NACC & Gates Ventures AD/ADRD Digital Pilot Program

Informational Webinar | January 22, 2024

Gates Ventures

NACC

NIH National Institute on Aging (NIA)
Alzheimer's Disease Research Center Program

Welcome!

NACC & Gates Ventures
AD/ADRD Digital Pilot Program

About:

The NACC & Gates Ventures AD/ADRD Digital Biomarker Pilot Program aims to accelerate AD/ADRD research and discovery through impactful digital data collection.

We will fund up to three proposal at **$250,000 to $1,000,000** (direct costs) each.

We are interested in projects that leverage digital technology to capture richer and more objective data with less burden and/or that advance the development and/or validation of digital biomarkers for early detection, diagnosis, prognosis, or monitoring.

Applications are open to anyone with at least two ADRC collaborators.

Application Deadline Extended to February 21!

Learn more and apply here!

Scan code or visit:
bit.ly/DGP_Awards

NACCmail@uw.edu

Gates Ventures

NACC

Digital Biomarker Webinar Speakers and Panelists

Gates Ventures

NIRANJAN BOSE, PHD
Managing Director of Health & Life Sciences at Gates Ventures

ADRC Program

NINA SILVERBERG, PHD
Alzheimer's Disease Research Center (ADRC) Program Director at the National Institute on Aging (NIA)

Academic-Industry Partnerships

RHODA AU, PHD, MBA
Professor of Anatomy and Neurobiology at Boston University, Director of Neuropsychology for the Framingham Heart Study, and Consultant to Global Cohort Development for the Davos Alzheimer's Collaborative

NACC & Digital Pilot Program Overview

SARAH BIBER, PHD
Executive Director of the National Alzheimer's Coordinating Center (NACC)

Gates Ventures

Niranjan Bose, PhD (Gates Ventures)

Gates Ventures' Alzheimer's Disease Program Focuses on Five Programmatic Pillars

1 Disease Biology — Better understanding the etiology and disease pathways — AMP®-AD

2 Biomarkers & Dx — Easy to use diagnostic — Diagnostics Accelerator; EDoN Early Detection of Neurodegenerative diseases; AHA-SFRN; Bio-Hermes; Chariot: Pro; The Swedish BIOFINDER STUDY

3 Therapeutic Pipeline — More shots on goal — Dementia Discovery Fund; alzheimer's association; PART THE CLOUD; EQT

4 Clinical Trials — Faster and more efficient clinical trials — IQVIA; BrightFocus® Foundation, Cure in Mind. Cure in Sight.; USC; Davos Alzheimer's Collaborative

5 Data — Facilitate broader data sharing, access and usability — ADDI Alzheimer's Disease Data Initiative; epnd European Platform for Neurodegenerative Diseases

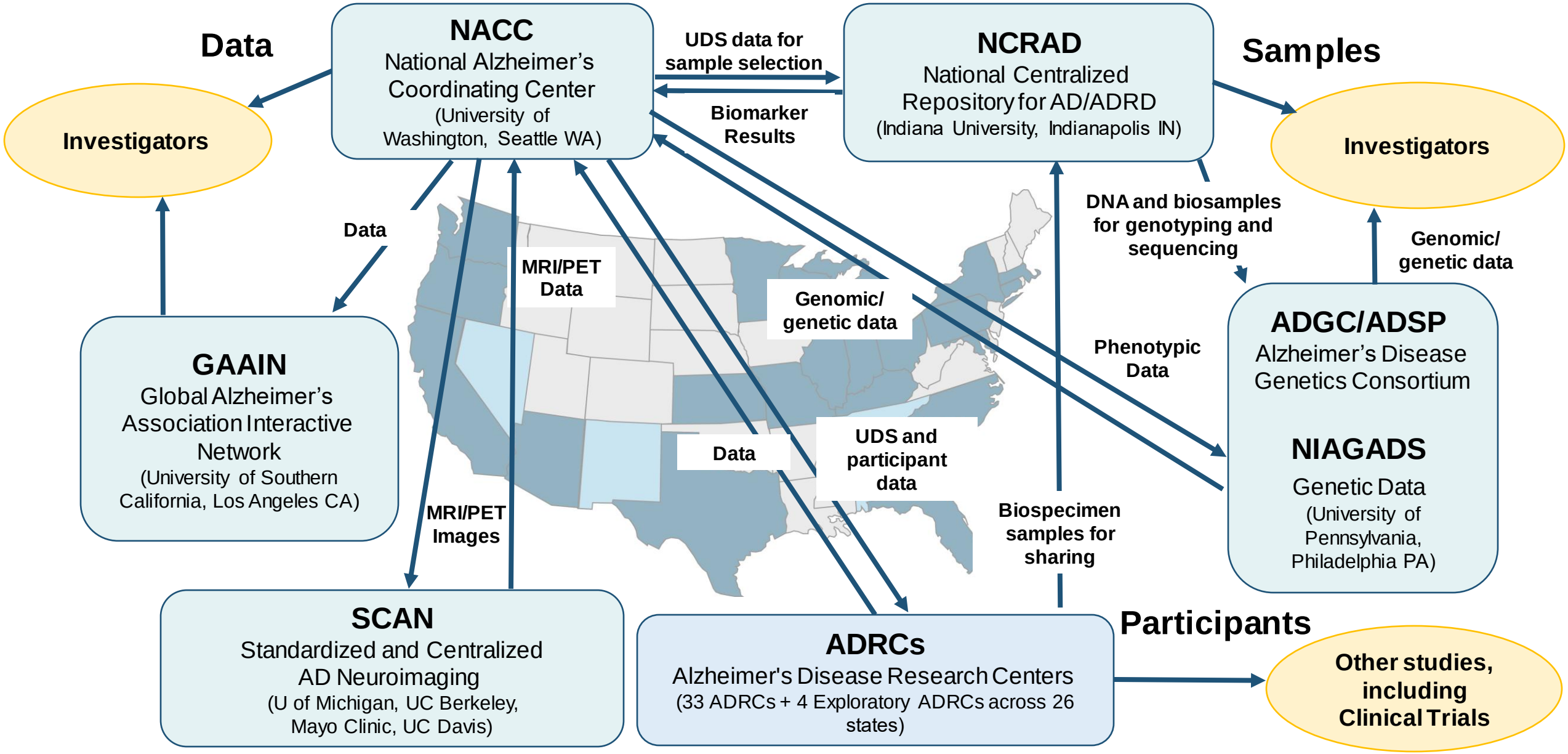
In 2023, we expanded our portfolio of philanthropic investments in diagnostics via some new partnerships

