



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Nonclinical Development Network

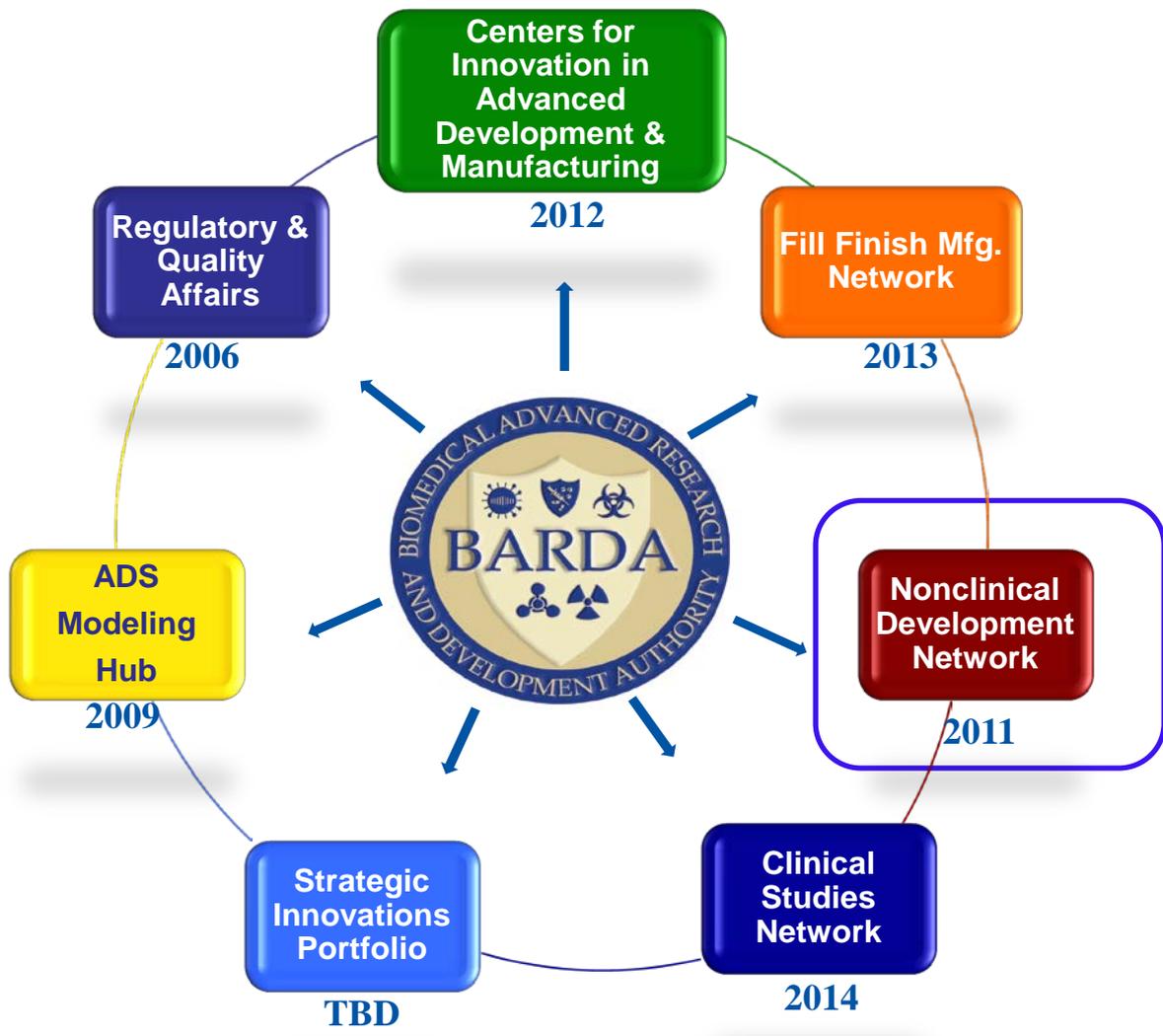
BARDA Core Service Overview

BARDA Industry Day
November 13, 2013

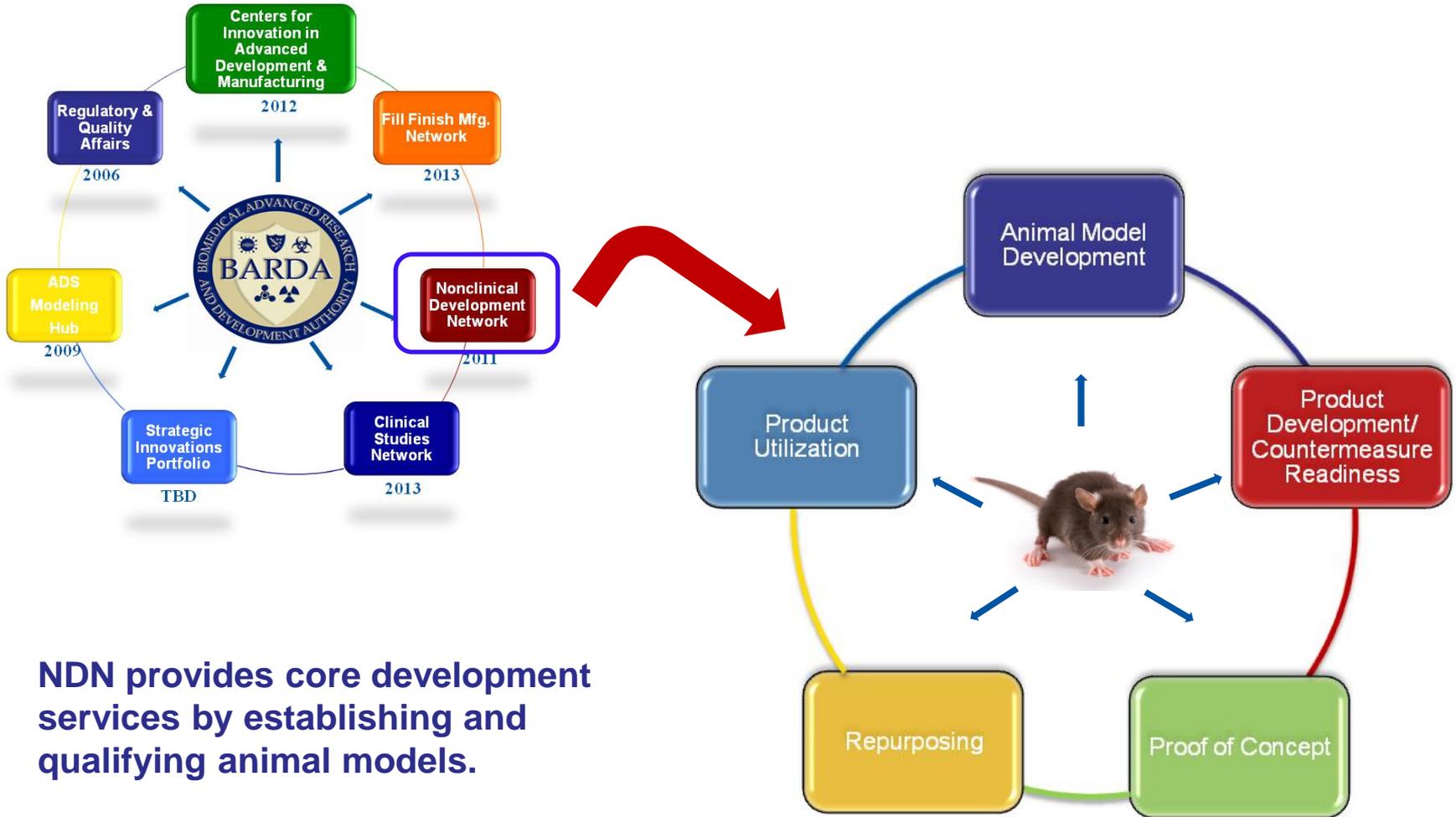
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The Nonclinical Development Network is a BARDA Core Service



Nonclinical Development Network: Capabilities



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



Mission

**ASPR Strategic
Plan - Goal 3**

Provide core advanced development and manufacturing services to medical innovators.

