



# BARDA INDUSTRY DAY

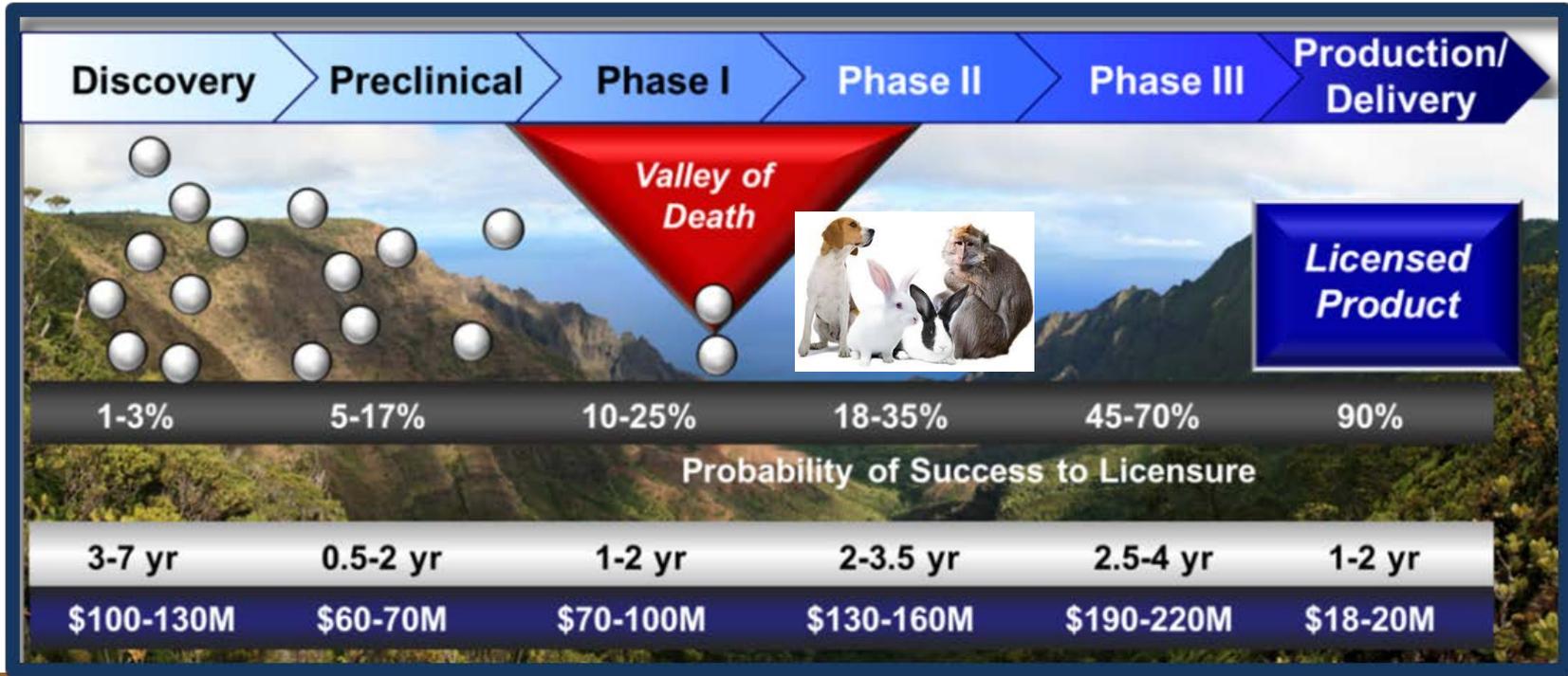
## **Non Clinical Network:** Developing Nonclinical Models with Partners Biological Examples

BARDA Industry Day  
Michael Merchlinsky  
HHS/ASPR/BARDA

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



# Product Development Under the Animal Rule



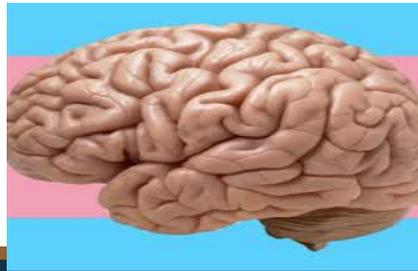
# Animal Models

- **Role of Animal Models in Product Development**



# Anthrax: Regulatory Landscape

- Aerosol models developed under NIAID and USAMRIID
- Added Benefit
- CNS Lesions



**1 + 1 > 2**

# Anthrax Model Development: BARDA perspective



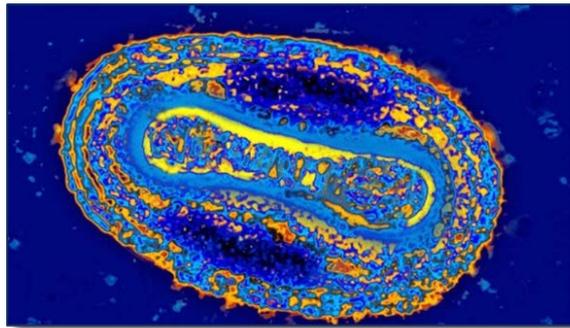
# Advantages of NCN Model Development

- Money
- Time
- Animals



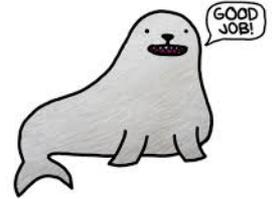
# Smallpox Regulatory Landscape

- NHP MPXV Challenge Model
- NHP Variola Virus challenge model
- Advisory Committee Meeting December 2011
  - Rabbits
  - Mice



# “Smallpox” Animal Models

**SEAL OF APPROVAL**



Natalie Des.com

- **IM challenge in rabbits with RPXV**
  - Moyer lab-adapted for regulatory use
  - Recapitulates smallpox disease course
- **IN challenge in Balb/C mice with ectromelia**
  - Buller lab-adapted for regulatory use



**ASPR**  
ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE



*Saving Lives. Protecting Americans.*

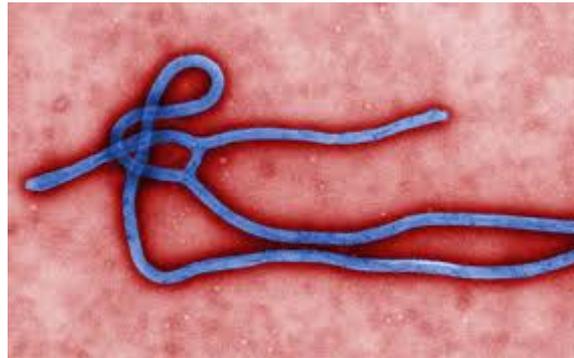
# Filovirus Regulatory Landscape

- BARDA supporting both vaccine and therapeutics
- Scientific models available, regulatory use uncertain
- Limited capacity



# Filovirus Animal Model Development

- Models for Ebola, Sudan, and Marburg
- *Cynomolgus* macaques 1000pfu IM challenge
- Efforts in progress, informal FDA meeting October 19



# Conclusions

- **Model development success**
- **Mechanism to develop important regulatory tools for product development**
- **Resources saved**

