Continuous in-home assessment: New approaches to assessing health

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

Jeffrey Kaye, MD
Layton Professor of Neurology & Biomedical Engineering
Oregon Center for Aging & Technology
NIA - Layton Aging & Alzheimer's Disease Center
kaye@ohsu.edu

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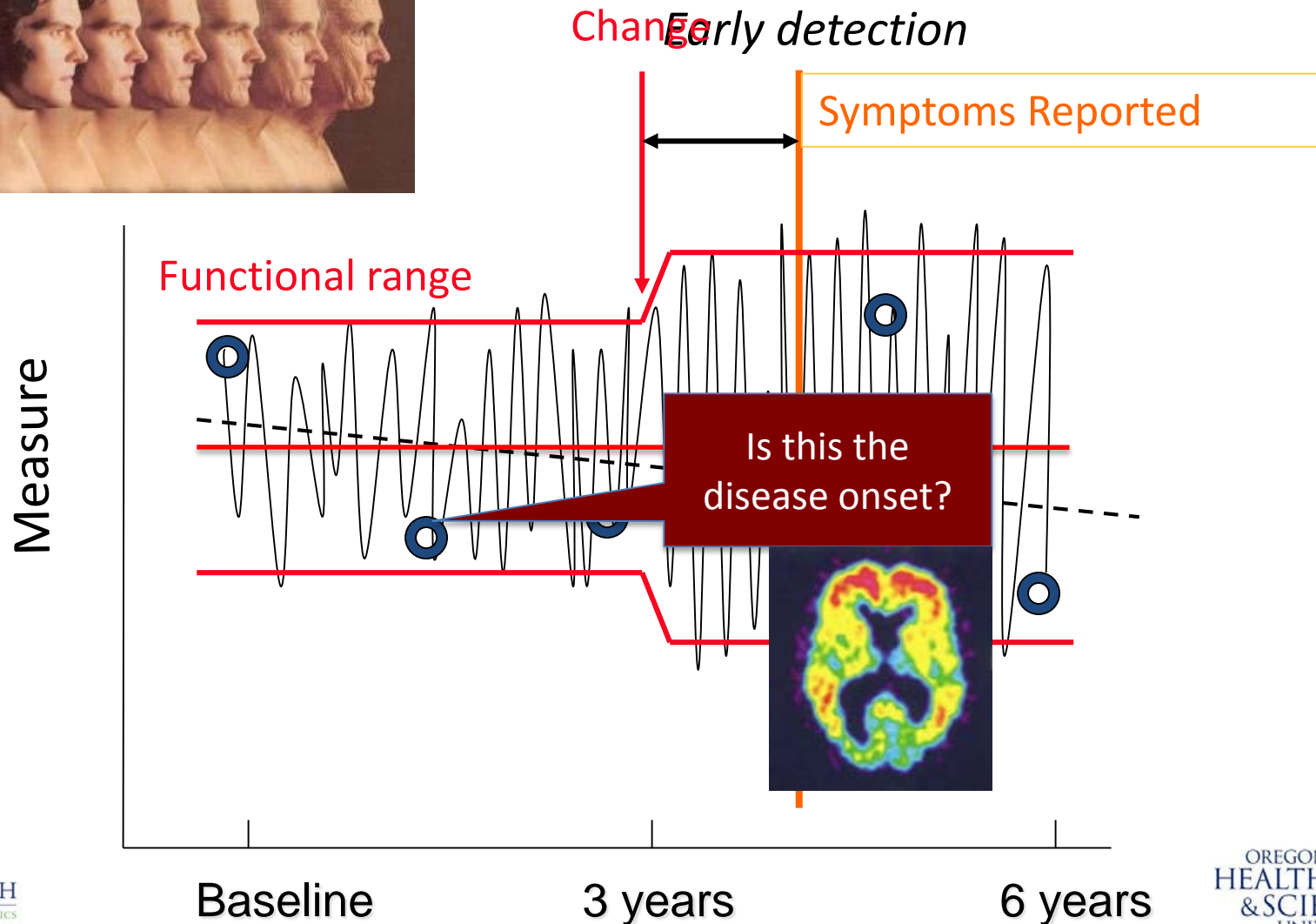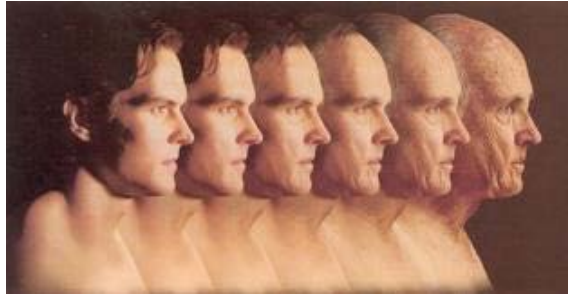OREGON HEALTH & SCIENCE UNIVERSITY
OHSU

A fundamental limitation of current dementia research and clinical care... detecting meaningful change

Cardinal features of change - *slow decline punctuated with acute, unpredictable events* - are challenging to assess with current tools and methods.

QUESTIONNAIRE

Very often

Often

Sometimes

Rarely

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Detecting meaningful change is hard …
And how to improve detection of change

Changing the Assessment Paradigm

- **Brief**
- **Episodic**
- **Clinic-based**
- **Subjective**
- **Obtrusive**
- **Inconvenient**

➢ **Pervasive Computing**
➢ **Wireless Technologies**
➢ **"Big Data Analytics"**

- **Real-time**
- **Continuous**
- **Home-based**
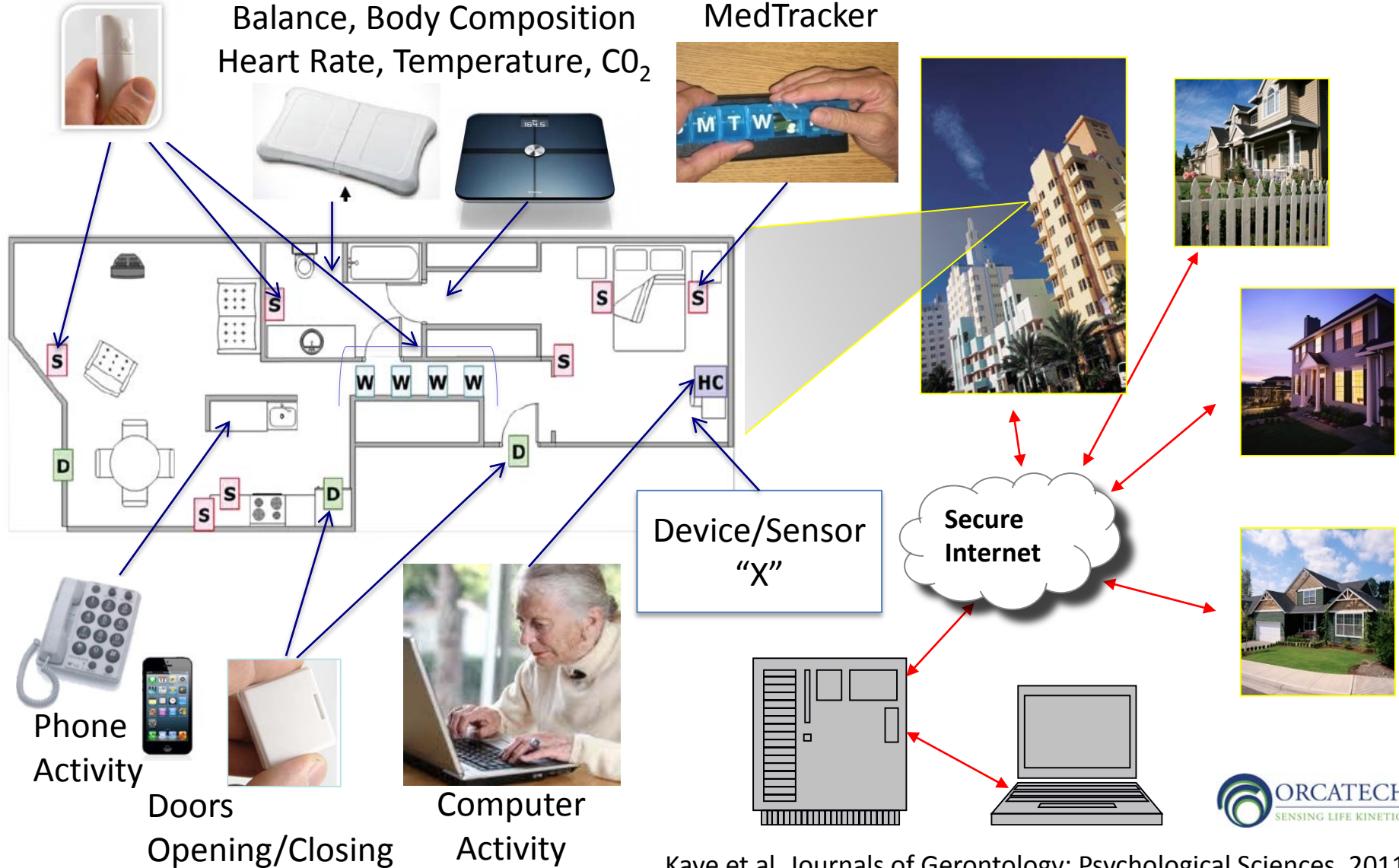- **Objective**
- **Unobtrusive**
- **Ambient**