1. **Disease Biology** — Better understanding the etiology and disease pathways
   - gnpc
2. **Biomarkers & Dx** — Easy to use diagnostic and implementation science/research
   - NEURii
   - AD-RIDDLE Advancing Solutions for Alzheimer's Disease
   - SpeechDx Unlocking Alzheimer's Disease through Voice-Based Biomarkers

ADRC Program

Nina Silverberg, PhD (NIA)

ADRC Data, Sample and Participant Sharing Infrastructure



ADRCs global role in AD/ADRD research

- Lead the field scientifically, develop new approaches
- Support justice and equity
- Provide standardized data, samples and participants **across dementias and severity** to support recruitment for clinical trials and other national research efforts (e.g., ADNI, AGMP, ACTC, Diverse VCID, MarkVCID)
- Sustained support enables **strong community ties**, better retention
- **Train the next generation in a multidisciplinary environment**
- **Autopsy** services support participants, families and major research advancements
- Part of a **larger infrastructure** – NACC, NCRAD, SCAN, NIAGADS/AGSP
- Work both as part of a network and locally within the (public and research) community

ADRCs uniquely cover the etiologic spectrum whereas other projects are in one etiologic lane

Table 1. Prominent active cohort studies related to ADRD and their primary enrolling diagnosis

Cohort*	Size (Goal)	AD	VCID	LBD	FTLD	Atypical	LATE	Imaging A/T PET	purpose
CLARiTI	(2,000)	Y	Y	Y	Y	Y	nk	Y	Etiologic characterization of ADRD mixture
DVCID**	(2,250)	n	Y	n	n	n	nk	N	vascular risk for cognitive decline* will partner
ADNI4	(1,100)	Y	n	n	n	n	nk	Y	Clinical trial planning for AD with biomarkers
LEADS	(700)	Y	n	n	n	n	nk	Y	Clinical trial planning in early onset AD
ALLFTD	1,479	n	n	n	Y	n	nk	N	Clinical and biomarker progression
PPMI	(4500)	n	n	Y	n	n	nk	N	Biomarker progression in PD
DLBC	200	n	n	Y	n	n	nk	N	Dementia with Lewy bodies
DIAN	(600)	Y	n	n	n	n	nk	Y	Cohort of autosomal mutation carriers

Notes: *Single-site aging and AD-risk cohorts are not listed.
Nk= not known
LATE is a neuropath entity—clinical criteria are not defined and it is assumed all older cohorts contain some as yet unknown burden of LATE-NC; LBD includes Dementia with Lewy Bodies and Parkinson's disease dementia and their prodromes. Other abbreviations: VCID vascular cognitive impairment. LEADS Longitudinal early onset AD study; PPMI Parkinsons Progression marker initiative; DLBC Lewy Body consortium;

**DVCID Diverse VCID study: Participants may co-enroll because DVCID does not do PET and the core MRI is the same and will be at SCAN

Slide credit: CLARiTI, B Mormino and S Johnson

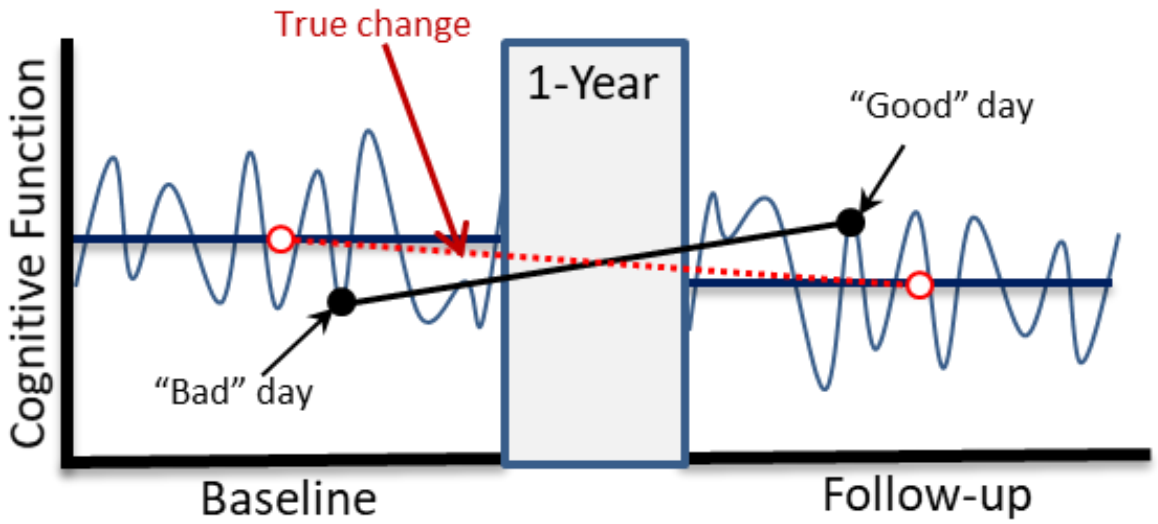
LIMITATIONS OF TRADITIONAL COGNITIVE ASSESSMENTS

ARTIFICIAL

- Assessments very removed from patient's reality.
- Environments and social contexts fundamentally dissimilar.
- Feeling of being "tested" by other person.
- "White-coat" testing effects.
- Effects of daily stressors (fatigue, mood, illness, traveling to sites).

"ONE-SHOT"

- Testing typically completed in one extended session

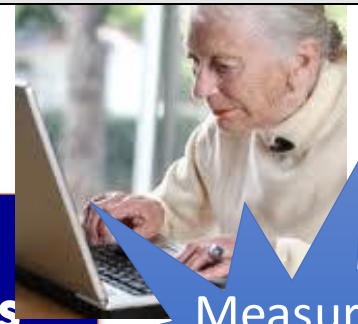


High Variability = Drastic reductions in statistical power.

Slide credit: Jason Hassenstab
Figure credit: Marty Sliwinski

In home technology – Changing the clinical research paradigm

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



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

Measure the real thing!!!

