

NIAID Resources to Facilitate Medical Countermeasure Development

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Concept Acceleration Program

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Translational Research (OBRRTTR)

Division of Microbiology and Infectious Diseases (DMID)

NIAID, NIH, DHHS

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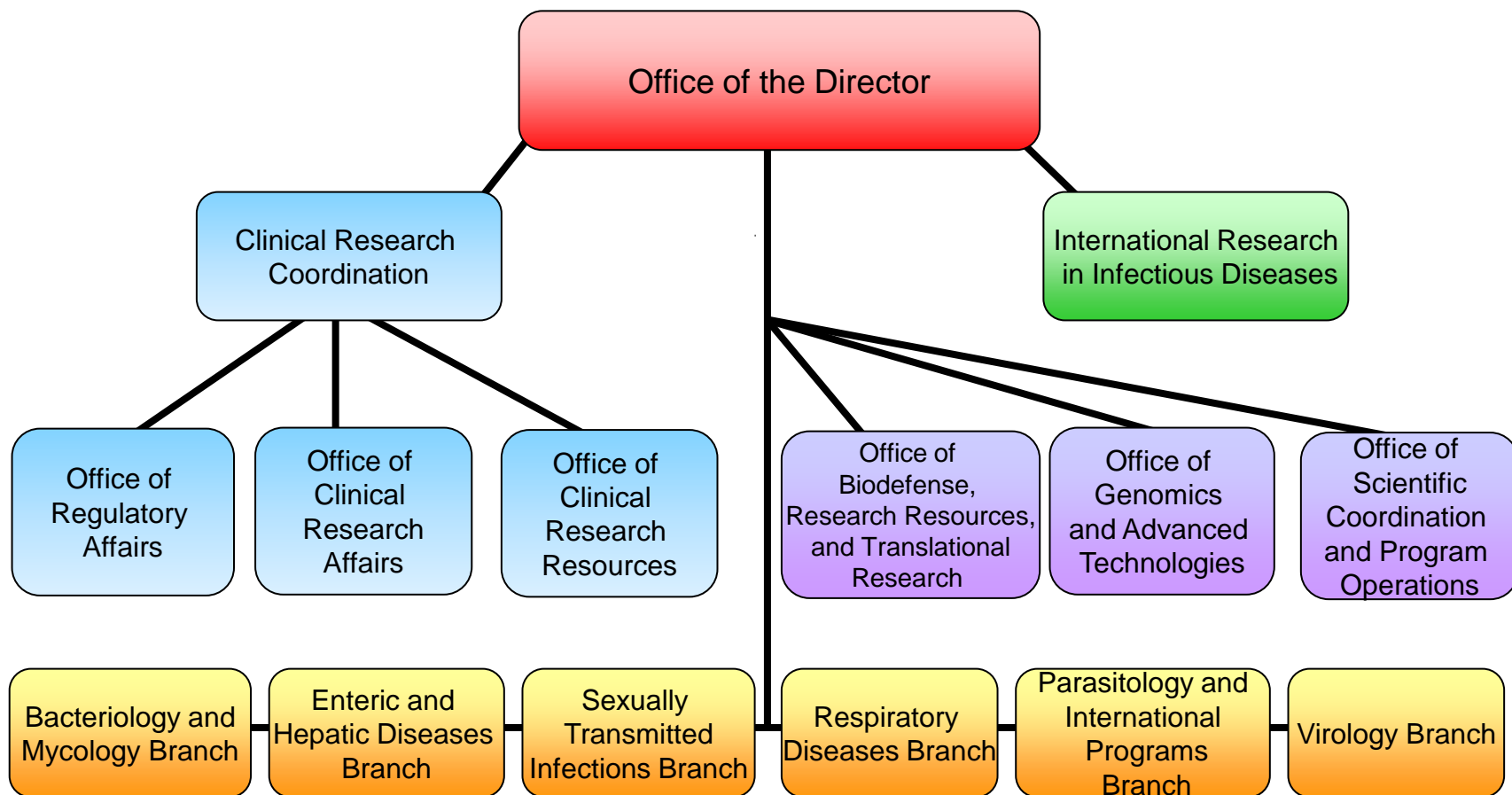
National Institute of
Allergy and
Infectious Diseases

NIAID Focus & Capabilities

- Basic research
- Discovery & early stage product development
- Address existing public health threats