- New Observations & Discovery
- Maximally Effective Clinical Research & Trials
- Better Outcomes for Patients & Families

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Pervasive Computing Platform for Assessment: *Community-wide 'Life Lab'*

Activity, Sleep, Mobility Time & Location

Balance, Body Composition Heart Rate, Temperature, CO_2

MedTracker

Device/Sensor "X"

Secure Internet

Phone Activity

Doors Opening/Closing

Computer Activity

Kaye et al. Journals of Gerontology: Psychological Sciences, 2011

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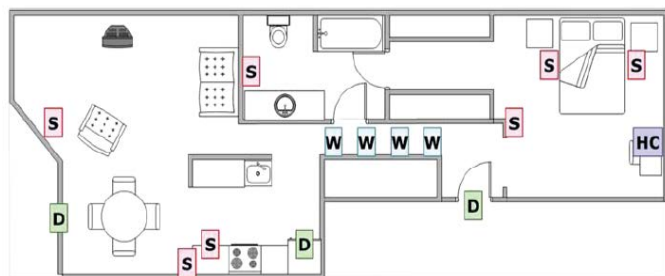# Research Process & Infrastructure

UNDERSTAND THE STAKEHOLDERS/KEY QUESTIONS
ROI (Response Over Internet) surveys, Focus Groups
Participant/End-User Assessment

UNDERSTAND REAL WORLD USE
Life Lab: Large Scale Deployments Relevant Health
& Wellness Measures & Interventions in Everyday
Environments

Secure Internet

UNDERSTAND THE DATA
ORCATECH Data Repository, Data Aggregation,
Measurement Analytics & Outcomes
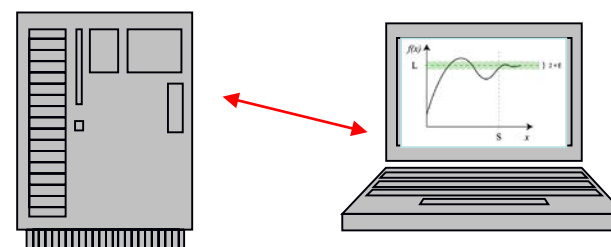
UNDERSTAND THE TECHNOLOGIES
Point of Care 'Smart Apartment' Lab:
Focused Sensor/Measurement Technology Development & Assessment

I only use a landline phone. I do *not* use a cell phone.

I use my landline often, but have a cell phone for emergencies.

I use both a landline phone and a cell phone, depending on which one is more convenient.

I use my cell phone most of the time, even at home, but I still have a landline that I use occasionally.

I don't have a landline phone, I *just* use a cell phone.

What can you see?
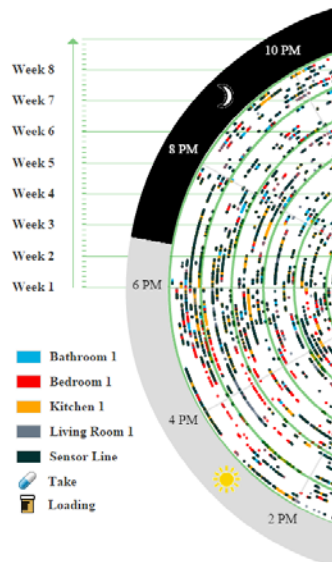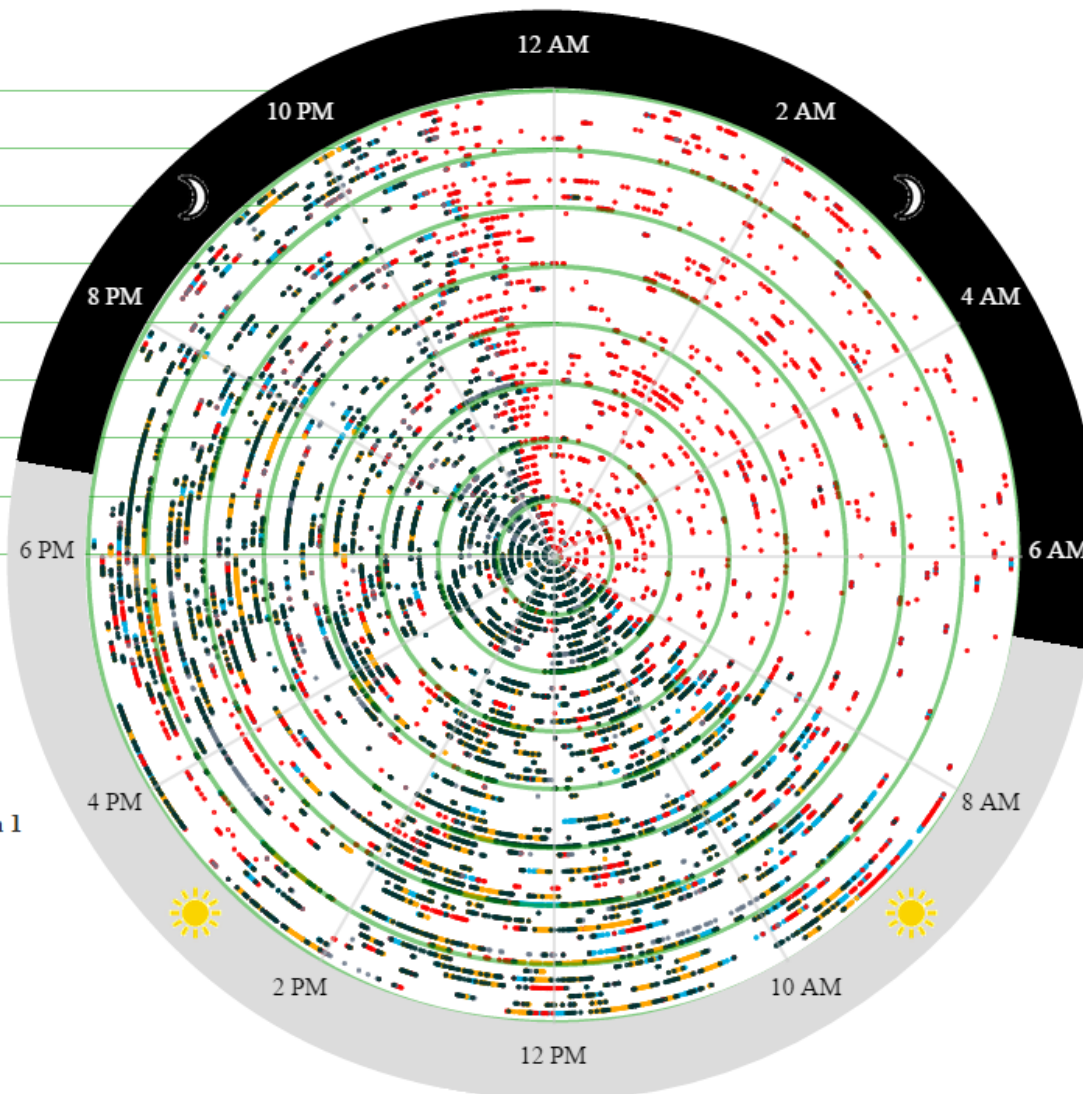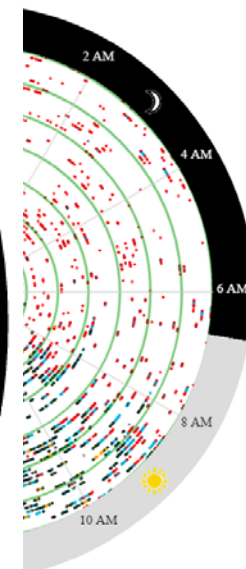
Differentiation of early MCI: Total Activity & Walking
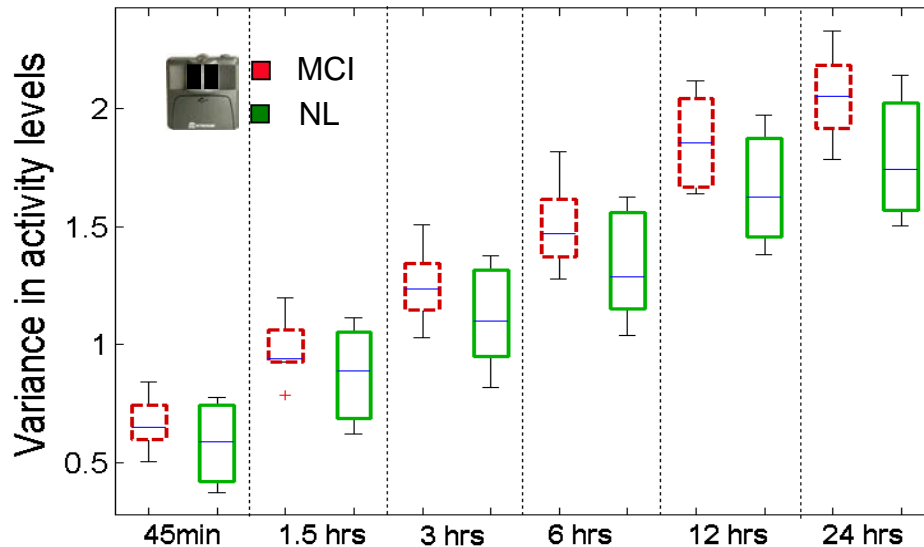
Activity patterns associated with mild cognitive impairment

