

The NIH-RAID Pilot – A Roadmap Project (Rapid Access to Interventional Development)

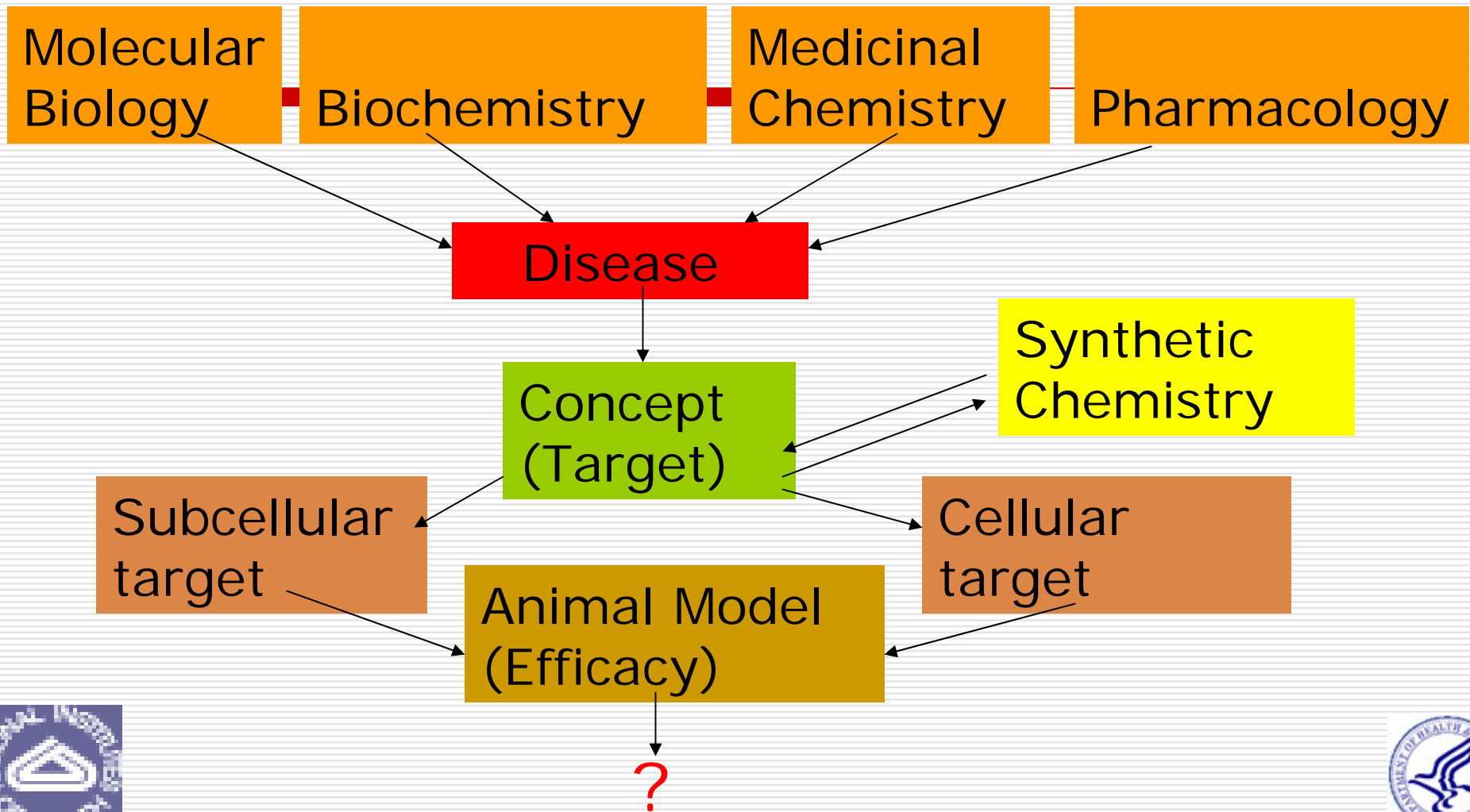
PhRMA Briefing

Wednesday, May 24, 2006

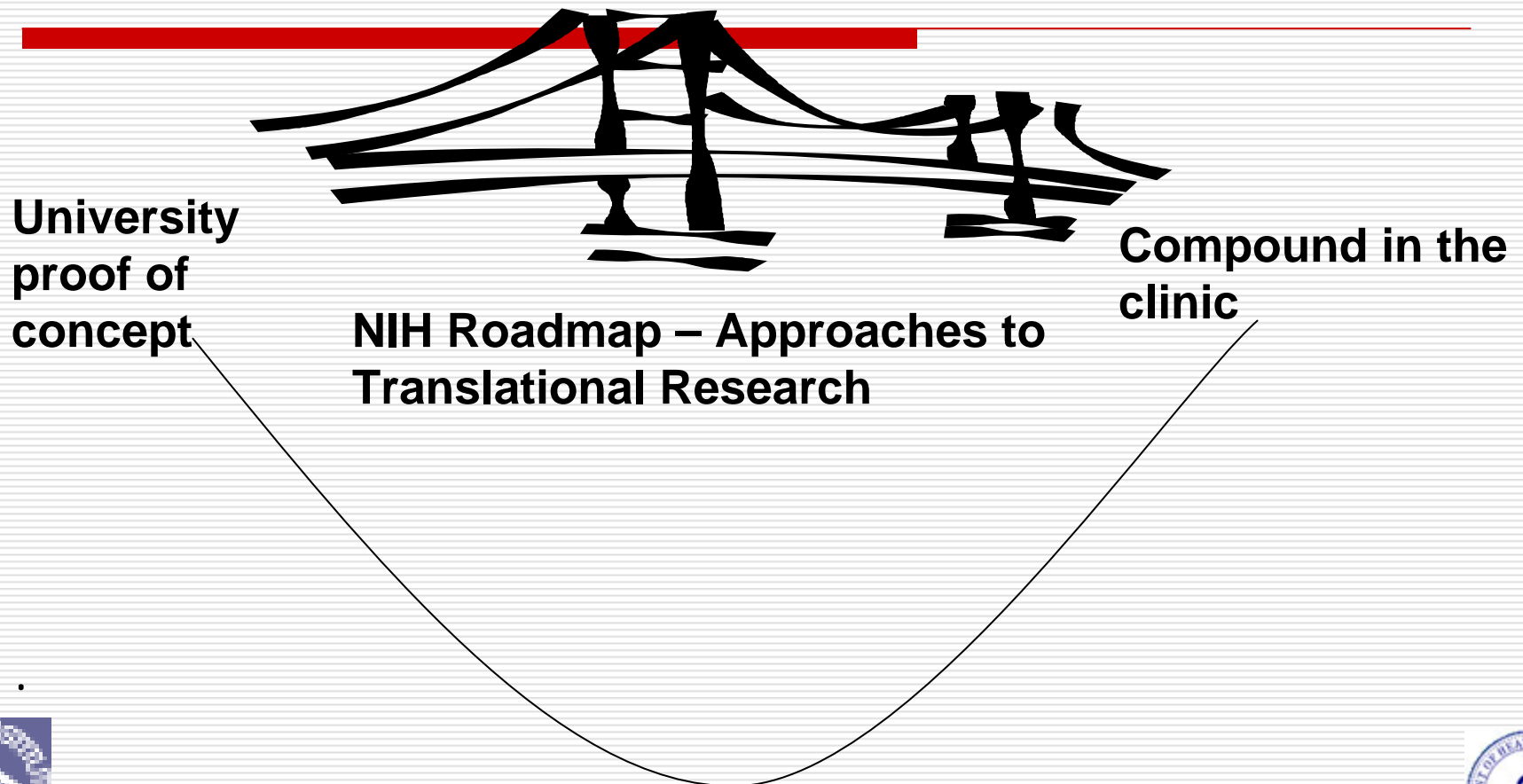
St. Regis Hotel, Washington, DC



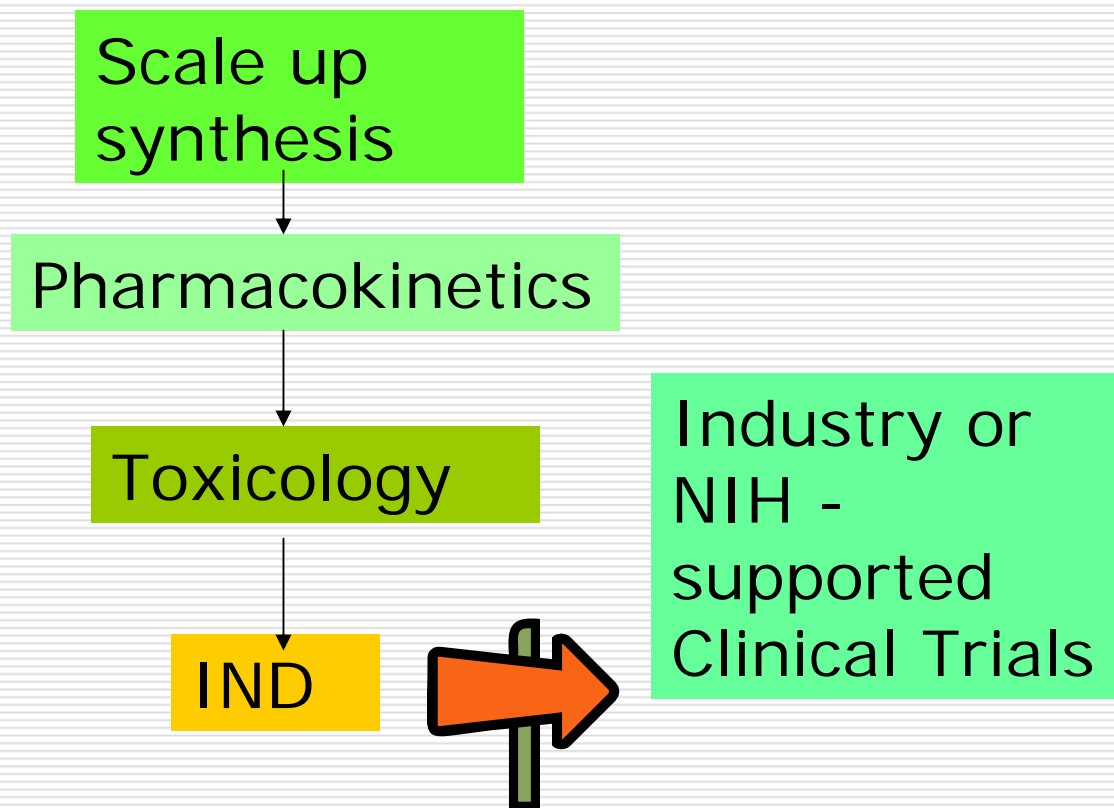
Traditional Academic Drug Development Scheme



The Valley of Death



The Added Value of Translational Research, from NIH-RAID, is designed to help academia enlist corporate support



NIH-RAID Pilot Overview

Translational Research Core Services

Gives 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

Intellectual property and project control remains with originating institution and investigator;

Complements and facilitates private sector infrastructure and support.



ELIGIBILITY

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

Domestic and foreign institutions are eligible

Each request will have an academic Project Leader with an NIH-assured Institutional Review Board or involve formal collaborations with a staff member of such an institution.

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



Corporate Partners

Ideas arising solely from a corporate source without academic collaborators are not eligible in the Pilot Phase

For approved projects, the for-profit partner may attend meetings with the NIH staff, but the primary point of communication will be the academic Project Leader.



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
- ❑ 2-year extension of pilot is anticipated



Need for Independent Product Development Plans

- ❑ Supplement expertise in regulatory aspects
- ❑ Clarify modules in project, and potential costs
- ❑ Help identify milestones and potential decision points
- ❑ Help identify additional funding needs and attract sources for them.



Annual Critical Dates

	Preliminary Proposal submission	Preliminary evaluation	Full proposal submission	Outcome notification
Cycle I	February	March	May	August
Cycle II	June	July	September	January



Causes for rejection

- Low Programmatic Priority*
- Project duplicates ongoing efforts*
- Resources needed do not correspond to those available*
- Sources of support for later development do not exist*
- Applicant has not demonstrated feasibility*



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