**BARDA Strategic
Plan - Goal 2**

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

NDN Goals

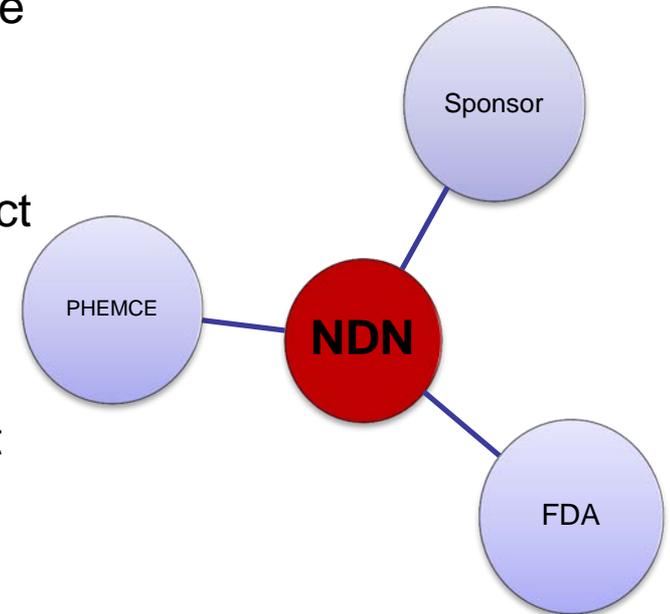
Develop models that meet the requirements of scientific validity and endure regulatory procedure in support of BARDA portfolio.

Implement cost and time savings through coordinated development efforts and data sharing.

Create opportunity for collaboration and data sharing among PHEMCE partners.

NDN engages our partners through:

- Quarterly Animal Model Interagency Committee (AMIC) Meetings
- FDA Assessment
 - Supplemental Data Independent of Product Developer
 - Supplemental Data in support of Pre-Emergency Use Authorization (EUA)
 - Animal Model Qualification Letter of Intent (LOI)
 - *Bacillus anthracis*
 - *Burkholderia pseudomallei*
- USG Working Groups
 - *Burkholderia pseudomallei*
- Animal Model Development Qualification and Coordination Working Group (AMDQCWG)
- Sponsor Collaboration





Accomplishments



- 28 Task Orders Awarded
- Engaging Our Partners
 - 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