Hayes et al. Alzheimers Dement, 2008

Trajectories of walking speed over time

Dodge, et al. Neurology, 2012

MCI cases 9X more likely in Slow Group

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Differentiation of early MCI: Night-time Behavior & Sleep

Normal

NA-MCI

A-MCI

Hayes, et al. Alzheimer Dis Assoc Disord. 2014
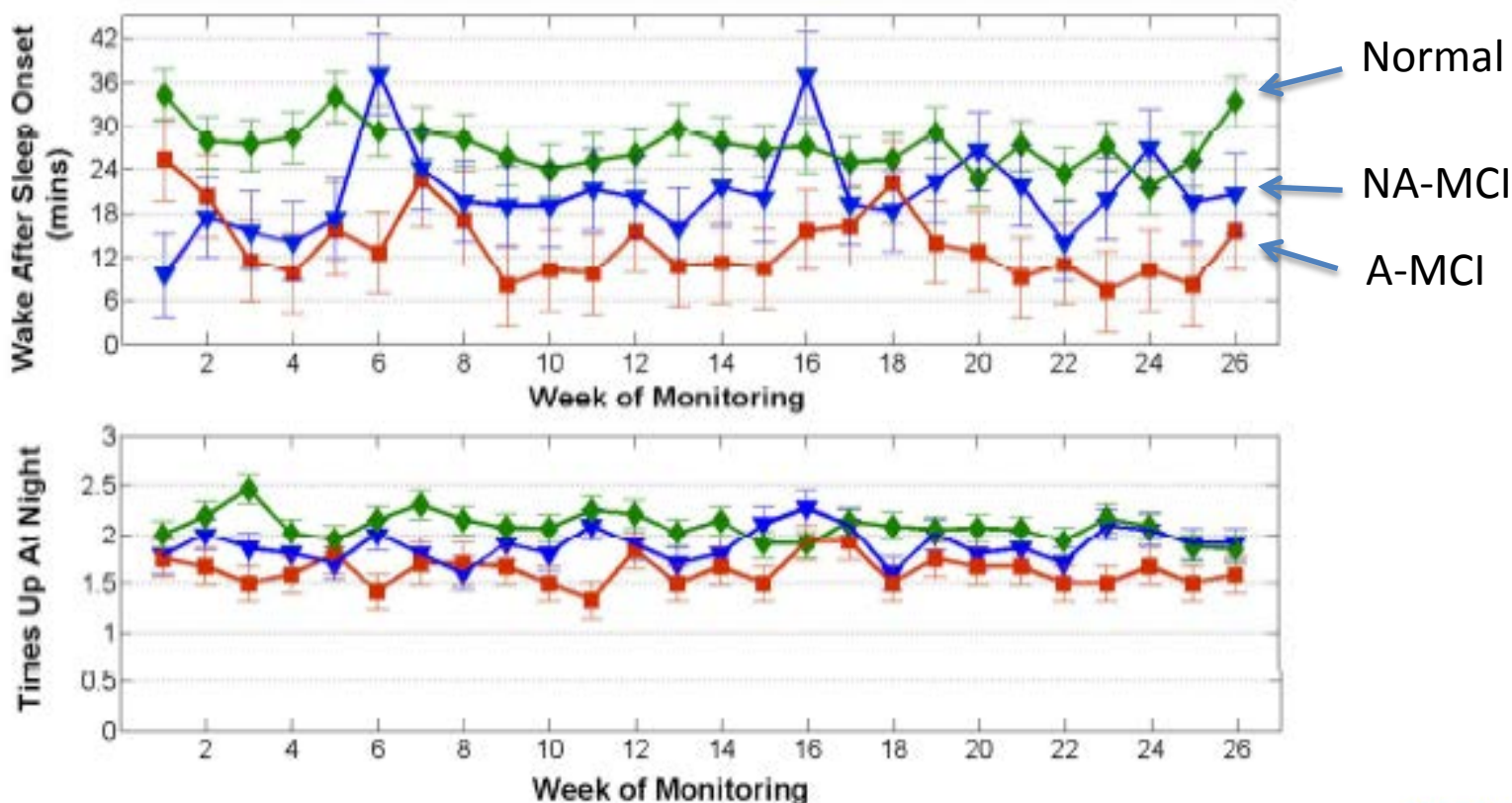
Every Day Cognition: Medication adherence as a measure of cognitive function
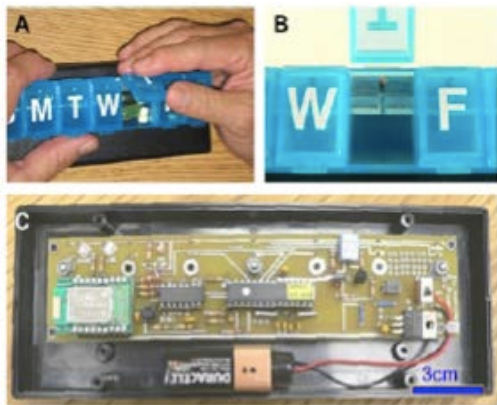
- Adherence assessed continuously x 5 wks with MedTracker taking a

- Mean Age - 83 yrs

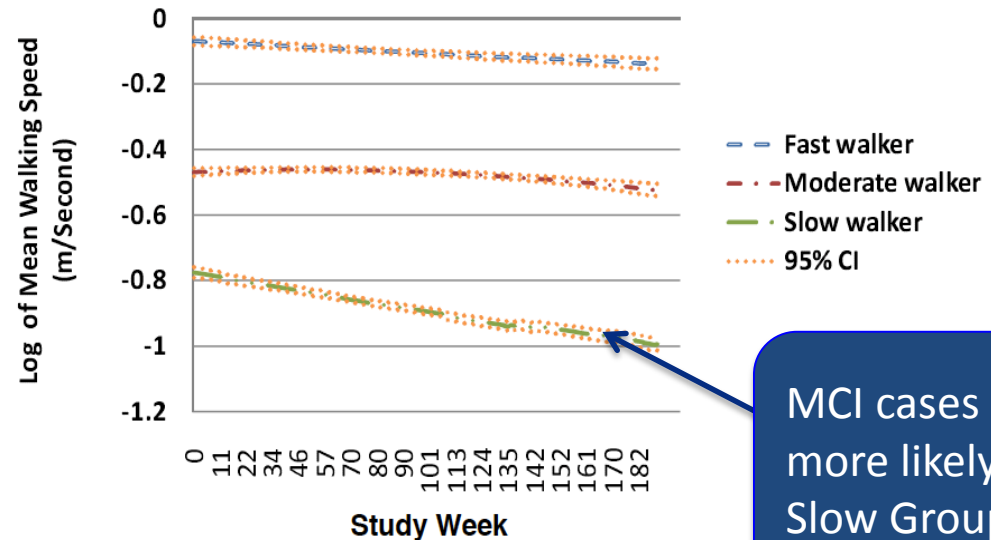- Based on ADAScog: Lower Cognition Group vs Higher Cognition Group

Hayes et al., *Proceedings : Engineering in Medicine and Biology Soc*, 2006; Leen, et al., *Technology and Aging*, 2007 ; Hayes et al. *Journal of Aging Health*, 2009; Hayes et al. *Telemedicine Jounal and E-Health*, 2009

