

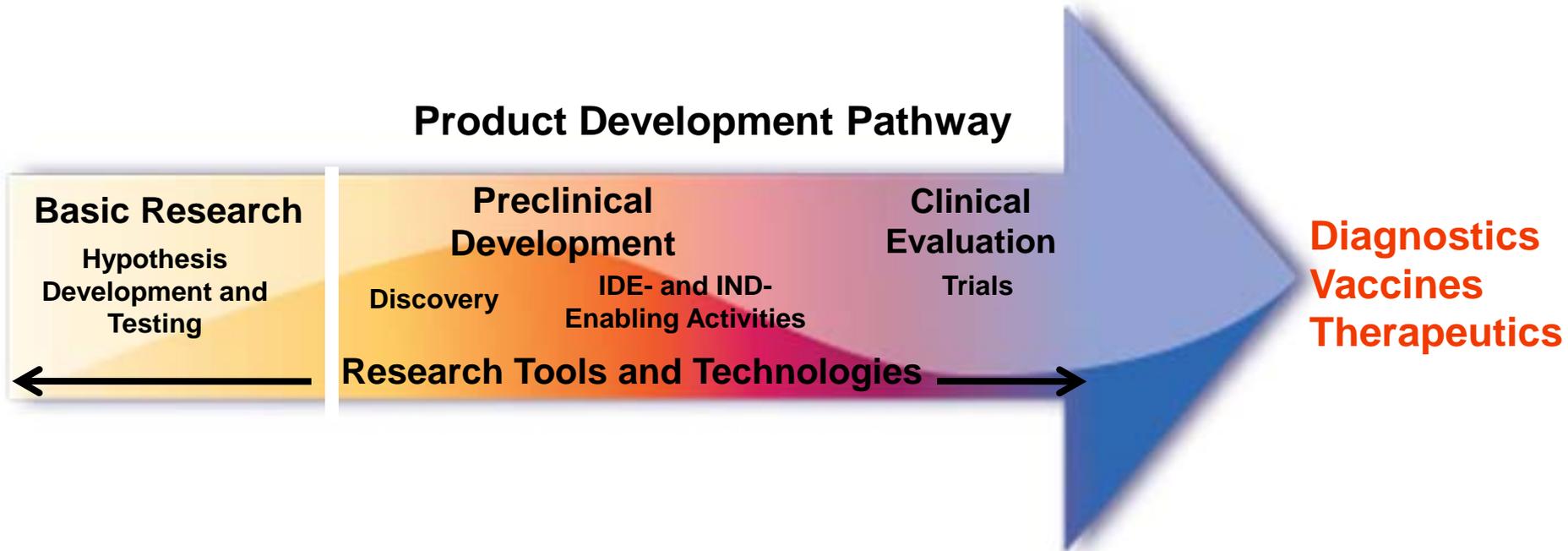
Animal Model Resources for MCM Development

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BARDA Industry Day



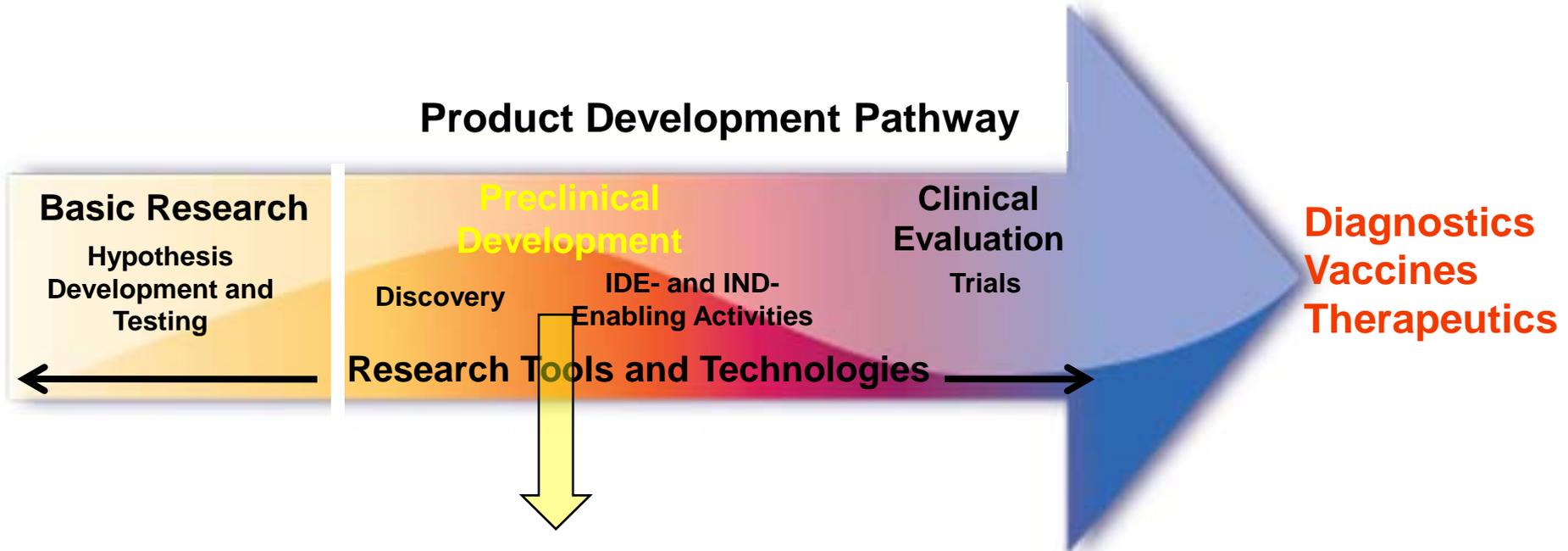
Resources for Researchers



- ▶ Funding opportunities
 - ▶ Research tools and technologies
 - ▶ Preclinical and clinical services to facilitate product development