- Pervasive Computing
- Wireless Technologies
- "Big Data Analytics"

EVIDENCE

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

ORCATECH
SENSING LIFE KINETICS

OREGON HEALTH & SCIENCE UNIVERSITY

Slide Credit: Jeff Kaye

CART

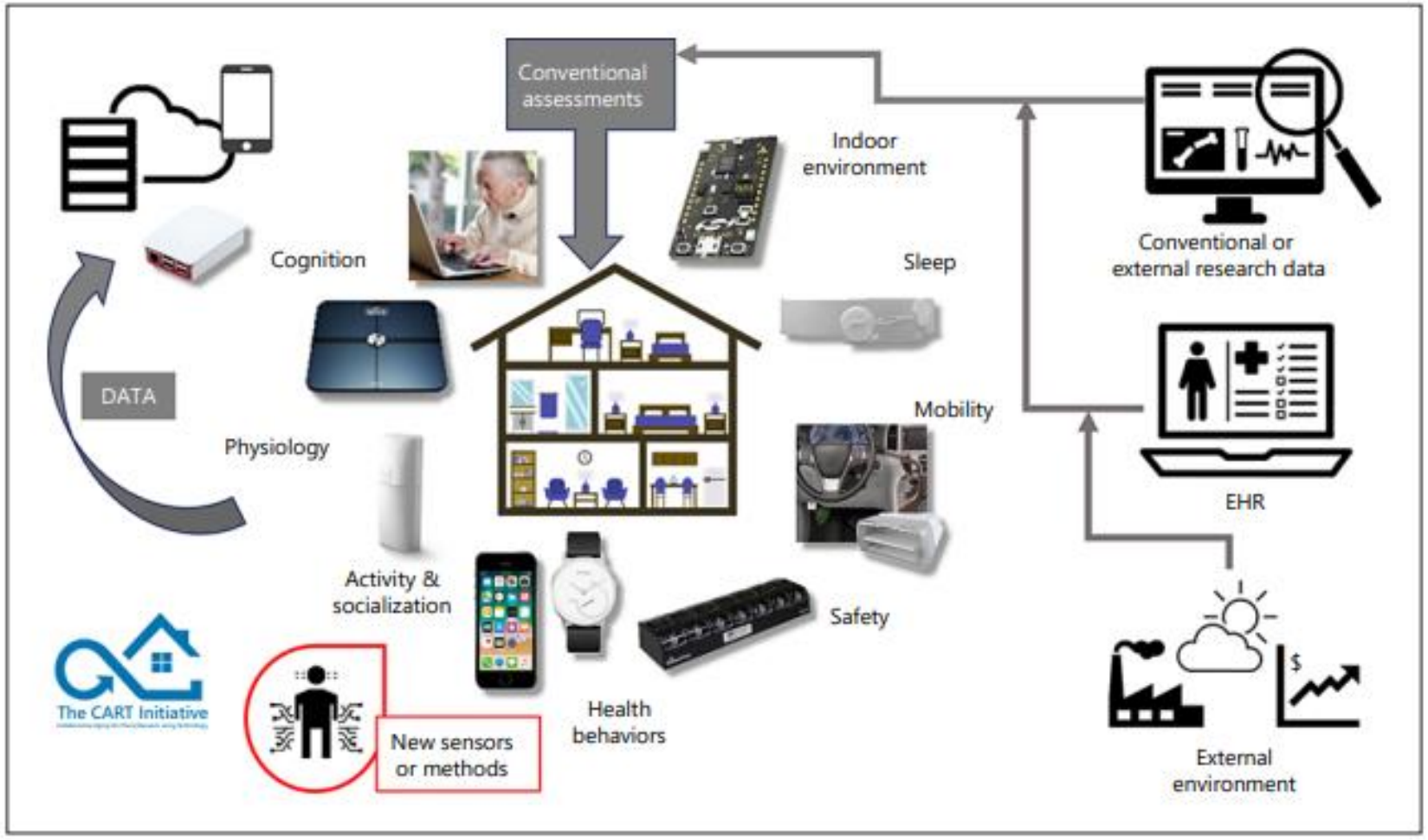


Fig. 2. Overview of sensors, devices, and data streams that can be integrated into the CART platform to monitor several health and wellness domains. CART, Collaborative Aging Research Using Technology; EHR, electronic health record.