Significantly Worse Adherence in Lower Cognition Group

Median time within 53.4 mins of goal

Median time within 12.0 mins of goal

% Adherent

Lower Cognition   **Higher Cognition**
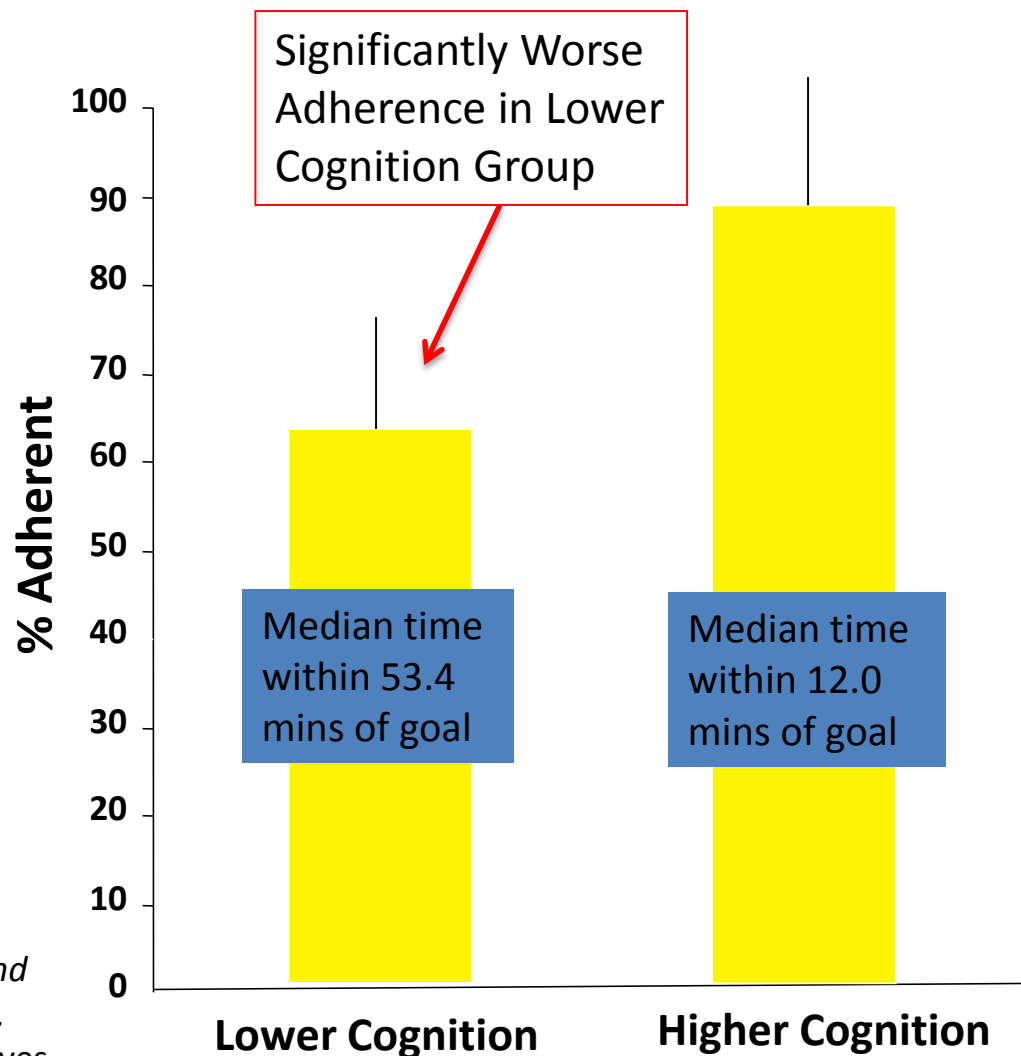
Every Day Cognition: Computer use changes over time in MCI (assessing decline *without formal cognitive tests*)
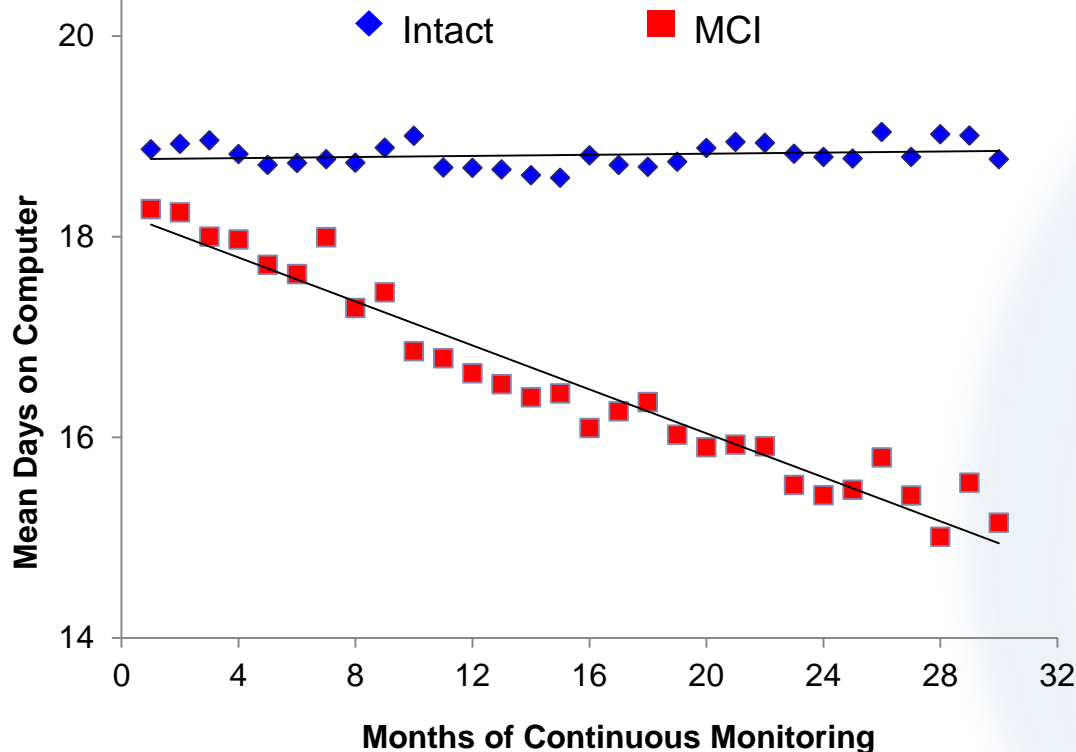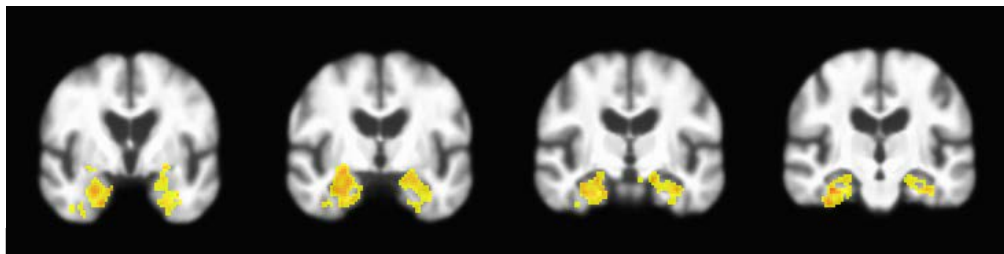
- At Baseline: Mean 1.5 hours on computer/per day
- Over time:
  - Less use days per month
  - Less use time when in session
  - More variable in use pattern over time

Kaye, et al. Alzheimers Dement. 2014; Silbert et al. submitted, 2015

Active, Frequent Assessments can be Delivered Everyday: RCT to Increase Social Interaction in MCI Using Home-based Technologies

Video Chat

- 6 week RCT of daily 30 min video chats
- 89% of all possible sessions completed; Exceptional adherence – *no drop-out*
- Intervention group improved on executive/fluency measure.
- MCI participants spoke 2985 words on average while cognitively intact spoke 2423 words during sessions; better discrimination of MCI than conventional tests (animal fluency and delayed list recall)

Dodge et al. Alzheimer's & Dementia: Translational Research & Clinical Interventions, 2015

