

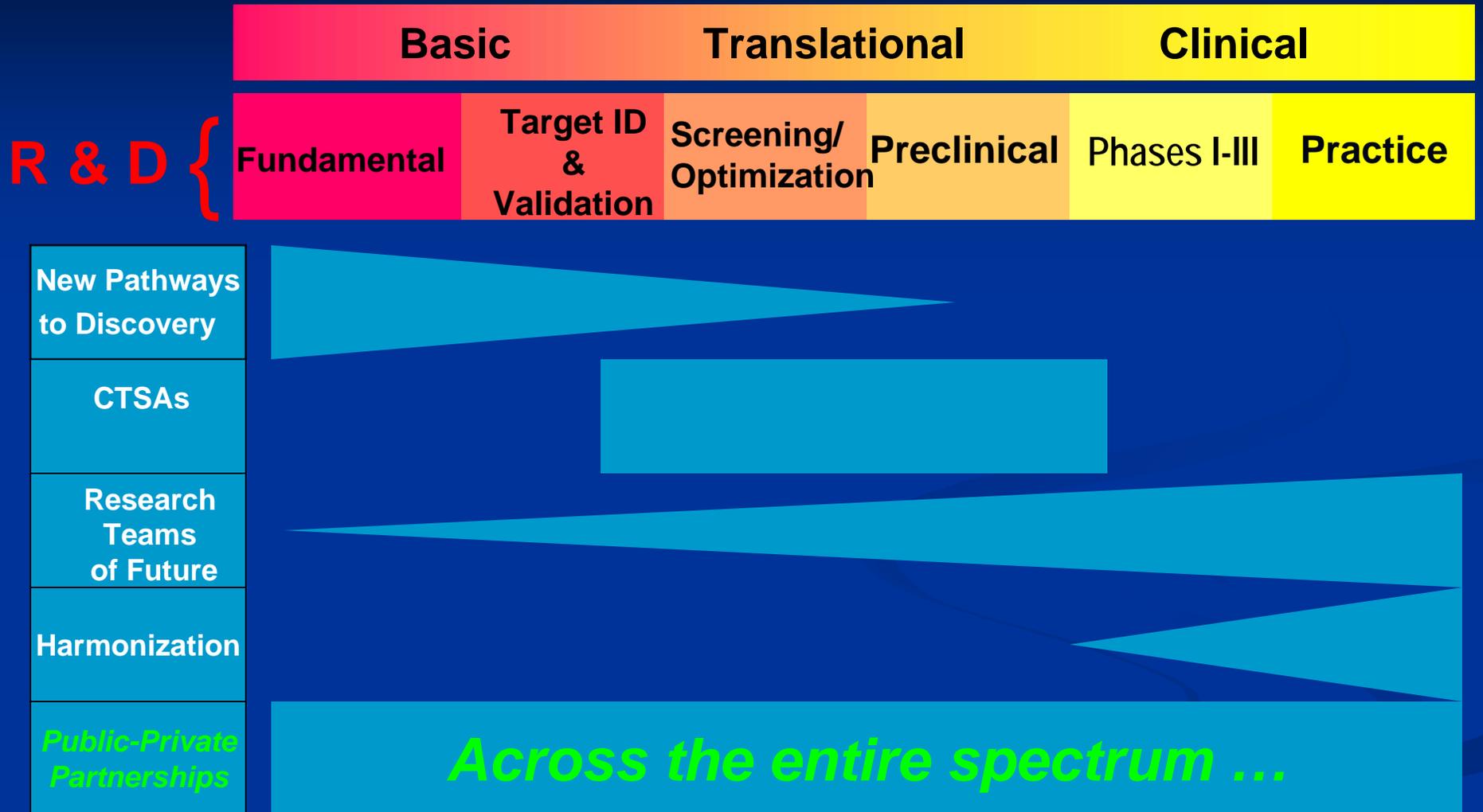
Program on Public-Private Partnerships



**Advisory Committee to the Director
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NIH Roadmap: A Systems Approach Across the Research Spectrum



Public-Private Partnership Program

- NIH Roadmap Activity
- Located in Office of Science Policy
- NIH working with broad array of others
- Mission consistent: Partnerships to promote the public health
- Science-driven and rigorous
- Leverage NIH resources to achieve synergy
 - Faster, better, cheaper
- Compliant with federal law, regulations and policies

Public-Private Partnerships

- Official Duty Activities, *not* outside activities.
- Provide another public face for the NIH.
- Requires attention to the details of partnership structure, policies, and goals.
- The PPP Program facilitates and promotes collaboration.