Enhancing the Animal Model Knowledge Base

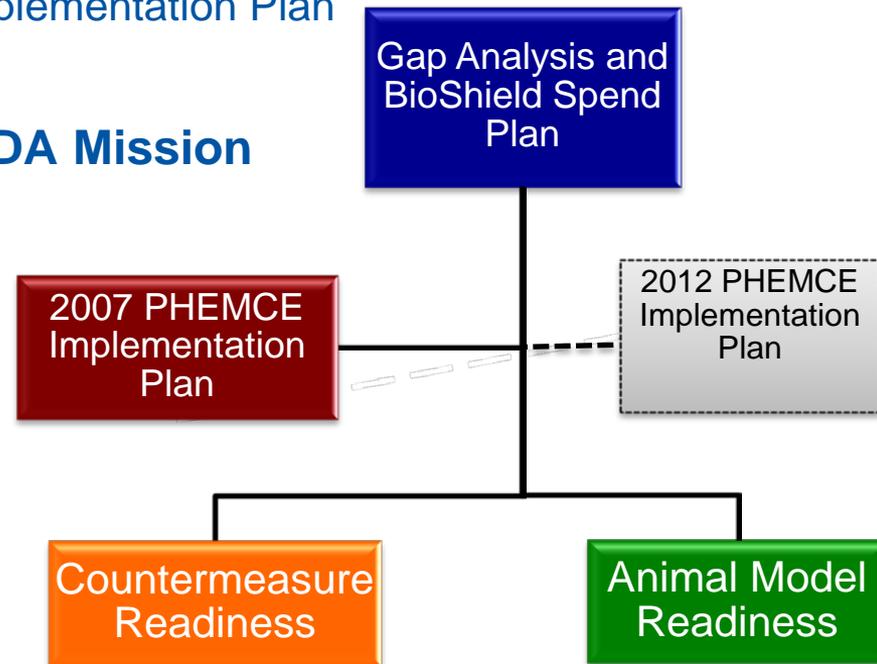


- Publications
 - Glanders: An Overview of Infection in Humans and Animals: Accepted to Orphanet Journal of Rare Diseases (Battelle)
 - Animal Models for *Francisella tularensis* and *Burkholderia* Species: Scientific and Regulatory Gaps Toward Approval of Antibiotics Under the FDA Animal Rule: Journal of Veterinary Pathology 2013 (BARDA)
 - Clinical Definition of Melioidosis: American Journal of Tropical Medicine and Hygiene, March 2013 (PHE)
- Presentations
 - 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)
- Availability of strains to scientific community
 - *Burkholderia pseudomallei* strain panel submitted to Biodefense and Emerging Infections Research Resources Repository (BEI)



Task Order Prioritization Tool

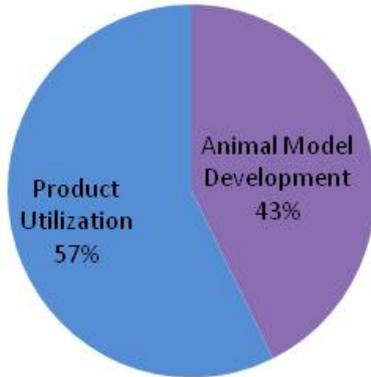
- Focused on DHS Material Threat Determinations (MTDs)
- Point system based on Four Levels of Evaluation
 - **Levels 1 and 2 – Emphasis on overall PHEMCE Mission**
 - Level 1: Gap Analysis from BioShield Spend Plan (2011)
 - Level 2: 2007 and 2012 PHEMCE Implementation Plan
 - **Levels 3 and 4- Emphasis on BARDA Mission**
 - Level 3: Countermeasure Readiness
 - Level 4: Animal Model Readiness



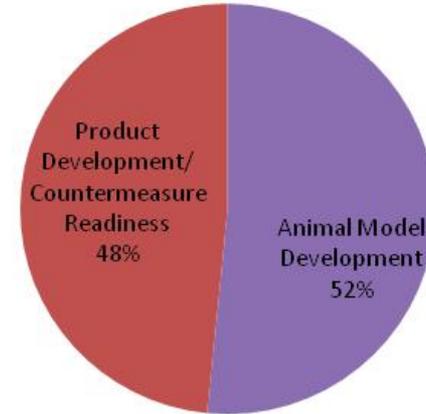


Functional Area Resource Allocation **ASPR** ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

