

ADNI-Private Partner Scientific Board Update

Robert Dean (Lilly), PPSB Chair

ADNI Steering Committee Meeting

Boston, April 24, 2017



FNIH

Foundation for the
National Institutes of Health

Current PPSB Partners for ADNI3

abbvie

ACT-AD
Accelerate Cure/Treatments for Alzheimer's Disease

alzheimer's  association®

BIOCLINICA®
Global clinical trial solutions. Real-world results.

 **Biogen.**


COGSTATE


DIAMIR

 **Eisai**

EUROIMMUN



Genentech
A Member of the Roche Group



Janssen 
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Johnson & Johnson

Lilly

Lundbeck 

Magou

 **MERCK**

 *PeopleBio*



 **Piramal**
knowledge action care



 **Saladax**
BIOMEDICAL

 **SERVIER**



 **FNIH**
Foundation for the
National Institutes of Health

Benefits of PPSB Partnership

- Membership in the ADNI Private Partner Scientific Board (PPSB)
 - Independent, pre-competitive forum for study-related scientific exchange among partners; convened monthly by the FNIH
 - Receive latest updates on ADNI progress/status
 - Representatives attend annual face-to-face ADNI Steering Committee meeting
 - Chair serves as liaison to ADNI Executive Committee
- Participate in ADNI Core open discussions (Biomarkers, Biostatistics, Clinical, Genetic, Informatics, MRI, Neuropathology, PET, Publications)
- Interact with NIH, FDA, ADNI PI/Core Leaders and industry colleagues
- Participate in industry-initiated Working Groups
- Participate in annual PPSB face-to-face meetings (Spring and Fall)

PPSB Face to Face Meetings

Spring Meeting / 23 April 2017

- ADNI Core Updates
- Readouts on ADNI-related innovation activities
 - DNA Methylation Study (Andy Sakin)
 - Metabolomics & Systems Biology (Rima Kaddurah-Daouk)
 - CSF Biofluid Biomarkers
 - Elecsys Platform (Sandra Rutz)
 - ADNI 1, 2 & GO data output (Les Shaw)
 - Standardization & next steps (Roundtable)

Fall Meeting / Date TBD

- Tentative theme: How PPSB member organizations have utilized ADNI data in trial design

ADNI Cores

PPSB Core Liaisons

PPSB chartered working groups

Biochemical Biomarker Les Shaw and John Trojanowski	Susan DeSanti
Biostatistics Laurel Beckett	Jerry Novak
Clinical Ron Petersen & Paul Aisen	Veronika Logovinsky
Genetics Andy Saykin	Aparna Vasanthakumar
MRI Cliff Jack	Adam Schwarz
Neuropathology John Morris	Susan DeSanti
PET Bill Jagust	Mark Schmidt
Publications Robert Green	Lee Honigberg
Informatics Art Toga	Open
RARC John Hsaio	Jerry Novak

P
P
S
B

PET Endpoints WG (2010 – present) Mark Schmidt, Gregory Klein
Biofluid Biomarkers WG (2012 – present) Susan DeSanti, Johannes Streffer
Clinical Endpoints WG (2013 – present) Veronika Logovinsky, Nandini Raghavan
rsfMRI WG (2012 - 2013) Mark Schmidt, Holly Posner
ADAS-Cog Plus WG (2009 – 2014) Mark Schmidt, Holly Posner
Aβ as a Biomarker WG (2009 – 2015) Jeff Waring
Informatics WG (2010 – 2013) Victor Lobanov

ADNI PI
Mike Weiner

PPSB Chair (transitioning)
Robert Dean (*Veronika Logovinsky*)

PPSB Working Groups

PET Endpoints Working Group

Chair: Mark Schmidt, J&J (Deputy: Gregory Klein, Roche)

- **Identify & control sources of PET imaging variability to improve detection of treatment effects**
- **Potential tau ligand alternatives to AV1451**
- **Discussion of early frame amyloid imaging for vascular flow (not chartered)**

