

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

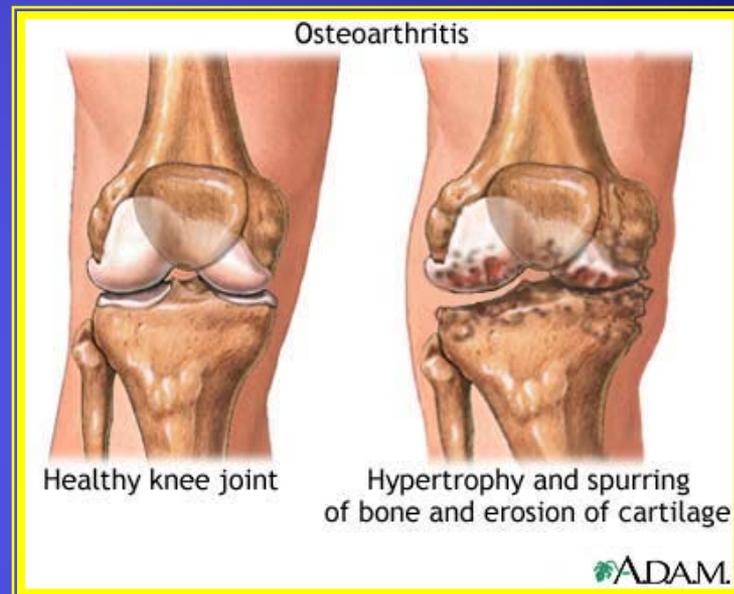
Partners: NIH, FDA, biopharmaceutical industry

Major deliverables:

Public repository of:

- Patient data
- Radiological information
- Biological specimens

Budget: \$50 million



<http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001460/>

NIH PPPs: Example #2

Alzheimer's Disease Neuroimaging Initiative (ADNI)

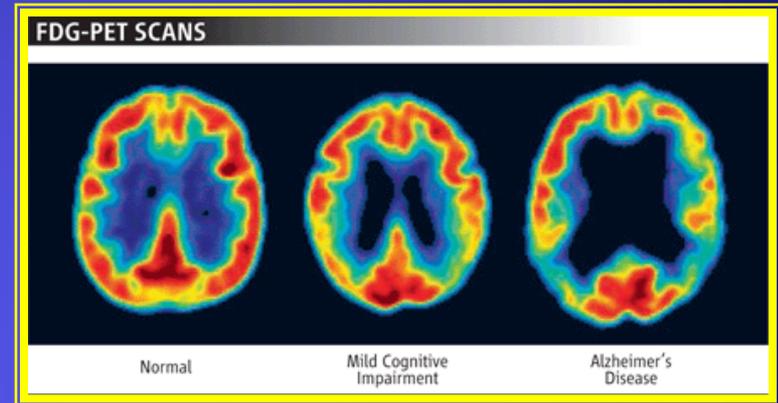
Goal: Identify biomarkers of mild cognitive impairment and Alzheimer's Disease in elderly subjects

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



Miller, Science, 16 October 2009

ADNI Private Sector Supporters: 19 companies and 2 non-profits

FOUNDATION
FOR THE
National Institutes of Health



Bayer HealthCare



Bristol-Myers Squibb



GlaxoSmithKline



INNOGENETICS
BIOTECHNOLOGY FOR HEALTHCARE

Johnson & Johnson



NOVARTIS



Schering-Plough

SYNARC
Start here, finish first.