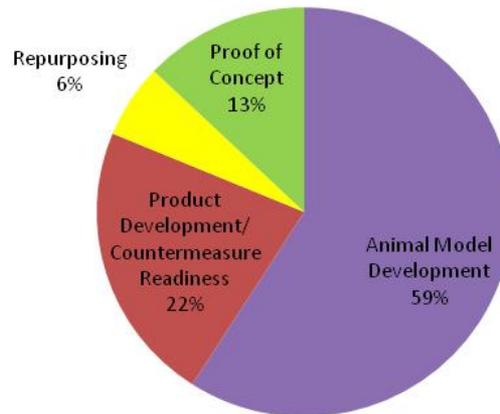
FY11



FY12



FY13





FY13 Task Orders

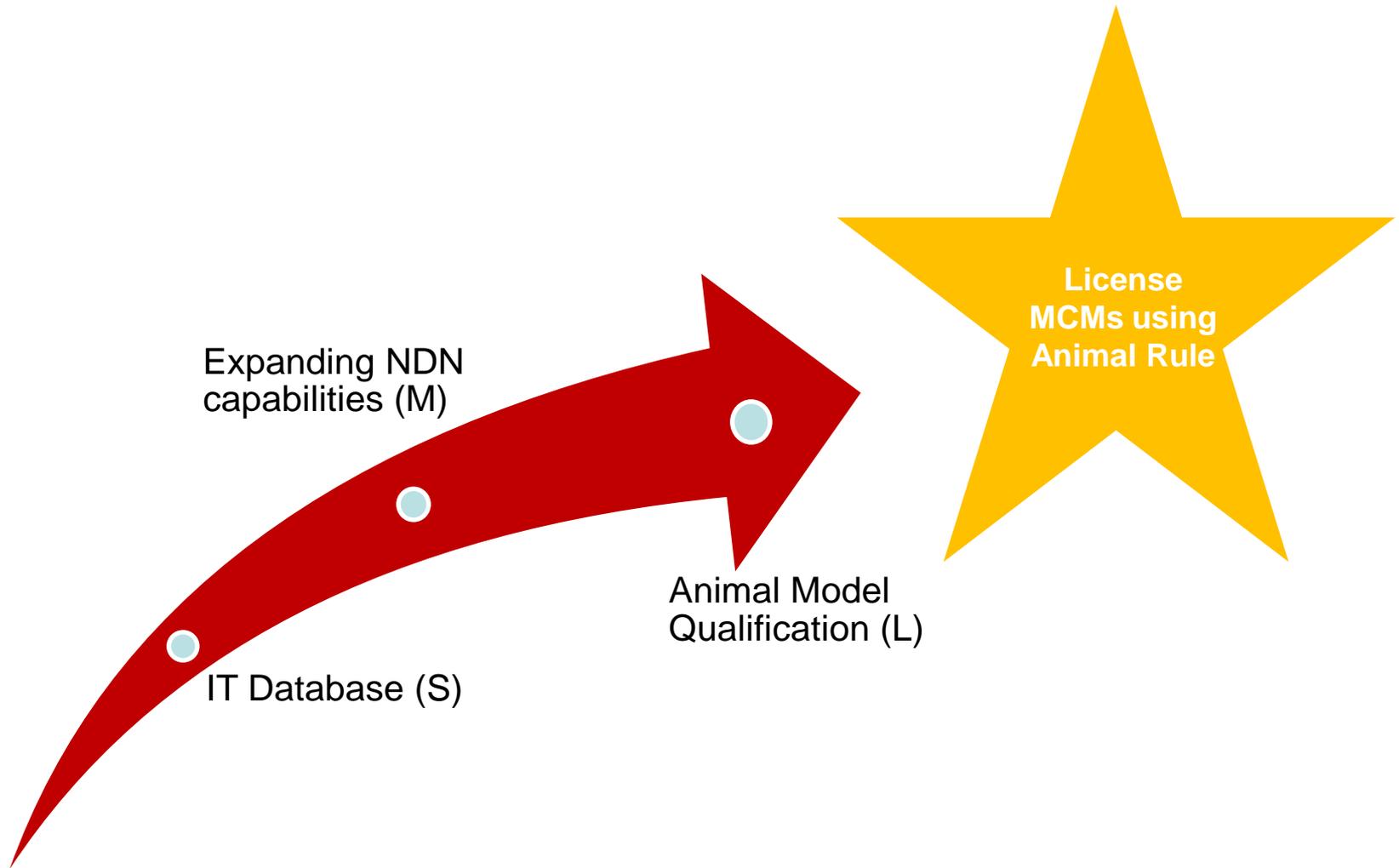


| FY13 Task Order Awards | Threat | Function |
|---|--------------|--------------------------|
| Ectromelia virus model development | Smallpox | Animal Model Development |
| Anthrax Natural History | Anthrax | Product Development |
| <i>Burholderia mallei</i> model development (small animals) | B. mallei | Animal Model Development |
| <i>Burholderia mallei</i> model development (NHPs) | B. mallei | Animal Model Development |
| Biodosimetry sample collection | H-ARS | Product Development |
| Ex-Rad Proof of Concept | GI-ARS | Proof of Concept |
| Supportive Care in NHPs | RadNuc (TBI) | Animal Model Development |
| Omeprazole Repurposing | RadNuc (TBI) | Repurposing |

28 projects initiated since May 2011



NDN Trajectory for the Future





Nonclinical Development Network



Battelle Pacific Northwest Division

IIT Research Institute

University of Illinois, Chicago

Battelle Memorial Institute

SRI International

BioQUAL, Inc.

Southern Research

Lovelace Respiratory Research Institute

MRIGlobal

University of Texas Medical Branch

Defence Science and Technology Laboratory, Porton Down

Public Health England, Porton Down