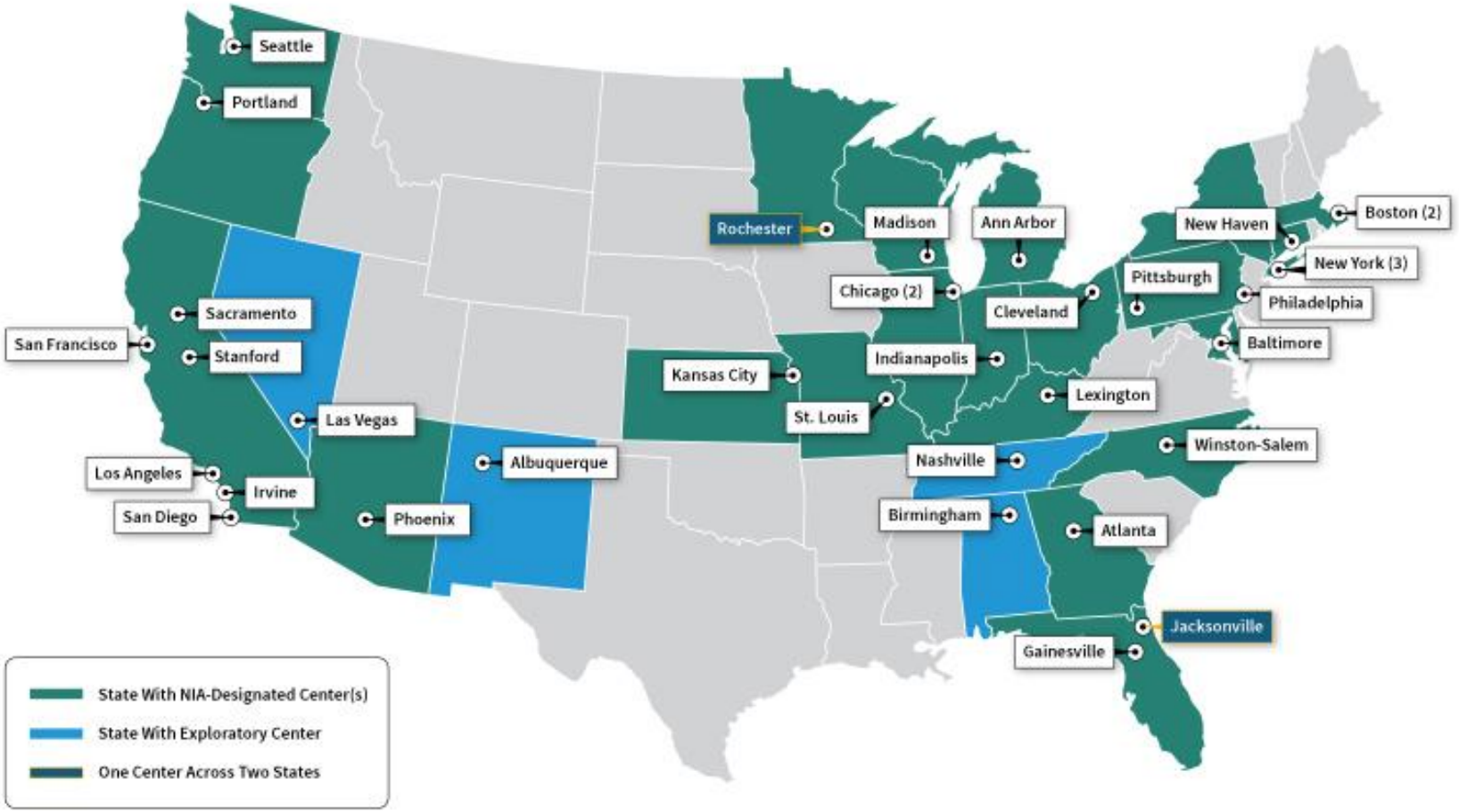
carthome.org

Connecting with technology partners from an academic lens

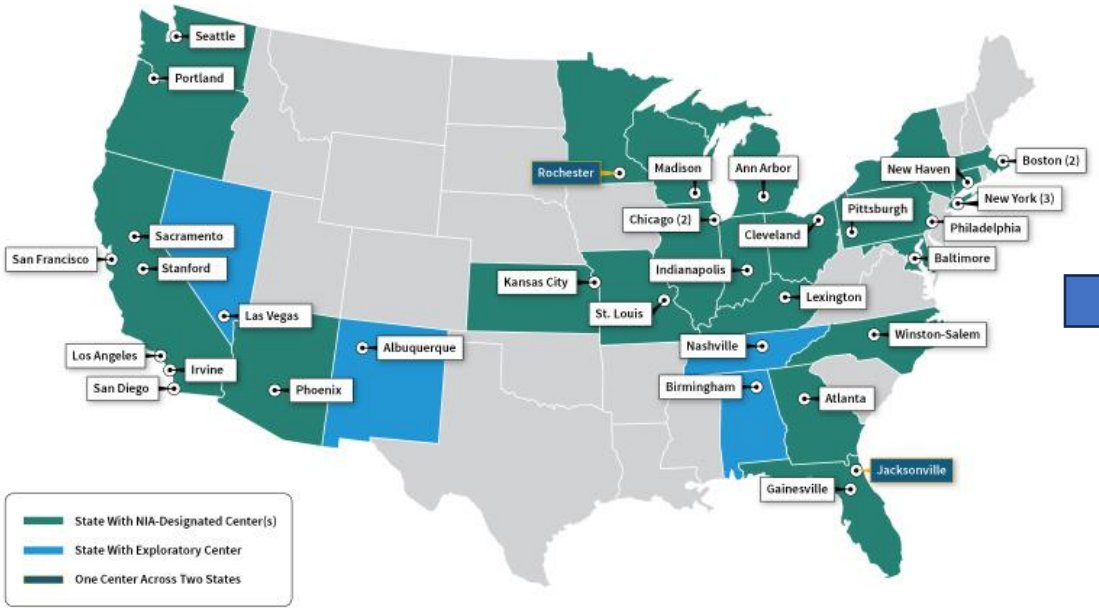
Rhoda Au, PhD, MBA (Boston University)

