

Program on Public-Private Partnerships



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Challenges Ahead: The Roadmap to the 21st Century

**New Pathways
to Discovery**



**Research Teams
of the Future**

**Re-engineering the
Clinical Research
Enterprise**

Public-Private Partnership Program

- NIH Roadmap Activity
- Located in Office of Science Policy
- NIH working with broad array of others
- Goal= 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.
- How NIH is seen, our protection of the public interest, and our protection of NIH in the view of the public, requires nuanced and scrupulous attention to the details of partnership structure, policies, and goals.
- The PPP Program is here to facilitate not to impede collaboration!

Focus of the PPP Program (1)

- Policies: *protecting the interests of the public health and the NIH*
 - Existing
 - PPPs vs technology transfer
 - Application of extant authorities
 - Practical, ethical, and public perception aspects of interaction with outside parties
 - Delegation of Federal Authority not permitted (for instance)
 - New
 - Manual of Issuance Chapters
 - PPPs (MC 1167)
 - MOUs (MC 1168 - pending)
 - Outside Support for Extramural Funding Initiatives (in clearance)
 - Policy re: use of the NIH name (in development)

Focus of the PPP Program (2a)

- Resources

- *Information*

- Printed and web-based: www.ppp.od.nih
- Listserv

- *Advice and Guidance*

- by phone
- in person

Focus of the PPP Program (2b)

- **Communication**
 - **Newsletter (Spring '08)**
 - **Seminars planned**
 - **IC meetings and presentations**
 - **PPP Coordinating Committee**
 - **Trans-NIH group representing all ICs and a number of OD offices and programs**
 - **Meets monthly for information exchange and outside speakers (e.g., NASA, SRC, IBM, DOE , FNIH, PhRMA)**

Focus of the PPP Program (3)

■ Relationships

■ *Connect NIH with outside potential partners*

- IC staff seeking partners for topics or projects deriving from NIH programs and priorities

■ *Connect potential outside partners with NIH*

- Identify IC contacts for outside parties seeking to partner with NIH

Focus of the PPP Program (4)

- Implementation assistance
 - Meetings
 - Workshops
 - Drafting and reviewing agreements and policies
- Coordination
 - Interface with OGC, Ethics, OTT, FDA and other Federal agencies, etc.
 - Example: The Biomarkers Consortium
 - Staff IC Directors serving on the BC Executive Committee
 - Support NIH co-chairs of Steering Committees
 - Operational and policy coordination with FNIH (managing partner), other Federal partners (FDA and CMS), and others

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

Policies and Planning Required

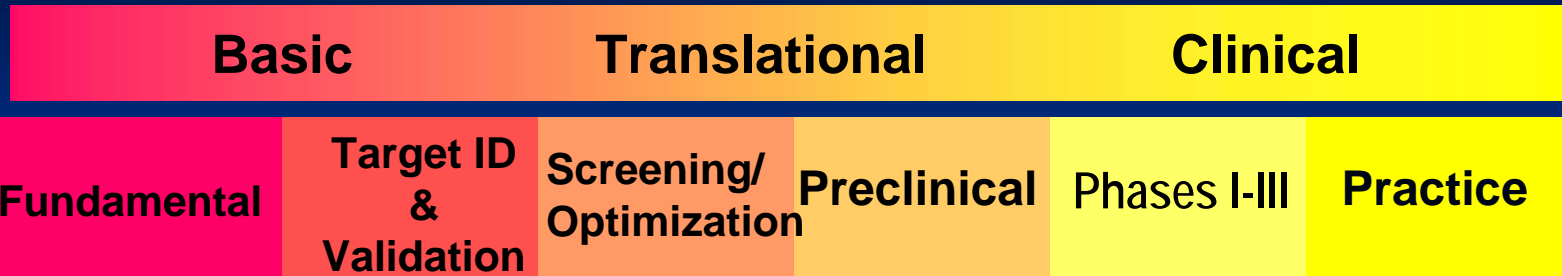
- Partnership role definition
- Governance of partnerships
- Data and sample sharing and access policies
- Intellectual Property policies
- Human subject protections, IRB policies and procedures across institutions and countries
- Ethical oversight, conflicts of interest at institutional level
- Priority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

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!

