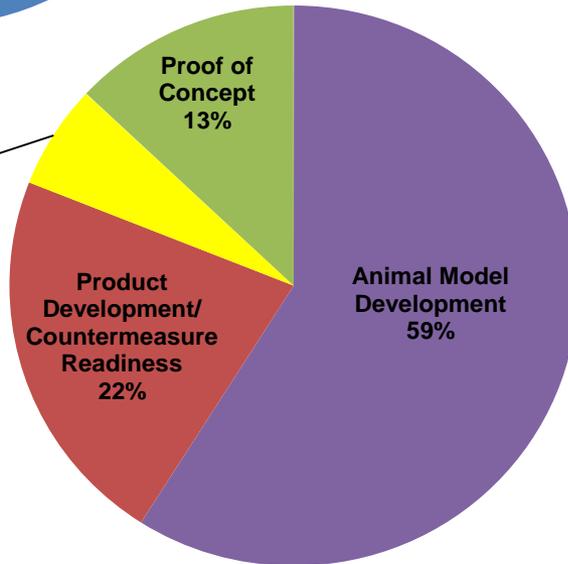


**FY12**

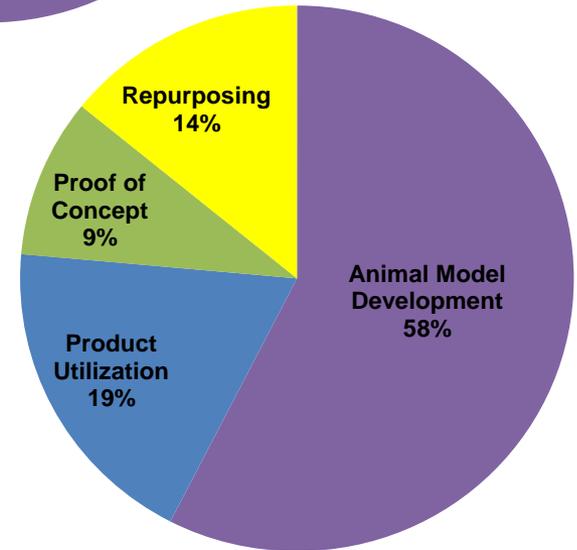


Repurposing  
6%

**FY13**



**FY14**





# FY15 Goals



## Nonclinical Development Network in FY15

Repurposing Studies

Utilization Studies

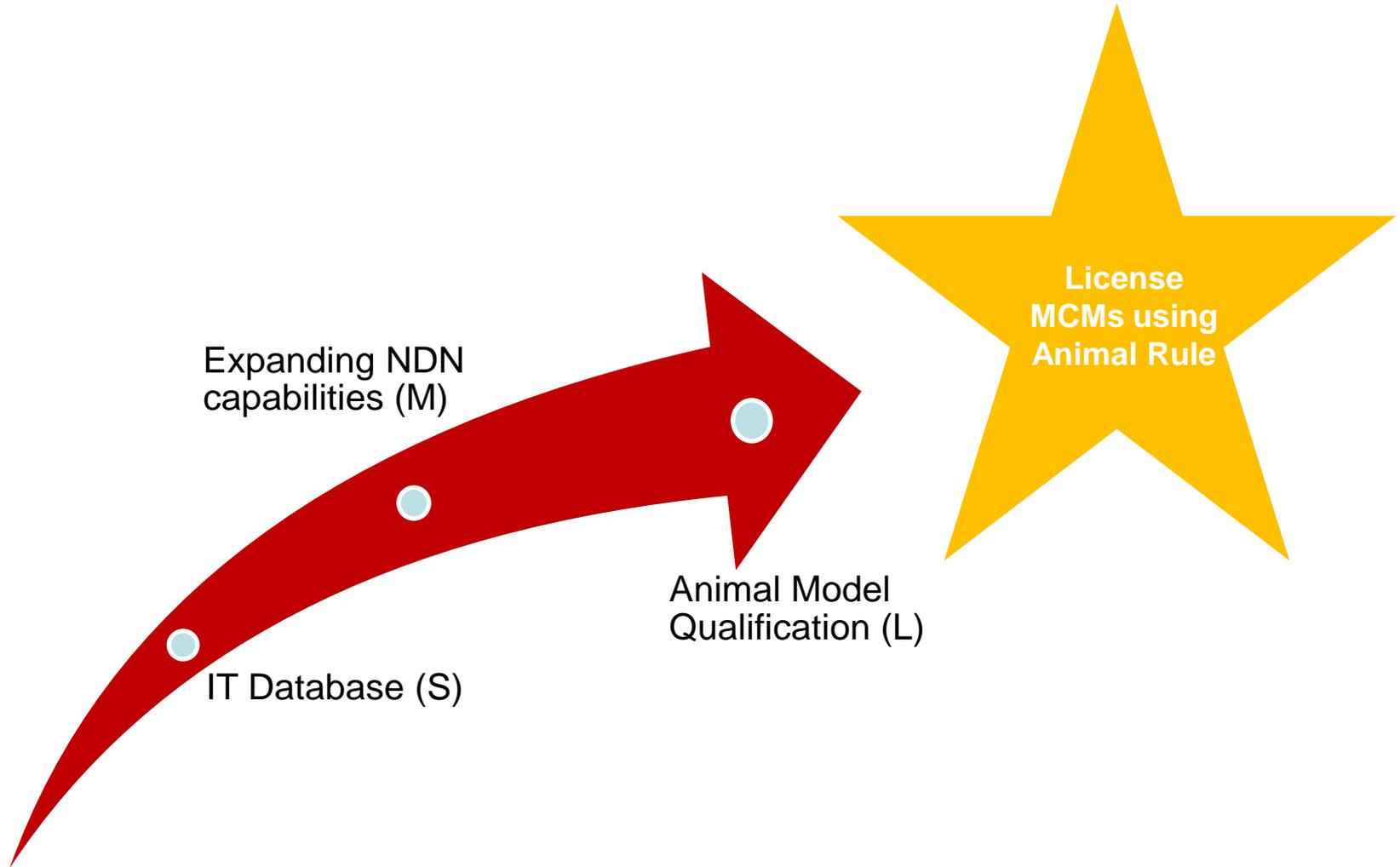
Standardizing Nonclinical Data Format

Strengthen NDN Partnerships

Expand Nonclinical Development Network for CRN



# NDN Trajectory for the Future





# Nonclinical Development Network