Direct to home visits: Novel assessment opportunities

http://psych.nyu.edu/freemanlab/research.htm
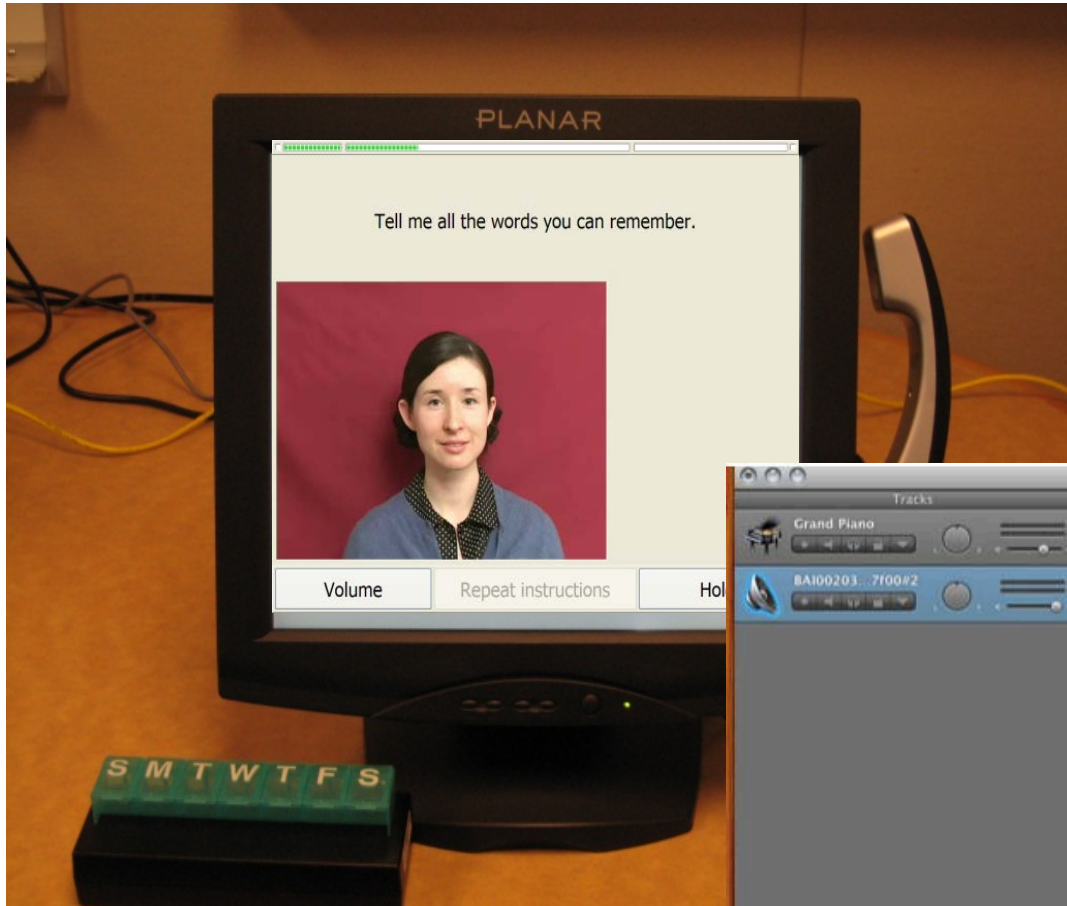
Alzheimer's Disease Cooperative Study Home Based Assessment Study (ORCATECH Kiosk System used in HBA Study)
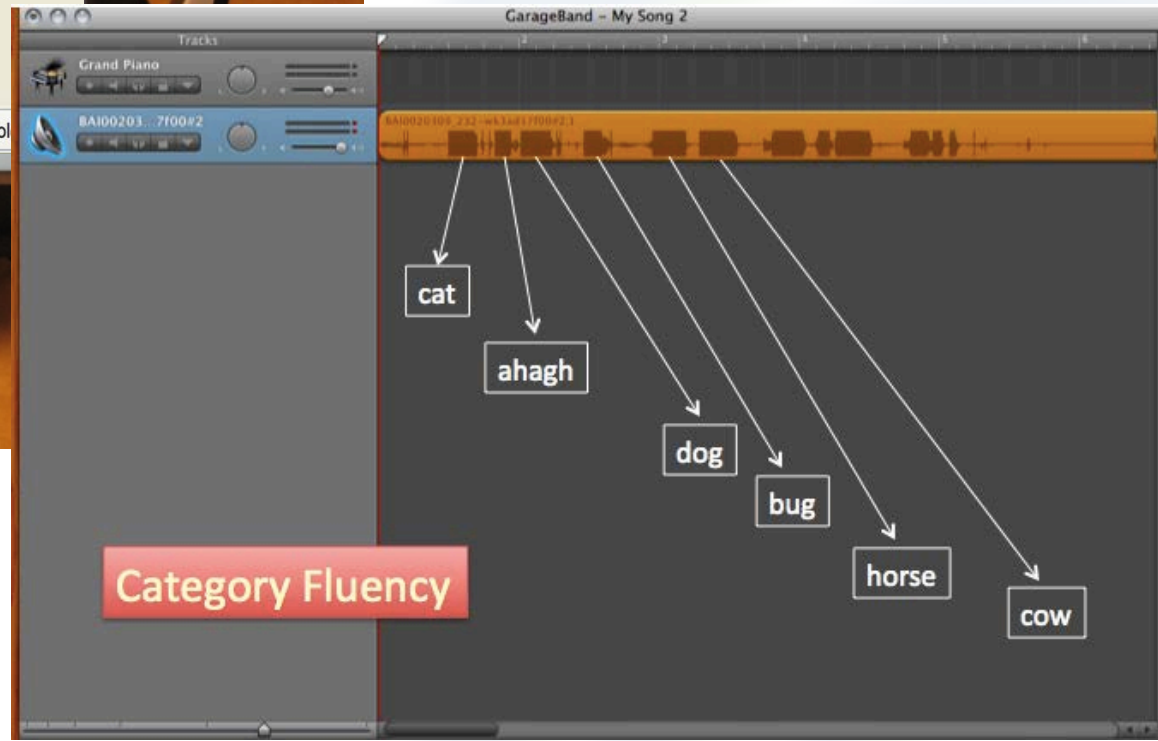
Putting it all together: Pervasive computing 'Big Data' for more informative research
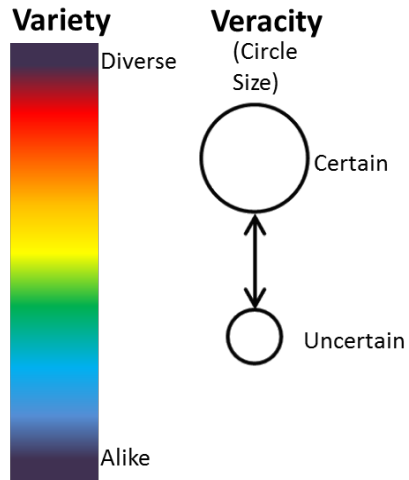
Austin, 2015
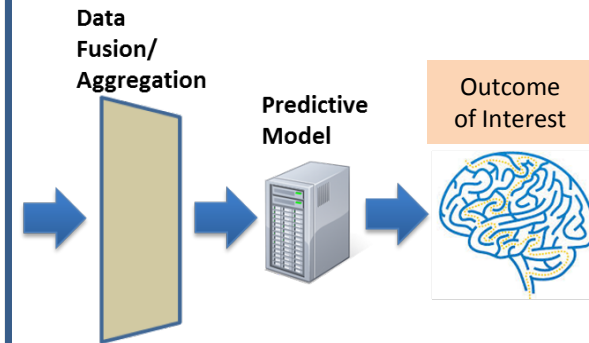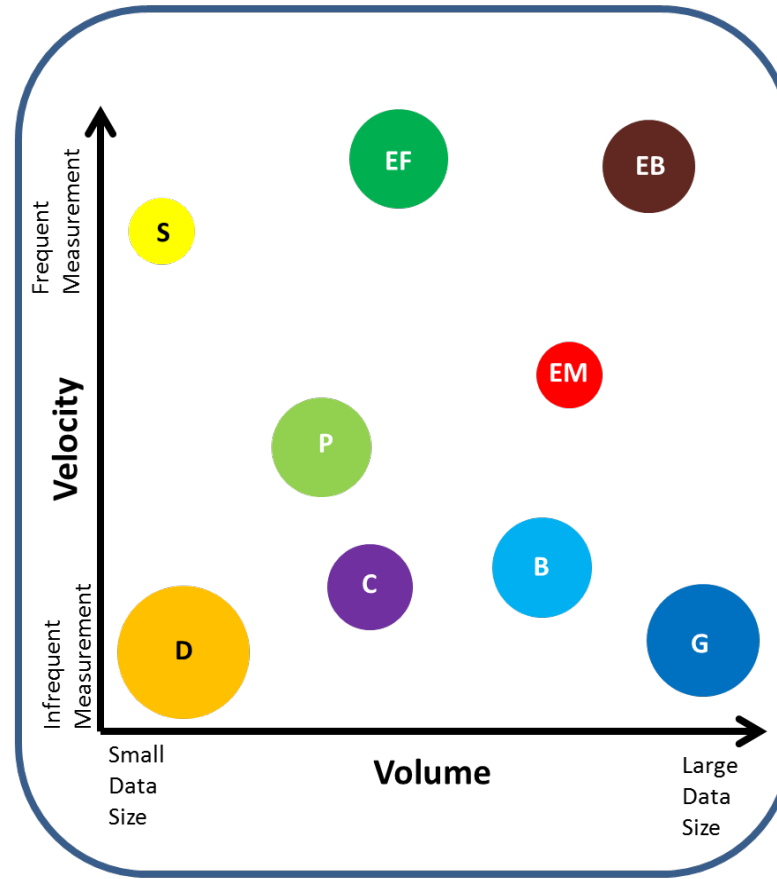
Putting it all together: High dimensional data fusion model predicting care transitions — 63,745,978 observations
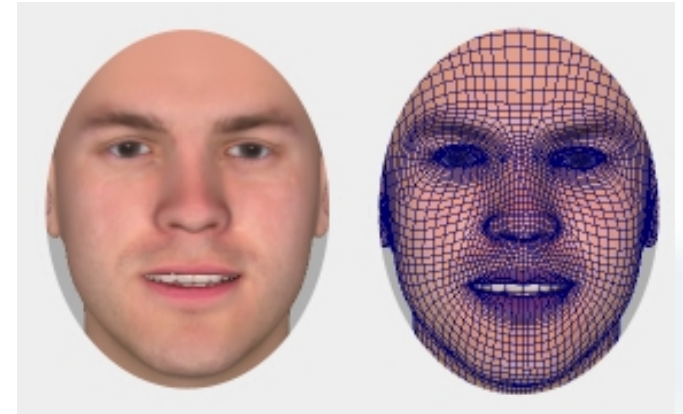
Behavioral - Activity Data: Computer use, time out of home, etc.