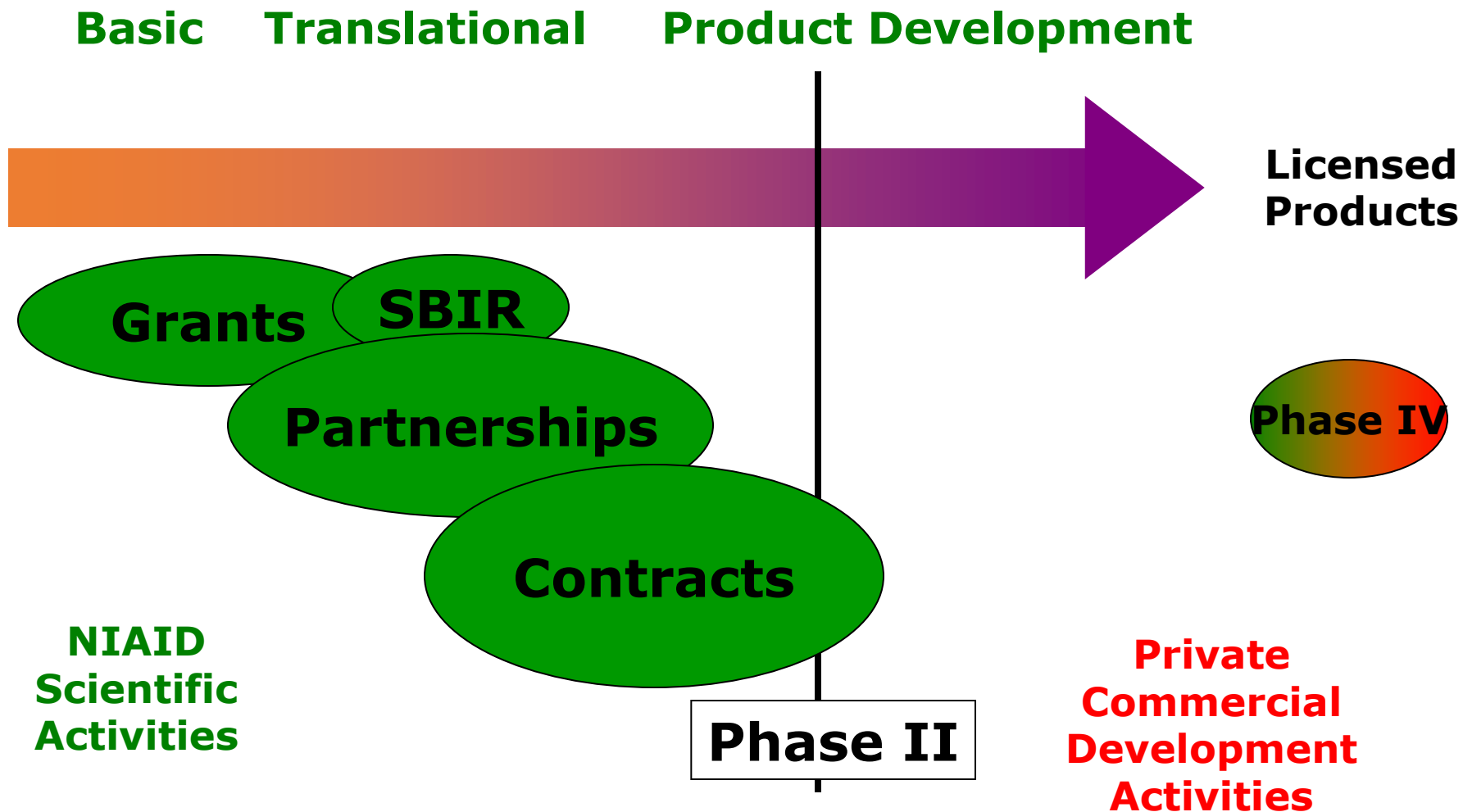
Division of Microbiology & Infectious Diseases (DMID)