Preclinical Services for MCM Development

Product Development Pathway



In Vitro Assessments of Antimicrobial Activity
Animal Models of Infectious Diseases
Therapeutic Development Services
Vaccine Development Services

Animal Models of Infectious Diseases

- Provision of a broad range of *in vivo* models
 - small animal
 - non-human primate
 - non-traditional models
- Development of novel models
- Refinement of existing models
- Screening of products
- Efficacy testing to support FDA submissions
 - Supplemental NDA for approved drugs



DMID Animal Model Program

	FY03	FY10
Pathogens	BioD	BioD & non-BioD
Contractors	10	38
Task Orders	82	55
Funding Directions	OBRA, ongoing	DMID, quarterly



Accomplishments

- Support of significant product investments
 - Vaccines for anthrax, smallpox
- Product neutral animal model development
 - Approved broad spectrum antibiotics, for *Y. pestis*
 - Novel anthrax antitoxins
 - Novel smallpox antivirals
- Gap-filling to move products/concepts forward

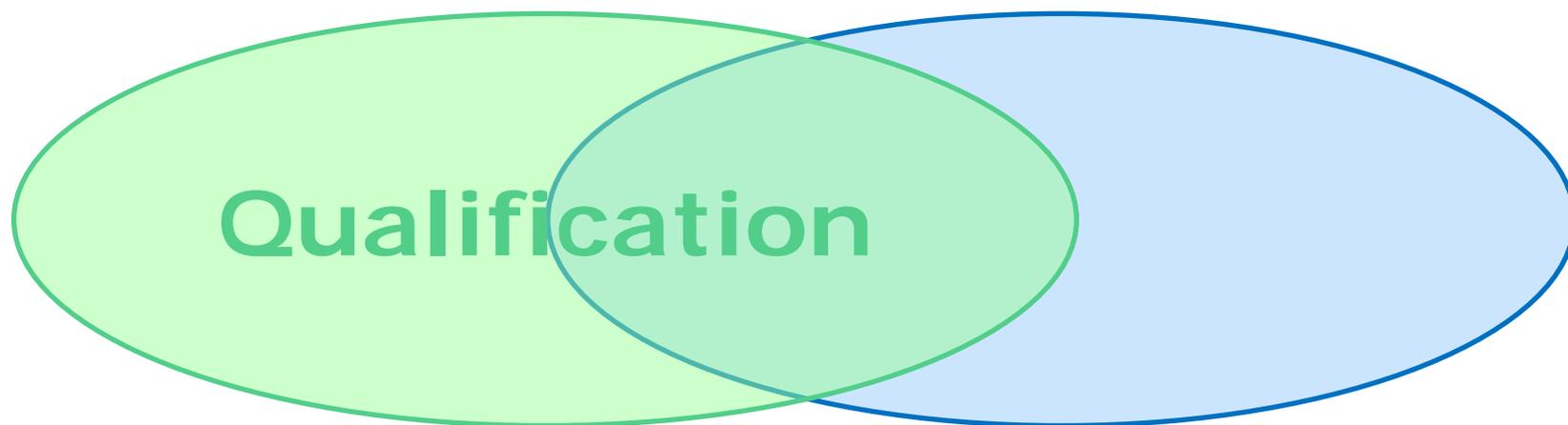




Animal Model Development Path

Model

Product



Product:

-independent

-dependent

-specific

1

2

3

4

5

6

7

8

9

Product neutral

DMID Animal Model Qualification Plans

- Near term, primary/major role:
 - Anthrax therapeutics – BARDA lead
 - Plague antibiotics
 - Tularemia antibiotics – BARDA support
- Willing to partner on:
 - Burkholderia
 - Filovirus
- Other ??



NIH/NIAID Radiation Nuclear Countermeasures Program

■ Achievements

- Five GLP animal facilities
- Rodent/NHP models of HE-ARS and GI-ARS
- Rodent/canine models for radionuclides

■ Next Steps

- MCM screening, optimization, and IND-enabling studies
- Characterization and qualification of animal models
Rodent/NHP animal model qualification for HE-ARS and GI-ARS



DAIT Product Development Support Services Contract: Animal Models

■ Hematopoietic:

- Mouse: Indiana University (C. Orschell)
- Dog: CiToxLAB (S. Authier)
- NHP: UMB (T. MacVittie), CiToxLAB (S. Authier)



■ Gastrointestinal:

- Mouse: Epistem (C. Booth)
- NHP: UMB (T. MacVittie)



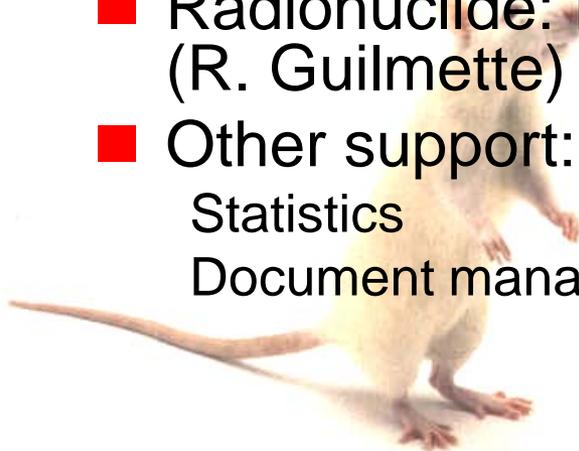
■ Lung: UMB (Z. Vujaskovic)

■ Radionuclide: Lovelace Respiratory Research Institute (R. Guilmette)

■ Other support:

Statistics
Document management

Pharmacokinetics
QA/GLP



Thank You!

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