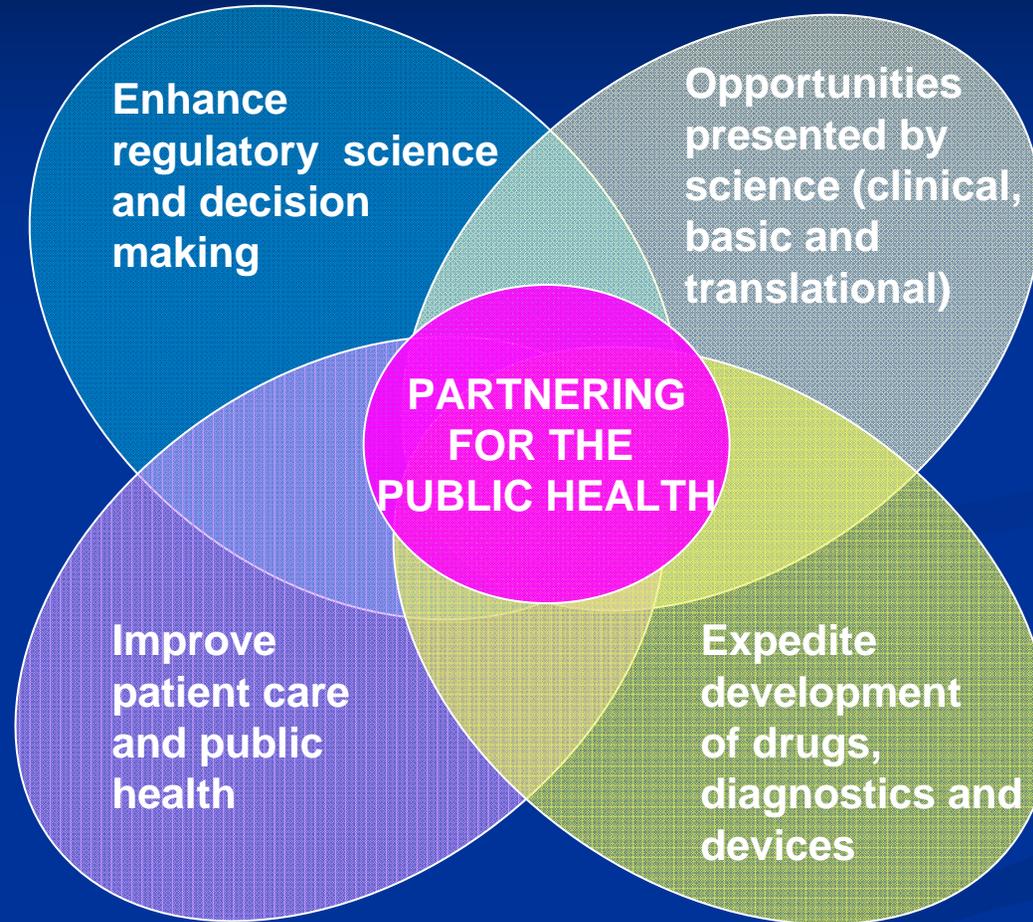
New Emphasis on Partnerships



PPPs for Synergy and the Public Health

FDA

NIH



PUBLIC

INDUSTRY

More petals on the diagram can represent more interests...

The Value Proposition

■ For the Public

- *Better, safer, more effective, cheaper and more rapid prevention, diagnosis, treatment, or cure*

■ For the Federal Government

- *Leverage resources to accomplish our mission(s) faster/better/cheaper*

■ For the Academic

- *Availability of more resources to do science*
- *Availability of better tools to provide patient care*

■ For the Commercial Sector

- *Access to best resources of federal government and other sectors*
- *Opportunity for fractional investment for total outcome*

Partners provide NIH:

- **Intellectual input and perspective**
 - Smart, thoughtful people
- **Resources, e.g.,:**
 - Patient recruitment
 - Data
 - Samples
 - Analytical techniques and platforms
 - Reagents
 - Financial contributions

Policies and Planning Required

- Partnership role definition
- Governance of partnerships
- Data and sample sharing and access policies
- Intellectual Property policies
- Human subject protections, IRB policies and procedures across institutions and countries
- Ethical oversight, conflicts of interest at institutional level
- Priority setting

The devil is in the details!

PPP Authorities

- **No new PPP Authority (!)**
 - PPPs represent “business as usual”
 - Official Duty Activity
- **Authorities relevant to PPPs:**
 - **Gift Authority**
 - Restricted gifts
 - Unrestricted gifts
 - **FNIH**
 - When co-equal governance is appropriate
 - When a donor represents a prohibited source or seeks distance from the work to be supported with the donation
 - NIH has a special relationship with FNIH

Contributions of the PPP Program

- 1. Policy analysis and development**
 1. Manual Chapters: PPP, MOU, Donors contributing to Extramural Funding Initiatives
 2. Official Duties Activities Policy
- 2. Resources**
 1. Informational- extant PPP agreements and policies
 2. Lessons learned
- 3. Communication and Relationships**
 1. Newsletter, trans-NIH coordinating Committee, portal
 2. Brokering between NIH ICs and potential partners
- 4. Assistance and Coordination**
 1. With OGC, Ethics, Grants, etc.
 2. Review and Clearance of Policies and Agreements

Don't do a PPP....

- *If the activity can be accomplished by any of the partners working alone, better NOT to develop a PPP!*

PPPs are for SYNERGY!

In general, the NIH:

- Favors the development of public resources
- Promotes inclusivity and fair access
- Is scrupulous about human subjects protections
- Desires the widest public dissemination, including commercialization, of NIH discoveries and IP
- *Underlying principle is rigorous science for benefit to public health.....*

Ongoing PPPs: examples

- Osteoarthritis Initiative
- Alzheimer Disease Neuroimaging Initiative
- Genetic Association Information Network
- Biomarker Consortium
 - www.biomarkersconsortium.org

Important Links

NIH PPP Program

www.ppp.od.nih.gov

Foundation for NIH

www.fnih.org

Biomarkers Consortium

www.biomarkersconsortium.org

FDA Critical Path

<http://www.fda.gov/oc/initiatives/criticalpath/>