Context: Weather, CCI, living in a retirement community, etc.

Weekly Self-Report: Mood, Pain, Falls, ER visits, Visitors, etc...

Annual Clinical Assessment: Cognition, physical function, biomarkers, etc.

Demographics: Age, education, socioeconomic status, etc.

Controls: Number of rooms in home, etc.

Model

Outcome

Care Transition

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Austin et al. 2014 GSA

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Predicting Care Transitions: Sensitivity Analysis

- Likelihood of a person transitioning within next six months – ROC AUC under curve= 0.974

Area under ROC curve = 0.9744

Austin et al. 2014 GSA
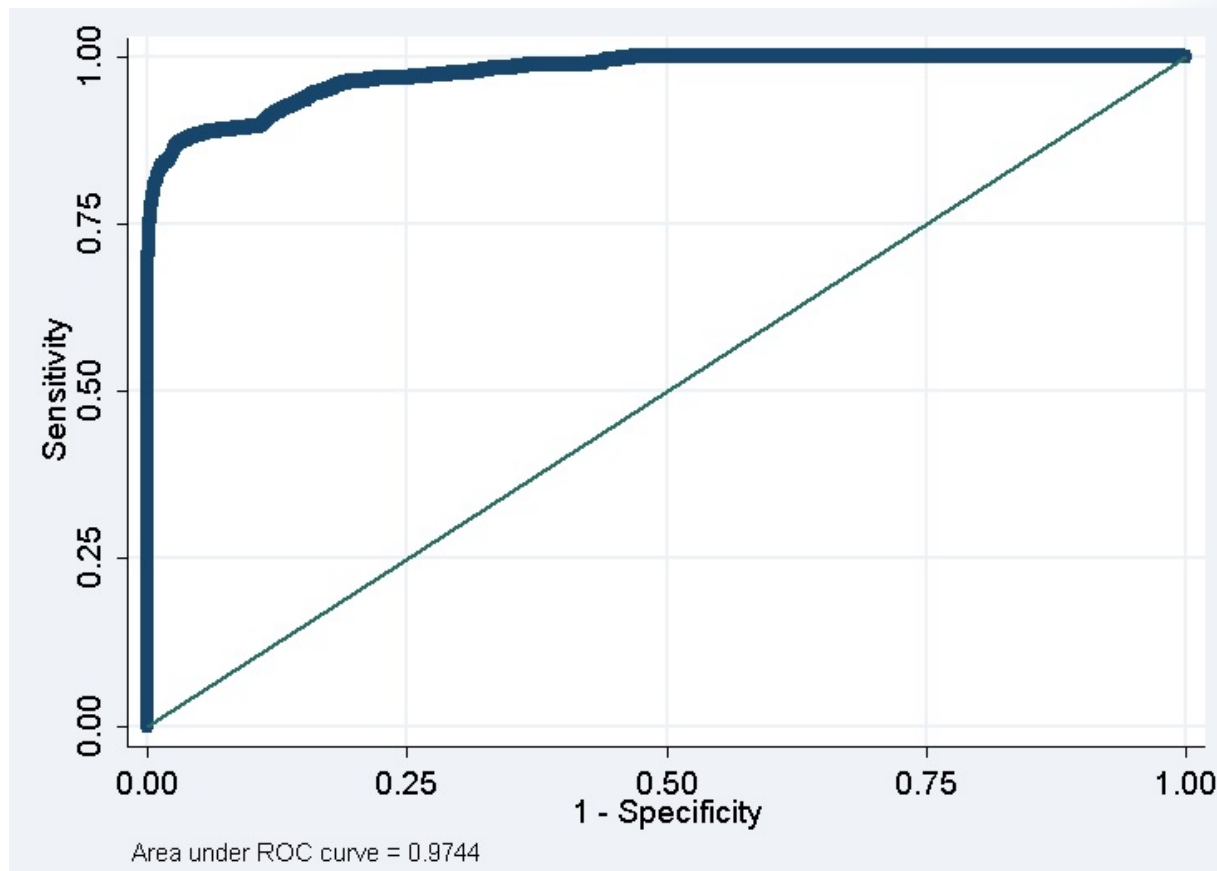
Putting it all together: High dimensional data fusion model predicting drug (analgesic) class

66,172,380 observations

Behavioral - Activity Data: Computer use, time out of home, etc.

Context: Weather, CCI, living in a retirement community, etc.

Weekly Self-Report: Mood, Pain, Falls, ER visits, Visitors, etc...

Annual Clinical Assessment: Cognition, physical function, biomarkers, etc.

Demographics: Age, education, socioeconomic status, etc.

Controls: Number of rooms in home, etc.

Model

Outcome

Analgesic Class

Austin et al. 2015 Under Review

Predicting Drug Class Effects: Case of analgesics
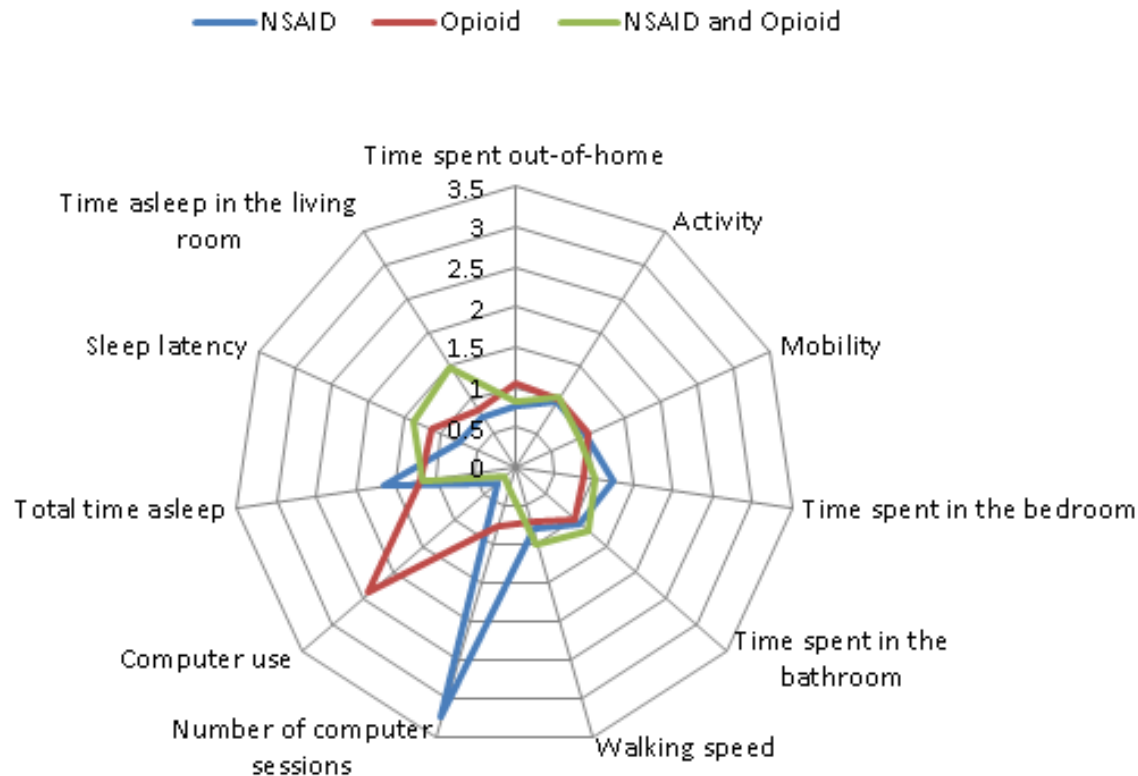
	NSAID	Opioid	Both
Sensitivity (%)	94.9	65.9	67.4
Specificity (%)	99.9	98.6	99.6
Positive Predictive Value (%)	99.7	82.6	86.1
Negative Predictive Value (%)	99.7	96.6	98.9
Correctly Classified (%)	99.6	95.6	98.6

Logistic regression models treated as classifiers (and model fit statistics)

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Observation period: July 2011 – March of 2014; 66,172,380 observations

Pervasive Computing Technology in Current Therapeutics Research

- Spectacular progress has been

But...