Biofluid Biomarker Working Group

Chair: Susan De Santi, Piramal (Johannes Streffer)

- **Access to residual ADNI biological specimens for assay manufacturers**
- **Efforts to standardize pre-analytical specimen collection & handling - Roundtable discussion (not chartered)**

PPSB Working Groups

Clinical Endpoints Working Group

Chair: Veronika Logovinsky (Deputy: Nandini Raghavan)

- **Four previous workstreams collapsed into one functioning group**
- **Monitoring implementation and data quality for the Financial Capacity Instrument – Short Form (FCI-SF)**
- **Monitoring collection of Cog State data**
- **Finishing a comparison of composite scales developed by different sponsors**
- **Finalizing manuscripts on earlier work completed by separate workstreams**

Coordination and Organization by FNIH

Joseph Menetski, PhD
Deputy Director, Research Partnerships
(301) 594-6596
jmenetski@fnih.org

Dinetta Parrot
Development Officer
(301) 594-2103
dparrot@fnih.org

Back ups

PPSB: Leadership

Chair	Robert Dean, Lilly
Chair-elect	Veronika Logovinsky, Eisai
FNIH	Joseph Menetski, Deputy Director* Rosa Canet-Aviles, Scientific Program Manager Dinetta Parrott, Partnership Development Officer# Meredith Donnelly, Partnership Development Officer Eric Barese, Partnership Development Officer Julie Wolf-Rodda, Director of Development
Past PPSB Chairs	Gerald Novak, J&J; Susan De Santi, Piramal; Jesse Cedarbaum, Biogen; Adam Schwarz, Eli Lilly; Johan Luthman, Eisai; Enchi Liu, Prothena; Mark Schmidt, J&J; Holly Soares, BMS; Patricia Cole, Takeda; Eric Siemers, Eli Lilly; Bill Potter, NIMH; Pete Snyder, Lifespan Hospital System
Core Team	PPSB company / organization primary representatives
Extended Team	Additional PPSB representatives

*Indicates primary Scientific contact

Indicates primary Development contact

ADNI-PPSB 2017 Spring F2F Meeting Agenda

REGISTRATION & BREAKFAST

WELCOME

Robert Dean (Lilly), PPSB Chair

Session 1: Progress Update: ADNI Cores

Overview

Mike Weiner (University of California, San Francisco)

Clinical Core

Paul Aisen (University of Southern California)

PET Core

Susan Landau (University of California, Berkeley)

MRI Core

Clifford Jack (Mayo Clinic)

BREAK

Biostatistics Core

Laurel Beckett (University of California, Davis)

Bioinformatics Core

Arthur Toga (University of Southern California)

Data and Publications Committee

Robert Green (Harvard Medical School)

LUNCH

Session 2: Progress Update - Genetics

ADNI DNA Methylation Study

Andy Saykin (Indiana University) and Aparna Vasanthakumar (AbbVie)

ADNI Metabolomics Studies

Rima Kaddurah-Daouk (Duke University) and Kwangsik Nho (Indiana University)

Additional Core Update

Neuropathology Core

John Morris (Washington University)

BREAK

Session 3: Progress Update – Biofluid Biomarkers

Roche Elecsys Background

Sandra Rutz (Roche Diagnostics)

Roche Elecsys Analysis

Les Shaw (UPenn)

Session 4: Roundtable discussion

Towards a Standardization of Fluid Biomarkers – Next Steps

Richard Batria-Utemann (Roche Diagnostics), Miguel Mendoza (Roche Diagnostics), Zivjena Vucetic (FujiRebio), John Lawson (FujiRebio), Alvydas Mikulskis (Biogen), Mary Savage (Merck), Leslie Shaw (University of Pennsylvania), Britta Brix (EUROIMMUN)

Closing comments

Robert Dean (Lilly), PPSB Chair

Mike Weiner (University of California, San Francisco)

ADJOURN