NIH Roadmap: A Systems Approach Across the Research Spectrum



- New Pathways to Discovery
- CTSAs
- Research Teams of Future
- Harmonization
- Public-Private Partnerships



New Emphasis on Partnerships

General Public

Scientists

Patients & Their
Advocacy Groups

Voluntary Organizations

NIH Staff

Scientific Review
Committees

Congress

U.S. President

Scientist Council
Members

Boards of
Scientific Counselors

Ad Hoc Advisors

Public Members of
Advisory Councils

Physicians & Other
Health Professionals

Professional Societies

Foreign Governments

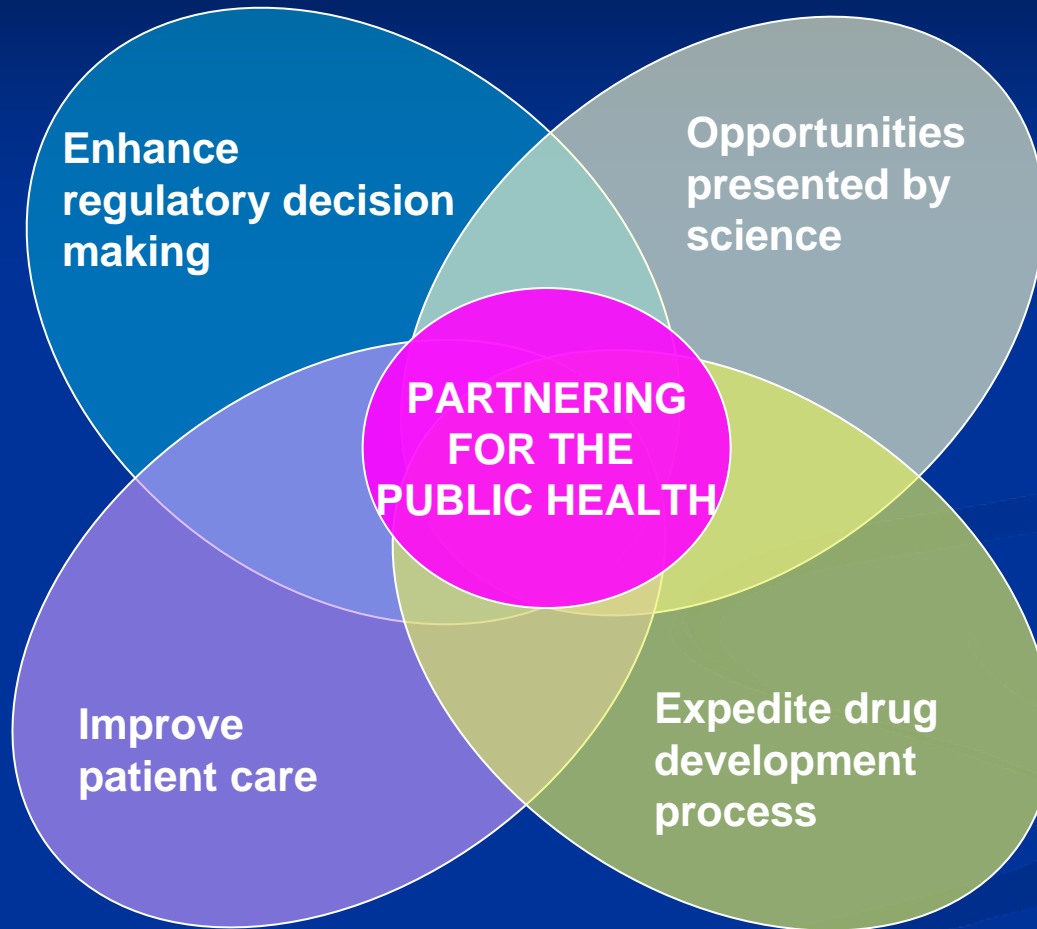
Industry



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
- Resources, e.g.,:
 - Patient recruitment
 - Data
 - Samples
 - Analytical techniques and platforms
 - Reagents
 - Financial contributions

In general the NIH:

- Favors the development of public resources
- Promotes inclusivity and fair access
- Is always 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

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/>