- *Pervasive computing technologies and selected biomarkers can radically change the way we conduct clinical research*
- *This will lead to major advances in detecting prodromal change, managing manifest disease and in transforming the effectiveness of clinical trials.*
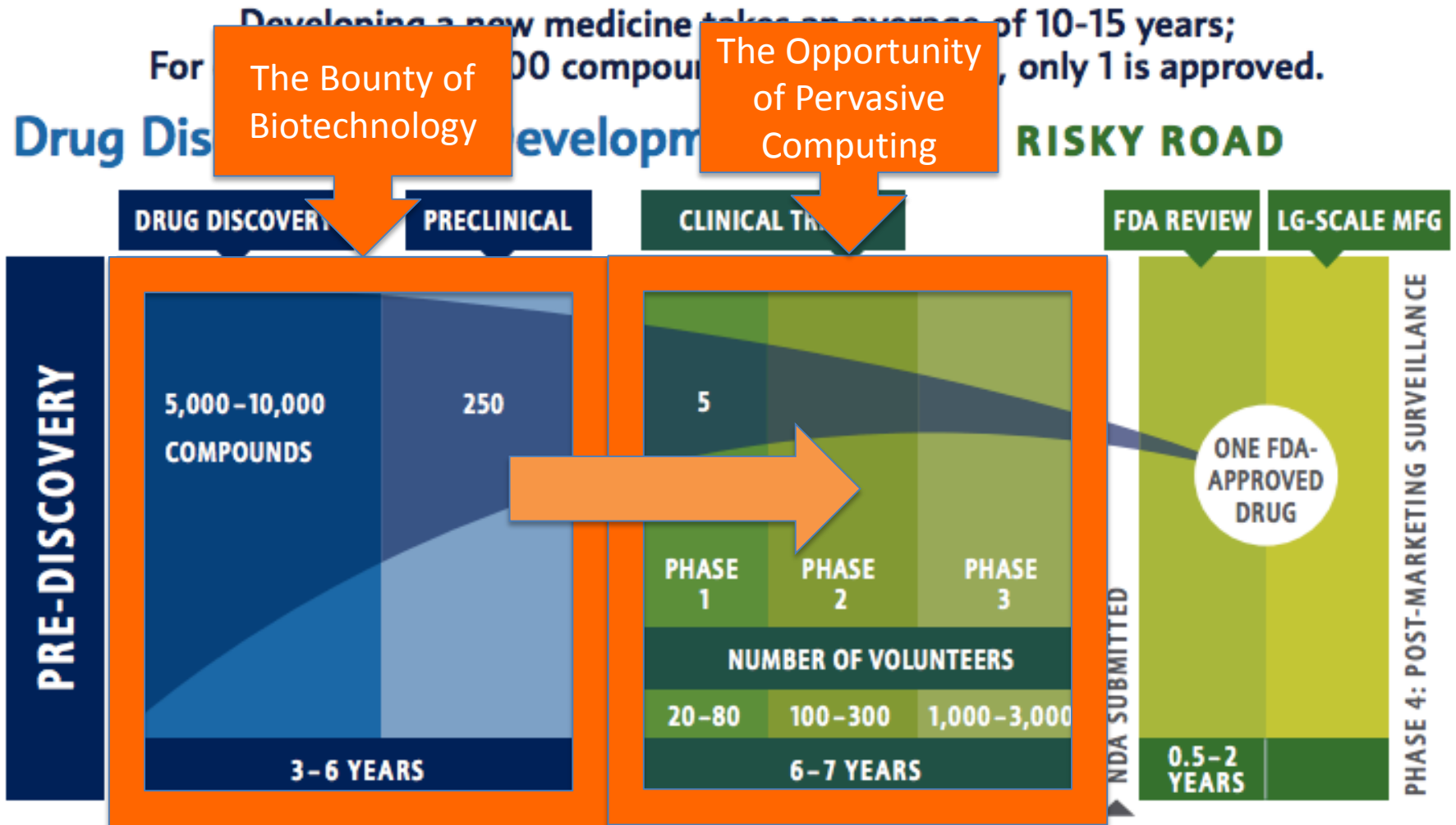
appreciably changed since 1747.

Harnessing the power of pervasive computing systems: *transform the conduct of clinical trials*

The Bounty of Biotechnology

The Opportunity of Pervasive Computing

Developing a new medicine takes an average of 10-15 years;
For ... 00 compou... only 1 is approved.

Drug Dis...evelopm... RISKY ROAD

| DRUG DISCOVERY | PRECLINICAL | CLINICAL TR... | FDA REVIEW | LG-SCALE MFG |

PRE-DISCOVERY

5,000–10,000 COMPOUNDS

250

5

3–6 YEARS

PHASE 1 | PHASE 2 | PHASE 3

NUMBER OF VOLUNTEERS

20–80 | 100–300 | 1,000–3,000

6–7 YEARS

NDA SUBMITTED

ONE FDA-APPROVED DRUG

0.5–2 YEARS

PHASE 4: POST-MARKETING SURVEILLANCE

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http://www.phrma.org/sites/default/files/Alzheimer%27s%202013.pdf

# Challenges to detecting meaningful change in clinical trials
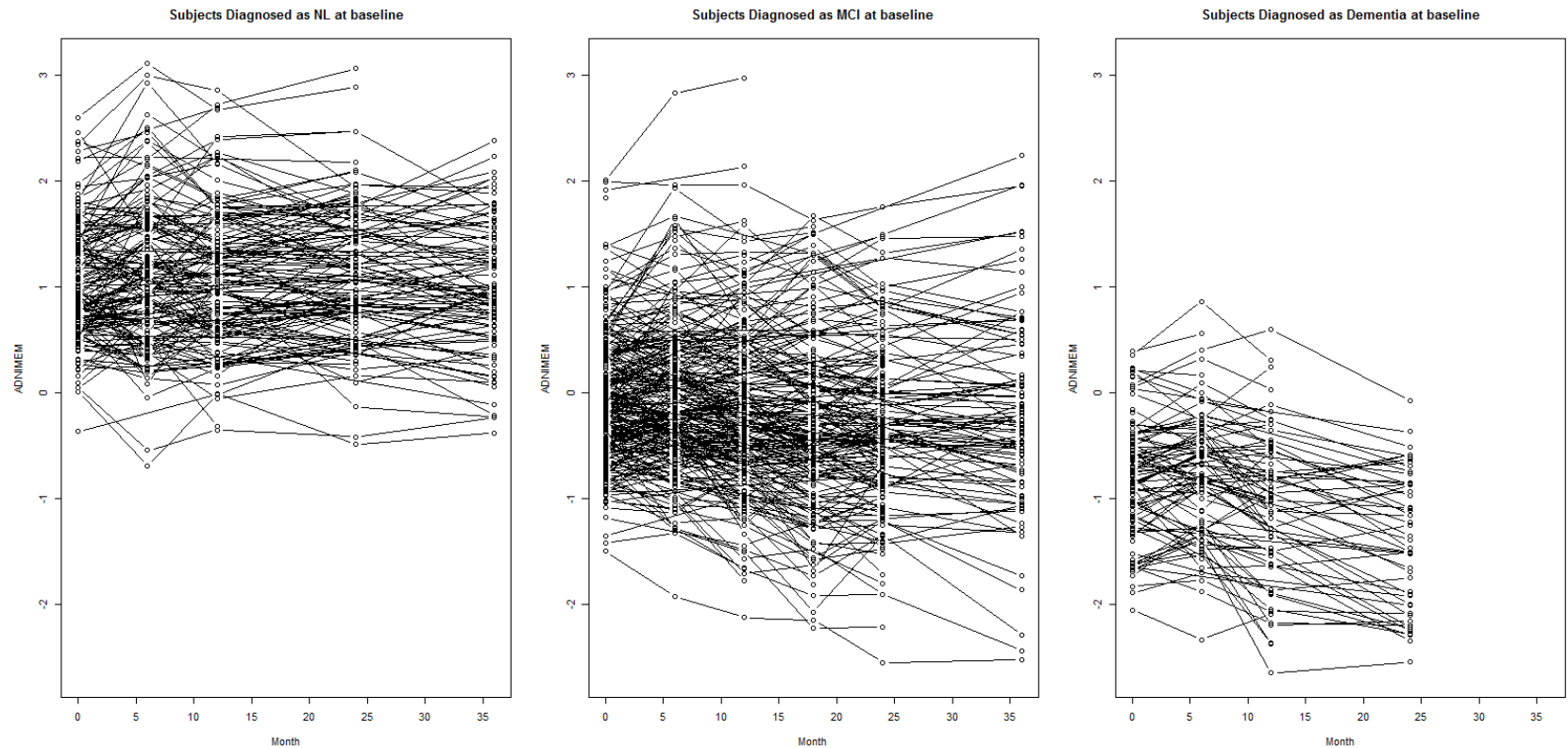
Dodge HH, et al. ADNI Biomarker progressions explain higher variability in stage-specific cognitive decline than baseline values in Alzheimer disease. Alzheimers Dement. 2014.