Our Scientific Dream

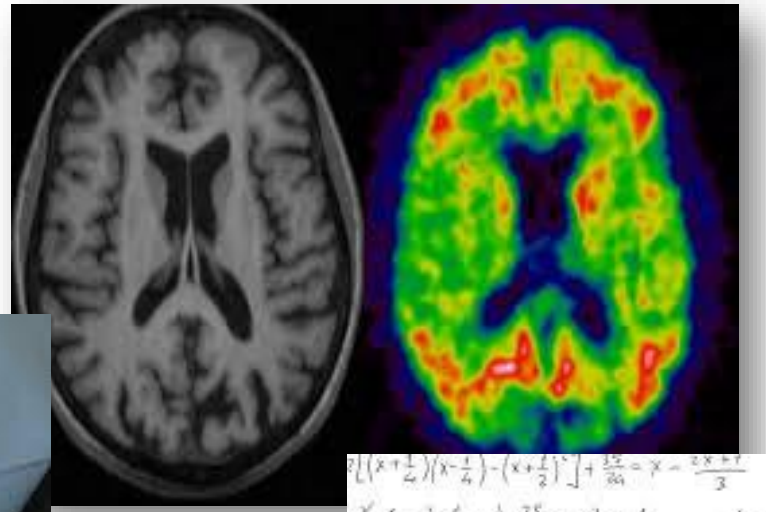
Our Scientific Instructure

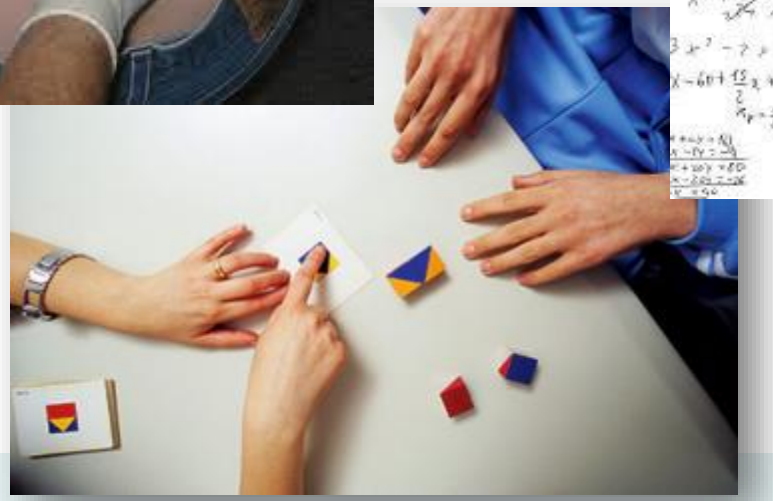


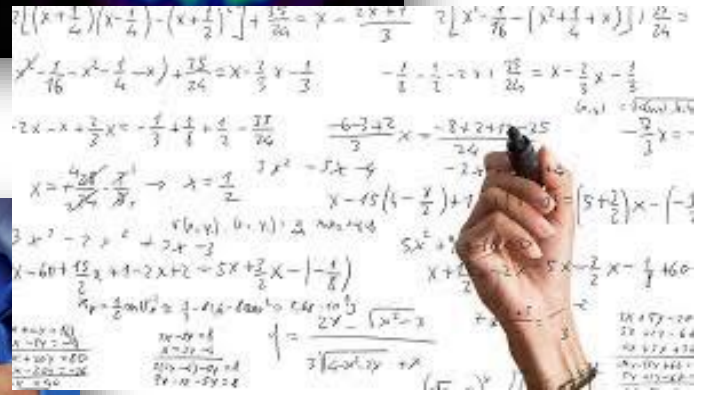
Our Research Objective

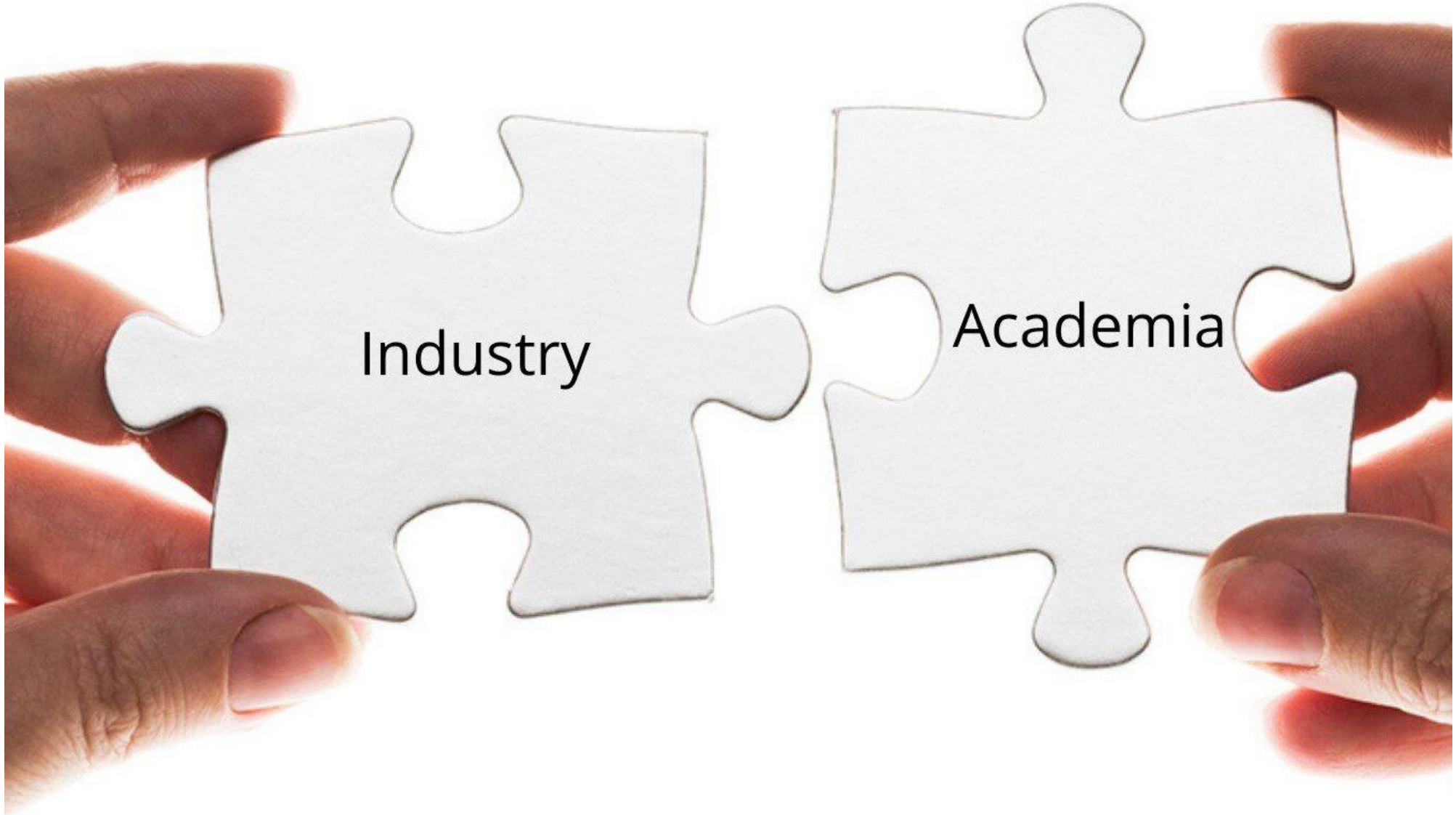


Can’t Get There From Here





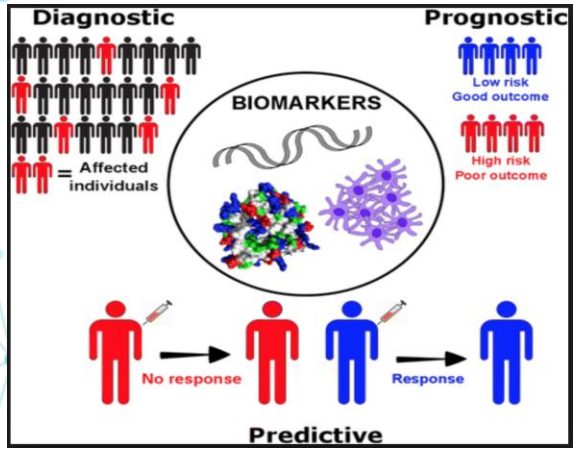


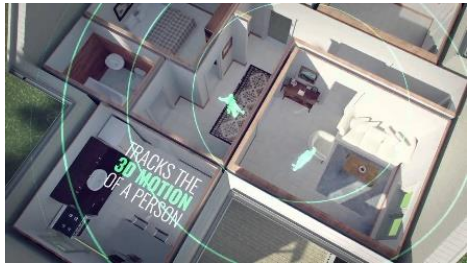

Industry
Academia

Establishing Successful Academic-Industry Collaborations

Clearly Define Strategic Objectives

Digital Biomarker Discovery

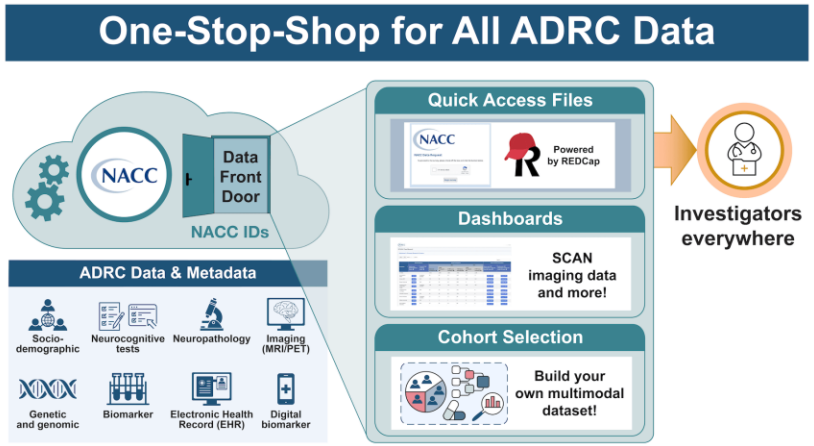




Shift to Ambient Monitoring

Achieve Representativeness

Broad Data Sharing



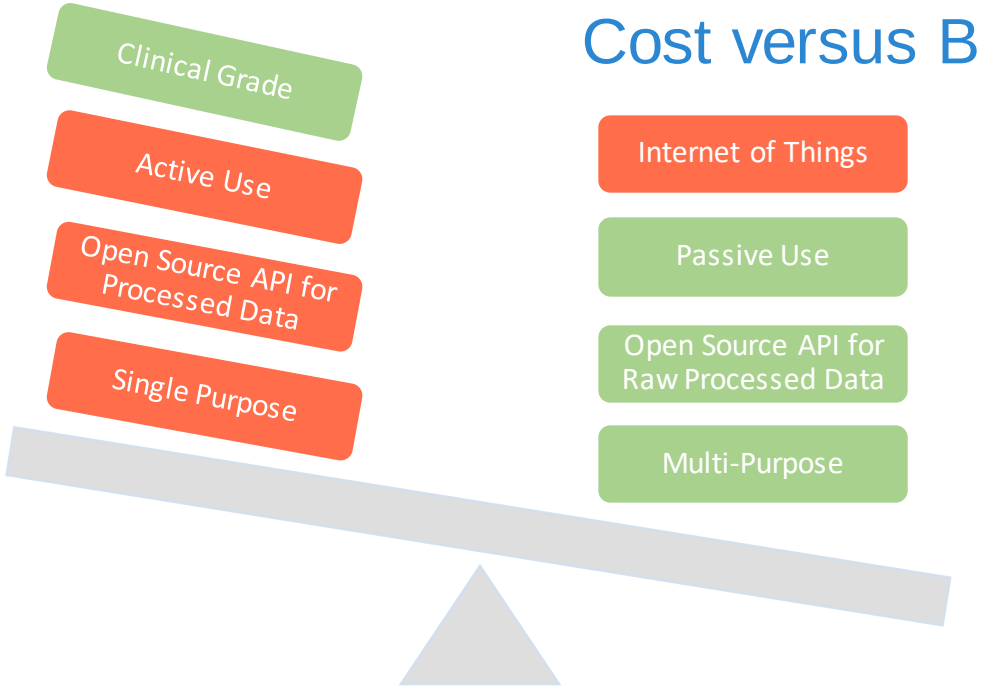
Proactively Seek Researcher Diversity

https://www.youtube.com/watch?v=gLQC0gMrSoo

Clearly Define Decision Criteria