Wyeth

alzheimer's association®

INSTITUTE FOR THE STUDY OF AGING

ISOA

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*



NA-ADNI



EU-ADNI



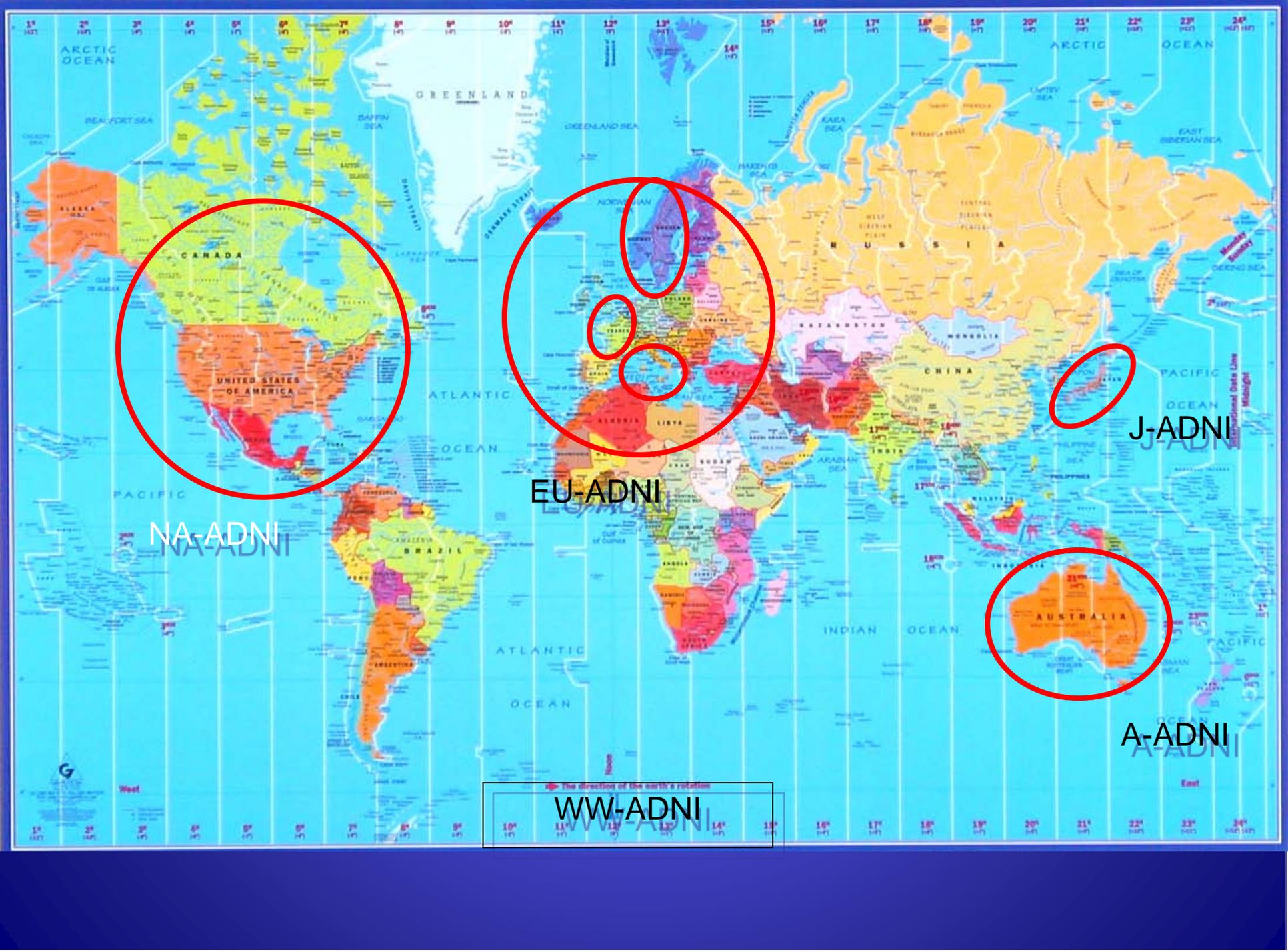
J-ADNI



A-ADNI

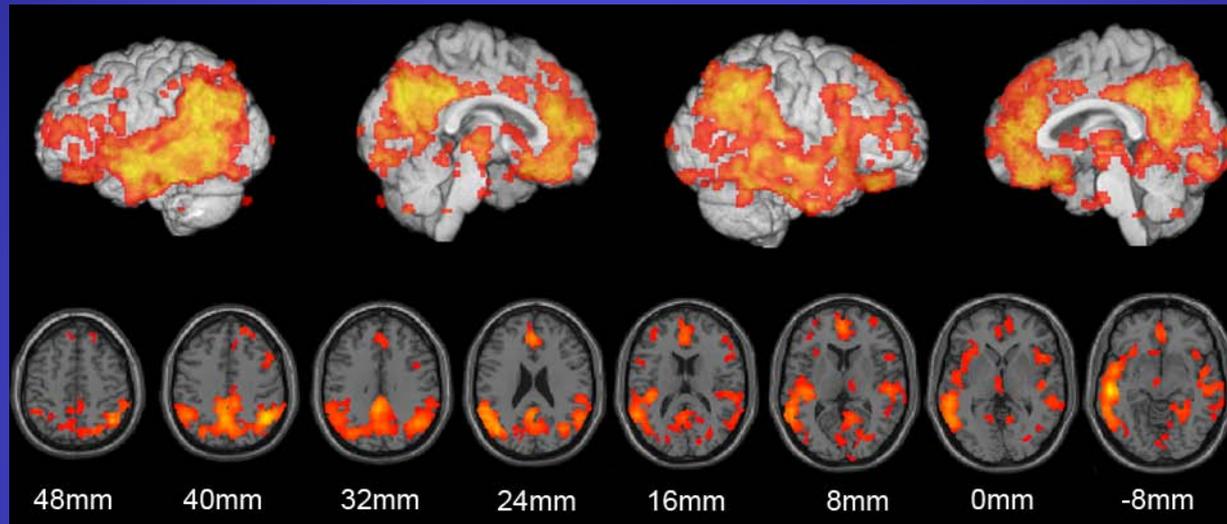


WW-ADNI



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

FDG PET
61

ADAS-COG11
612

MMSE
493

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

Science Daily (Nov. 30, 2007)

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?**