Cultivating Partnerships: Setting Goals and Defining Success

Session III
Aims

- Explore the defining features of a successful partnership
- Emphasis on establishing metrics and defining goals
- Focus on lessons learned from existing partnerships between the public and private sectors
  - Priority-setting,
  - Decision-making, and
  - Intellectual property agreements
NIH and Public-Private Partnerships (PPPs)

- A range of differing scales
- Three examples
- Challenges
- Considerations
- Outcomes and deliverables
The Scale of NIH Involvement in PPPs

- **Scale**: Can be measured in number of ways including participants and partners, complexity of projects, and magnitude of resources invested (e.g., dollars, time, expertise, personnel, data etc.)

  - **“Small” scale PPPs**:
    - Single IC with a single partner on a single project

  - **“Mid-size” PPPs**:
    - One or more ICs with a single focus area and one core project with spin-offs

  - **“Large” complex PPPs**:
    - Multiple ICs with multiple partners (20+) and multiple projects
NIH PPPs: Example #1

Osteoarthritis Initiative (OAI)

Goal: Further development of OA drugs

Overarching Aims: Establish resource for testing much-needed biochemical and imaging markers of disease progression

Partners: NIH, FDA, biopharmaceutical industry

Major deliverables:
Public repository of:
- Patient data
- Radiological information
- Biological specimens

Budget: $50 million
NIH PPPs: Example #2

Alzheimer's Disease Neuroimaging Initiative (ADNI)

Goal: Identify biomarkers of mild cognitive impairment and Alzheimer's Disease in elderly subjects

Overarching Aims: Combine serial magnetic resonance imaging, positron emission tomography, other biological markers (in blood, urine, and cerebrospinal fluid), and clinical and neuropsychological assessment

Partners: NIH, FDA, biopharmaceutical industry, non-profit and advocacy groups

Major deliverables: Establishment of a public resource for testing biochemical and imaging markers of disease progression

Budget: >$60 million
ADNI Private Sector Supporters: 
19 companies and 2 non-profits

PIB/PET Supplement: Alzheimer’s Association and GE Healthcare
Cerebrospinal Fluid Extension: Alzheimer’s Association, AstraZeneca, Cure Alzheimer’s Fund, Merck, Pfizer and an anonymous foundation
Genome-Wide Genotyping: Gene Network Sciences, Merck, Pfizer and an anonymous foundation
Genome-Wide Genotyping Genetic Analysis: NIBIB, Merck, Pfizer and an anonymous foundation
Empirically pre-defined statistical ROI for the assessment of 12-Month CMRgl declines in AD patients

Defined using data from 27 training-set patients using bootstrap with replacement

Number of AD patients per group needed in a 12-month multi-center RCT to detect a 25% treatment effect with power=80%, p=0.05 & no need to correct for multiple comparisons

<table>
<thead>
<tr>
<th>FDG PET</th>
<th>ADAS-COG11</th>
<th>MMSE</th>
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<tbody>
<tr>
<td>61</td>
<td>612</td>
<td>493</td>
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Characterized in 29 test-set patients (excluding HiRez & HRRT scanners)

Reiman et al
Banner Alzheimer Institute
NIH PPPs: Example #3

Genetic Association Information Network (GAIN)

**Goal:** identify specific points of DNA variation associated with occurrence of particular common diseases (studies focused on ADHD, bipolar disorder, diabetic nephropathy, major depressive disorder, psoriasis and schizophrenia).

**Overarching Aims:** Conduct Genome-Wide Association Studies

**Partners:** NIH, FDA, biopharmaceutical industry, non-profit and advocacy groups

**Major deliverables:** Data disseminated through the database of Genotype and Phenotype (dbGaP) of the National Library of Medicine

**Budget:** $32 million
PPP Outcomes and Deliverables

- **Foster Research**
  - Generate general new knowledge and new insights
  - Offer the potential for commercialization as one means of translating discovery into public health improvements

- **Enhance Clinical Trials**
  - Increase access to clinical trials
  - Facilitate recruitment and retention

- **Expand the pre-competitive space**
  - Create general public resources such as data sets, samples, reagents, platforms

- **Develop Medical Products and Technologies**
  - Collaborative and complementary work to translate discovery to marketable drugs, devices, diagnostics, and/or tools
Challenges

- Achieving an understanding and appreciation of the similarities and differences between and among partners—for example, with respect to processes, capabilities, resources, and constraints
- Developing common goals
- Reaching agreement on the tasks and requirements inherent in the collective effort to achieve the goals of the partnership
- Making and sustaining a shared commitment to open, regular communication
Considerations for PPPs with NIH

- Source of funding
- Expenses supported
- Exchange of non-monetary resources
- Products of the partnership (e.g., data, samples, reagents, databases, etc.)
- Intellectual property rights
- NIH review and management
- Privacy and integrity
Questions for Discussion

1. What attributes are key to the formation and sustention of a successful partnership?

2. In reference to existing partnerships:
   – How was success for each partner defined?
   – How were the expectations and responsibilities of each partner negotiated?
   – How were appropriate benchmarks for each partner determined?

3. In reference to NIH, what are appropriate metrics for success?

4. How should decisions be made in selecting and prioritizing projects? What factors need to be taken into consideration?

5. What have been the successes of public-private partnerships? What hurdles have been encountered in realizing the potential of these partnerships?