Secure

Cost vs Reach



Cost versus Benefit

Internet of Things

Passive Use

Open Source API for Raw Processed Data

Multi-Purpose

Raw Digital Data for Future Proofing

What's In it For Everyone

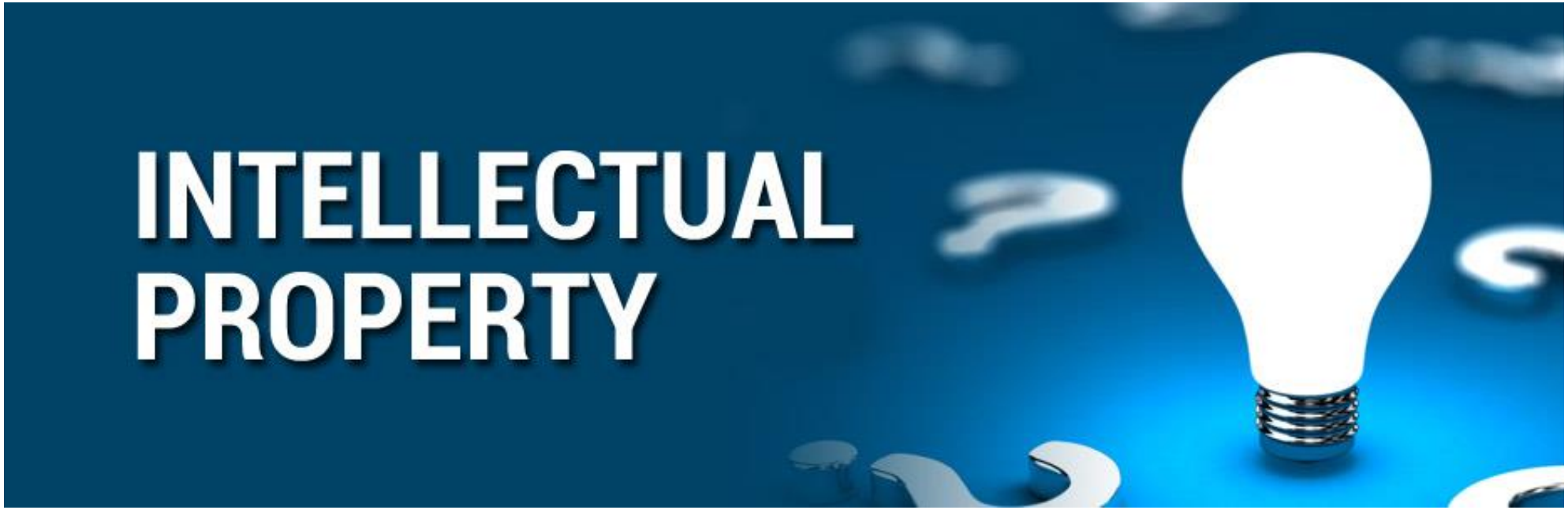
Value Proposition

User/Participant	Researcher	Business
• Health measures of personal interest • Personalized device mix • Confidentiality needs met	• Reliable e-health data collection platform • New study design/methods • Quality data to develop novel analytic approaches • New tech screening & validation studies	• Market ready health products/services • New business spin-offs • Tech validation process to de-risk e-health investments

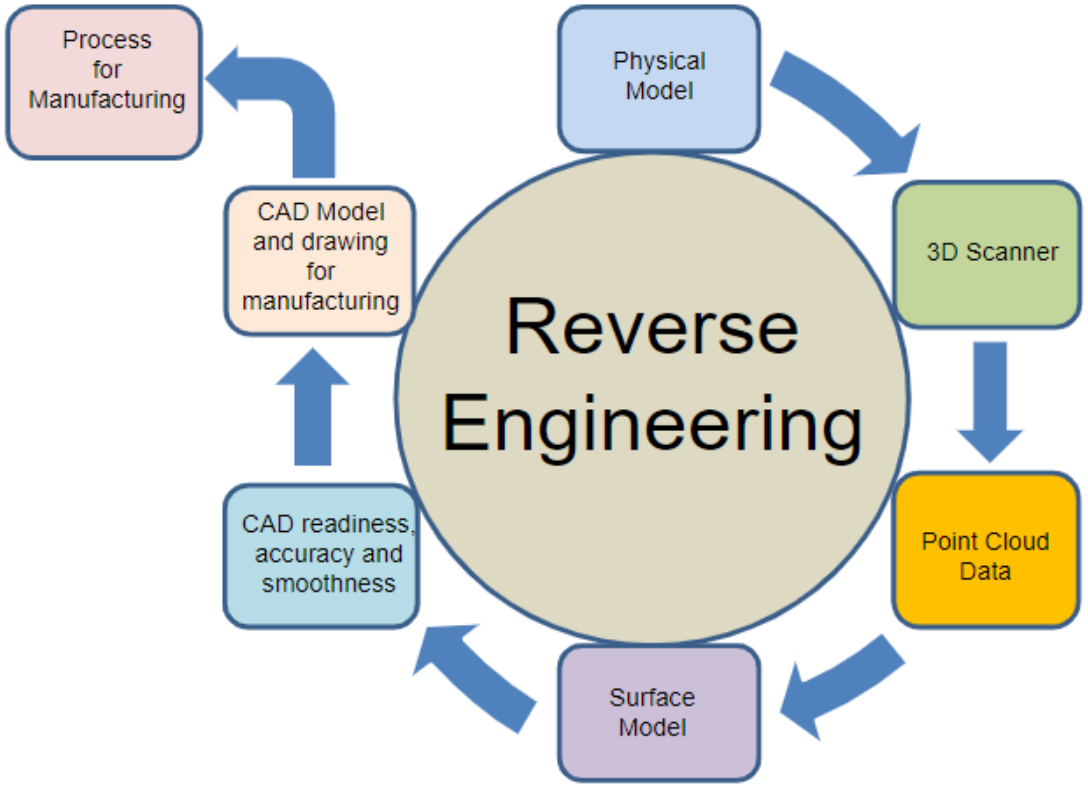
Barriers to Academic-Industry Collaborations