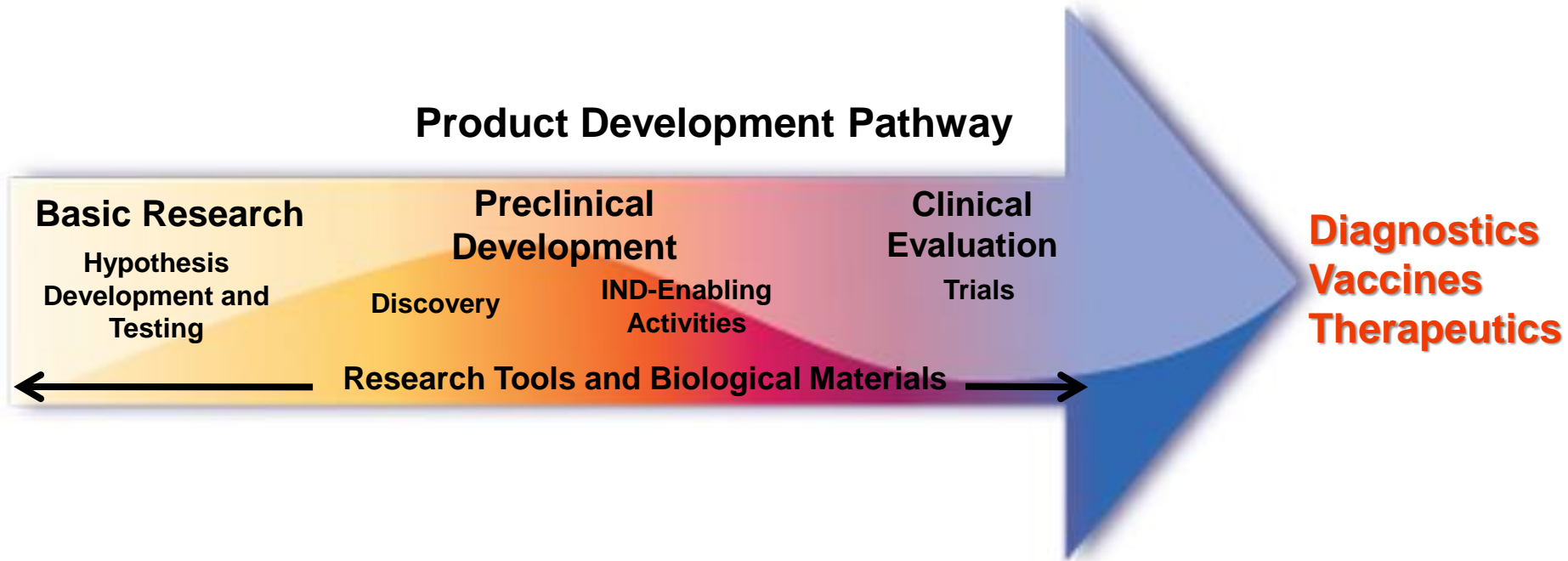
NIAID-DMID Strategy

- Emphasize broad spectrum solutions
- Emphasize innovative (expression/delivery) platform technologies
- Concept identification and development (Concept Acceleration Program – CAP)
- Target the full spectrum of development needs
- Maintain resources for product development
- Necessary regulatory science (in partnership with FDA)

