Non Clinical Network:
Developing Nonclinical Models with Partners
Biological Examples

BARDA Industry Day
Michael Merchlinsky
HHS/ASPR/BARDA
Product Development Under the Animal Rule

Probability of Success to Licensure:

- Discovery: 1-3%
- Preclinical: 5-17%
- Phase I: 10-25%
- Phase II: 18-35%
- Phase III: 45-70%
- Production/Delivery: 90%

Success Rates by Stage:

- Discovery: 3-7 yr, $100-130M
- Preclinical: 0.5-2 yr, $60-70M
- Phase I: 1-2 yr, $70-100M
- Phase II: 2-3.5 yr, $130-160M
- Phase III: 2.5-4 yr, $190-220M
- Production/Delivery: 1-2 yr, $18-20M
Animal Models

• Role of Animal Models in Product Development
Anthrax: Regulatory Landscape

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

- 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
Filovirus Regulatory Landscape

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

http://ebolaevirus.blogspot.com/
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