Improving clinical trials through continuous data collection: Smaller samples, more precise estimates, faster, and ecologically valid
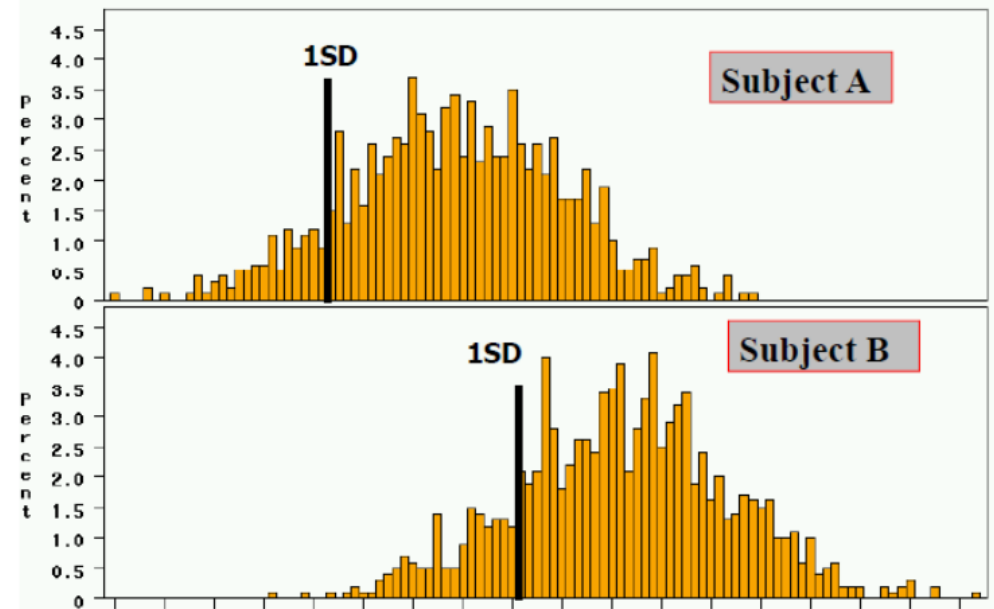
Conventional Approach
Group Bell curves compared
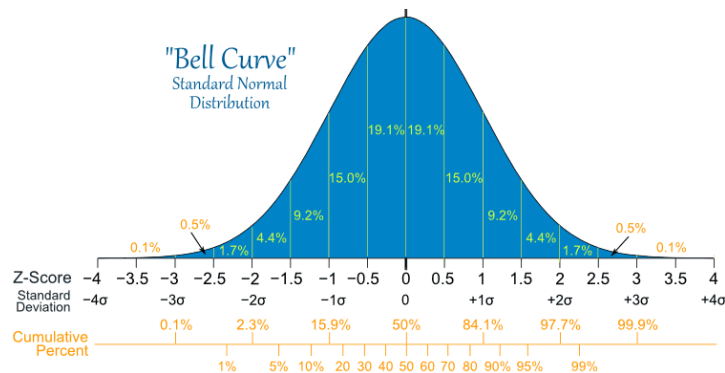
Distribution can be generated for _EACH_ individual within short duration data accrual periods

Continuously Monitored Approach
Individual Bell Curves

Walking Speed Observed During the First 90 days for 2 subjects

Your walking speed ≠ my walking speed OR Your computer use ≠ my computer use
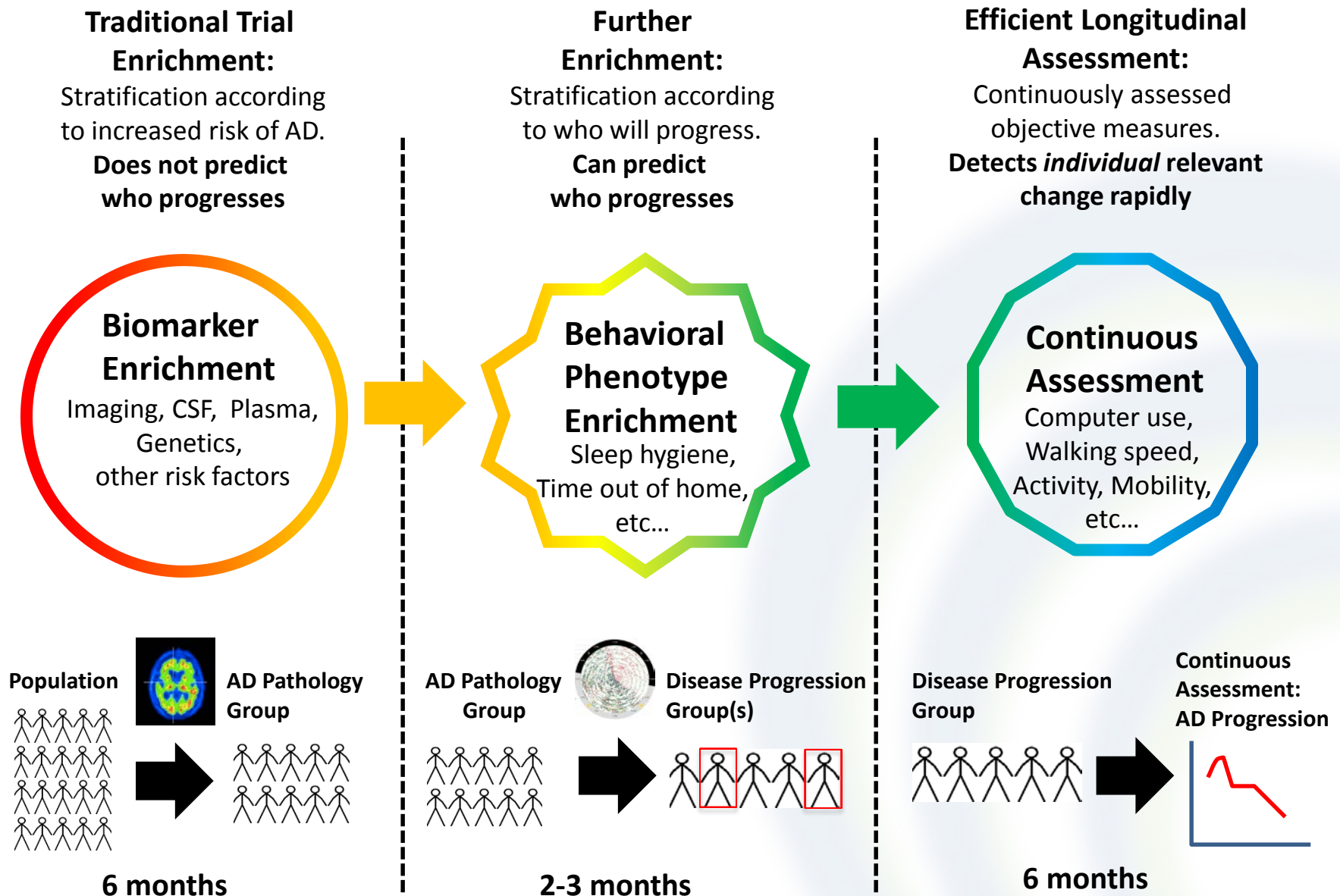
Courtesy of H. Dodge

Transforming Clinical Trials with High Frequency, Objective, Continuous Data: "Big Data" for Each Subject

- More precise estimates of the trajectory of change; allows for *intra-individual* predictions.
- Reduces required sample size and/or time to identify meaningful change.
- Reduces exposure to harm (fewer needed/ fewer exposed)
- Provides the opportunity to substantially improve efficiency and inform go/no-go decisions of trials.

MCI Prevention Trial – Sample Size Estimates

	Current Method	Continuous Measures	
	LM Delayed Recall*	Computer Use**	Walking Speed**
SAMPLE SIZE TO SHOW 50% EFFECT	688	10	94
SAMPLE SIZE TO SHOW 40% EFFECT	1076	16	148
SAMPLE SIZE TO SHOW 30% EFFECT	1912	26	262
SAMPLE SIZE TO SHOW 20% EFFECT	4300	58	588

Dodge, et al. AAIC, 2014

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Next Generation High Efficiency Clinical Trials (Focus on Phase II, early detection of efficacy)

Thank You!

1956

2006

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