Overlapping Funding Mechanisms



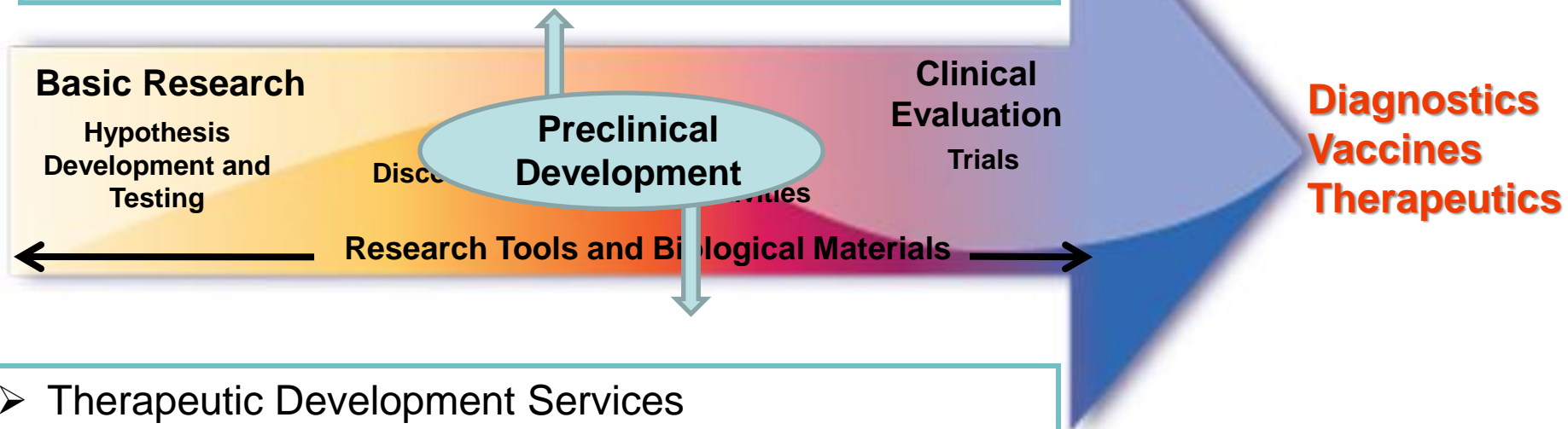
DMID Resources & Services



<http://www.niaid.nih.gov/LabsAndResources/resources/dmid/>

Preclinical Services to Support Product Development

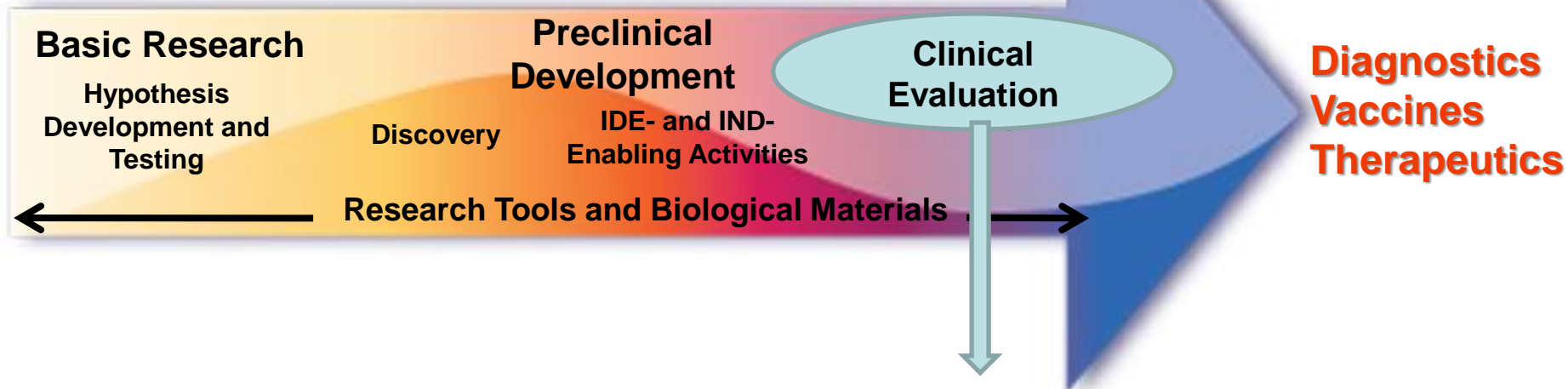
- Animal Models of Infectious Disease
- Vaccine Development Services:
 - *In vitro* & *in vivo* immunogenicity & efficacy
 - Process dev. & GMP mfg
 - Tox



- Therapeutic Development Services
 - Med chem & scale-up chem/mfg, formulation, incl. GMP
 - Biopharmaceutical development, incl. GMP
 - ADME & tox, incl. GMP
 - *in vitro* & *in vivo* potency & efficacy

Clinical Services to Support Product Development

Product Development Pathway



- Phase 1 Clinical Trial Units for Therapeutics
- Vaccine & Treatment Evaluation Units (Ph I-IV)
- Clinical sample access, e.g., for diagnostics validation
- Clinical Research Network – Antibacterial Resistance Leadership Group

NIAID Funding Opportunities

Grants: <https://www.niaid.nih.gov/researchfunding/ann/Pages/default.aspx>

- RFA-AI-16-03: Partnerships for Countermeasures Against Select Pathogens
- PAR-16-106: Rapid Assessment of Zika Virus (ZIKV) Complications
- RFA-AI-16-047: Partnerships for Structure-Based Design of Novel Immunogens for Vaccine Development
- RFA-AI-16-022: Human Tissue Models for Infectious Diseases

Contracts: <http://www.fedbizopps.gov>

- RFP-NIAID-DMID-NIHAI2016059: Pre-Clinical Models of Infectious Diseases
- BAA-NIAID-NIHAI2016064: Advanced Development of Multivalent Vaccine Candidates for Filovirus and Lassa Fever

Thank you!