

# Assistance for Academic Drug Development National Institutes of Health

- NIH-RAID Pilot: A ROADMAP Program

Rapid Access to Interventional Development

Nearly all NIH Institutes and Centers are participating in funding

The NIH-RAID Pilot projects will be co-sponsored by Roadmap resources (50%) and by one or more Institutes.



# Background & Rationale for RAID

- Roadmap Purpose: identify opportunities and gaps in biomedical research that no single institute at NIH could tackle alone
- NIH-RAID provides resources not readily available to academic investigators and associated small businesses; fill gaps in translational pipeline
- Complements private sector infrastructure and support.
- High-risk ideas or therapies for uncommon disorders frequently do not attract private sector investment



# The NIH-RAID Pilot Program

- The NIH-RAID Pilot Program is intended to reduce some of the common barriers between laboratory discoveries and clinical trials for new therapies
- The NIH-RAID Pilot Program provides services to approved projects through access to the extensive NCI contract network
- Eligible projects can span the spectrum of human disease, and may be supported by multiple Institutes



# The Valley of Death

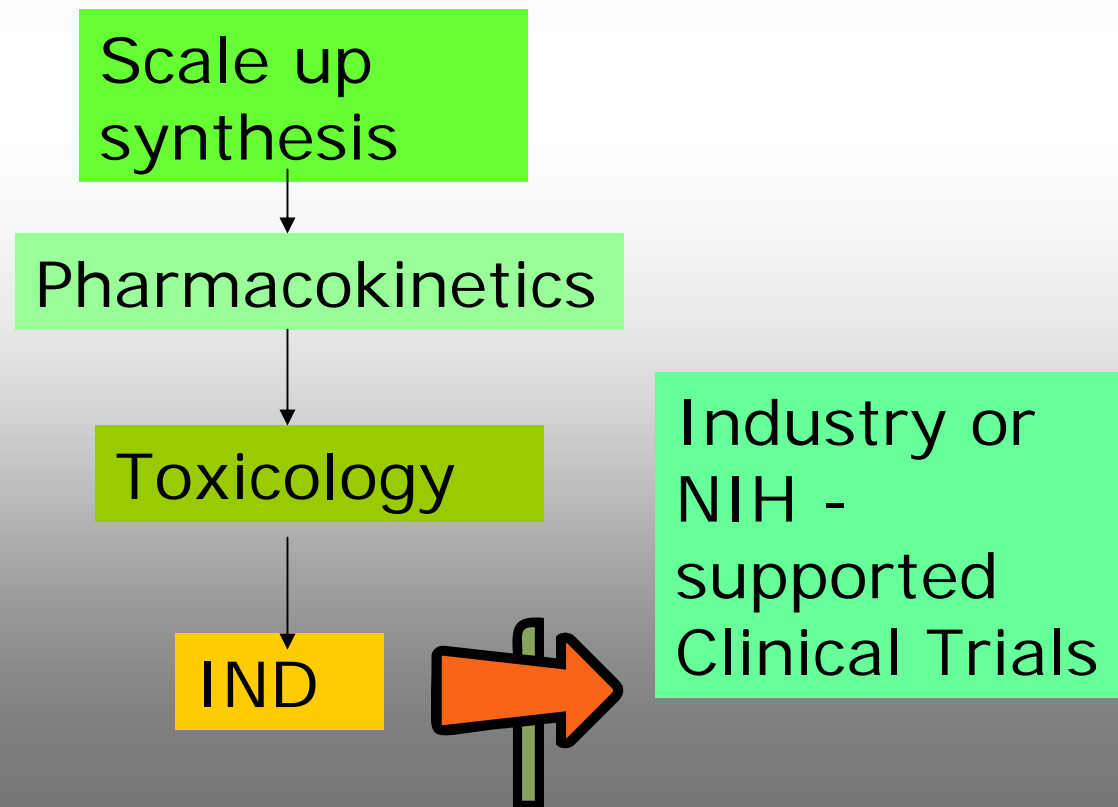


**University  
proof of  
concept**

**Compound in the  
clinic**

**NIH Roadmap – Approaches to  
Translational Research**

# The Added Value of Translational Research can help academia enlist corporate support



# NIH-RAID Pilot Overview

## Translational Research Core Services

Gives academic & non-profit applicants access to extensive centralized contract resources and expertise; modeled on the NCI RAID program

Not a grant mechanism; service provided

Investigator initiated; peer reviewed by CSR

Intellectual property and project control remains with originating institution and investigator



# ELIGIBILITY

Intended for use by academic discovery laboratories and not-for-profit organizations.

Domestic and foreign institutions are eligible

Partnerships with for-profit entities are critical in the development process, and products may be licensed to for-profit partners and still be eligible



# NIH-RAID Pilot Services

- ❑ Synthesis of small molecules and oligos, chemical synthesis of small peptides (GMP and non-GMP)
- ❑ Scale-up production to clinical-trials lot scale
- ❑ Development of analytical methods for bulk substances
- ❑ Isolation, purification of active entities from natural sources
- ❑ Development of pharmacology assays and conduct of pharmacologic studies





# NIH-RAID Pilot Services, cont.

- ❑ Development of suitable formulations
- ❑ Characterization of formulations
- ❑ Range-finding initial toxicology
- ❑ IND-directed toxicology
- ❑ Product development planning and advice in IND preparation



# Recently Announced New NIH-RAID Pilot Services

- ❑ The NIH-RAID Pilot will consider requests for manufacture of material for any clinical study.
- ❑ The NIH-RAID Pilot will consider requests for services to support later-stage preclinical development of monoclonal antibodies, recombinant proteins, and gene therapy agents.
- ❑ Requests for synthesis of monoclonal antibodies, recombinant proteins, and gene therapy agents will not be considered.



# Application Process

- Applications are received electronically through Grants.gov.
- The NIH-RAID Pilot Program uses the NIH Resource Access (X01) award mechanism.
- Three receipt dates per year are announced.
- Applicants are allowed an initial submission and two resubmissions





# INVESTIGATOR

**Proposal submission**

**Stage I -  
Administrative assessment**

**Stage II –**

**CSR Peer Review**

**Decision on Seminar Invitation**

**IC/Roadmap-  
Funding decision**

**Access to Resources**



# Examples of Approved Projects

- Development of HGF Mimetic (Refanalin) for Hepatic Fibrosis
- Safety Pharmacology Studies for an IND for Beta Thalassemia \*
- Metastin Administration in Humans: Preclinical Toxicology Studies \*
- Redox Encrypted Therapeutics for Treatment of Friedreich's Ataxia
- Advanced Studies with 5HMF –Potent Antisickling Agent
- Preclinical Development of CDD-0102 Treatment of Alzheimer's disease
- cGMP Synthesis of Selective Kappa Opioid Receptor Antagonist JDTC

# Summary – NIH offers development resources

**The Roadmap and other such translational activities are aimed at adding value by assisting with early-stage drug development.**

**Good regulatory and business advice is provided to develop a workable product development plan.**

**With preclinical data on small molecule therapeutics, and an IND plan, the academic investigator is in a position to interest venture capital and/or the biotech and pharmaceutical industry.**



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