The Evil Empire

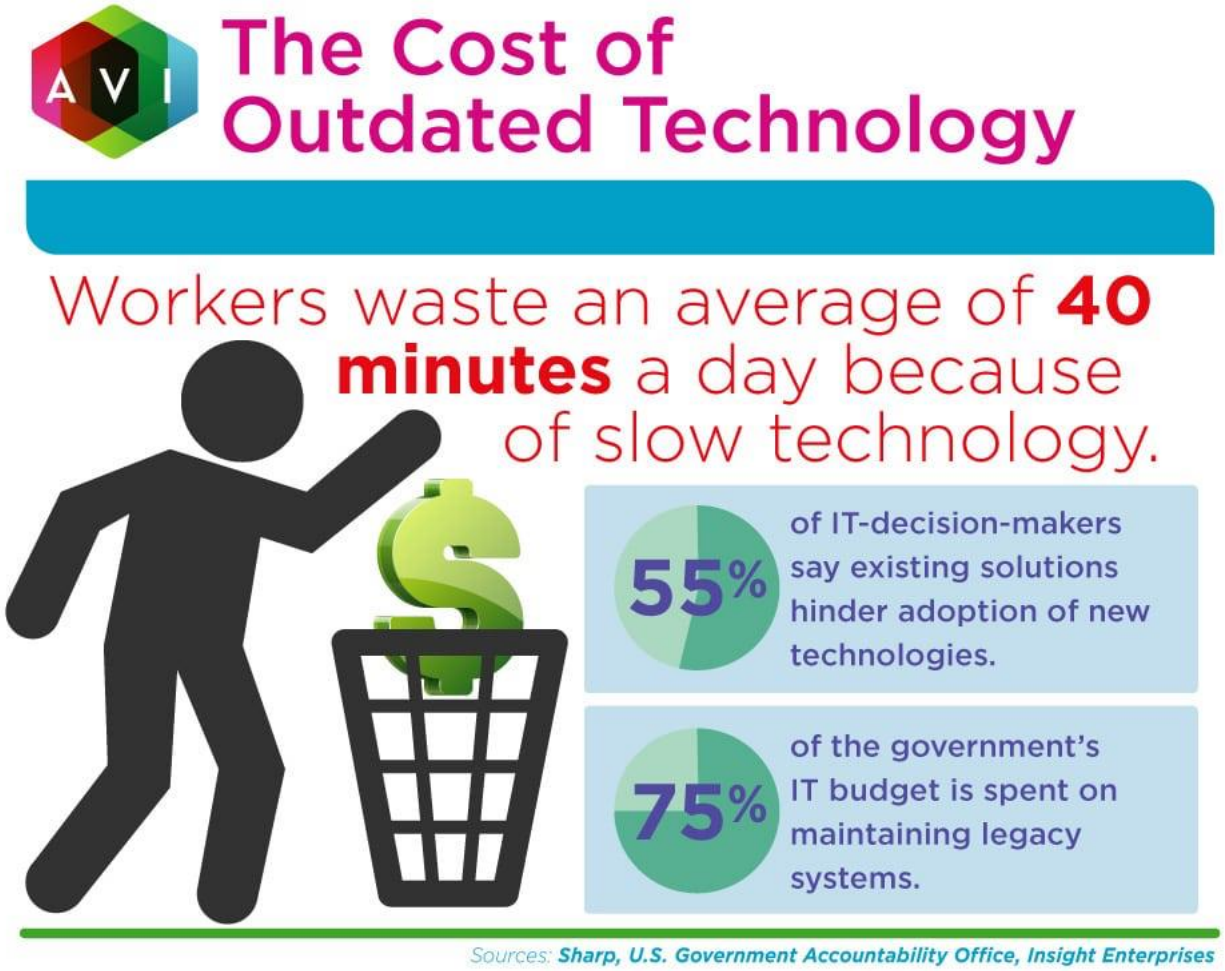
Who Owns What



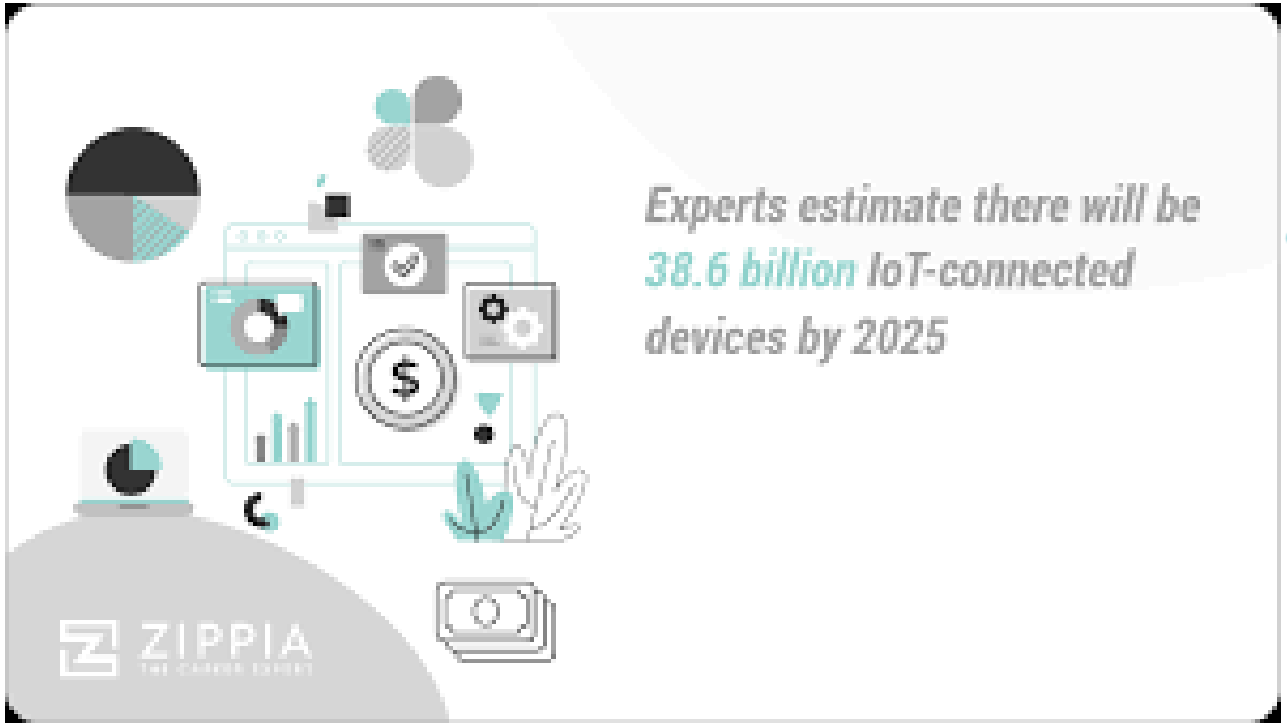
Protection of Proprietary Information



Versioning Lifecycle

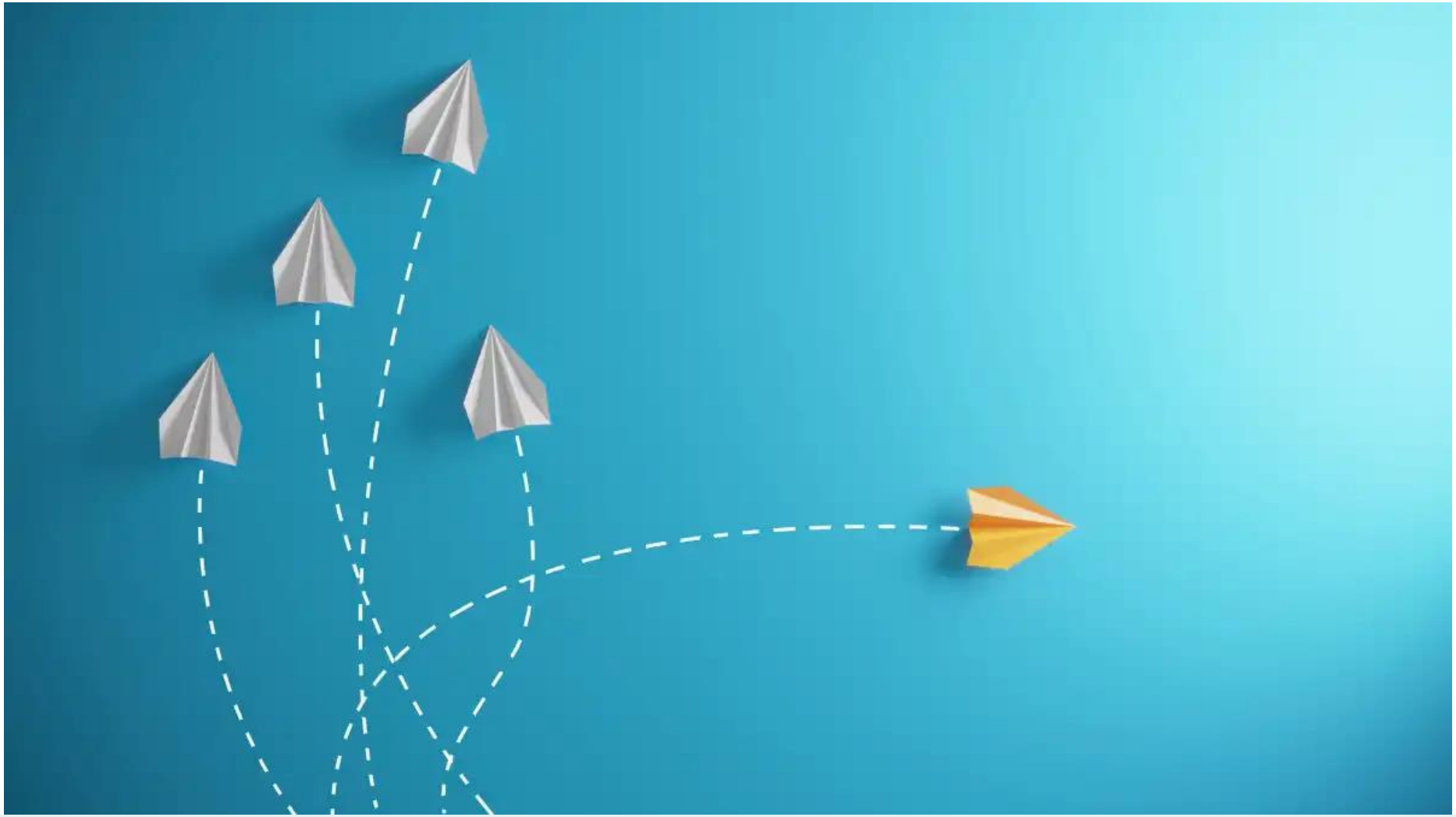


Obsolescence



Data Harmonization

Market Forces



Change in Leadership

GET ACQUIRED


OUT OF
BUSINESS

A Prepared Partnership

THANK YOU!

NACC and Digital Pilot Program Overview

Sarah Biber, PhD (NACC)

NACC

THE NIA ALZHEIMER'S DISEASE RESEARCH CENTERS PROGRAM

National Alzheimer's Coordinating Center

NACC serves as the data coordination hub and centralized data repository for NIA's ADRC Program

National Institute on Aging (NIA)
Alzheimer's Disease Research Center Program

Penn Memory Center, University of Pennsylvania Health System
KU Alzheimer's Disease Center, The University of Kansas Medical Center
Massachusetts Alzheimer's Disease Research Center
Mayo Clinic
Icahn School of Medicine at Mount Sinai
Arizona Alzheimer's Consortium
Alzheimer's Disease Research Center
Yale School of Medicine
Wake Forest University School of Medicine
Rush University
Stanford Medicine, Stanford Alzheimer's Disease Research Center, Principal funding from the NIH / National Institute on Aging
UCI MIND
UC San Diego, Department of Neurosciences
UT Health San Antonio
Cleveland Alzheimer's Disease Research Center
Emory University, Goizueta Alzheimer's Disease Research Center
Vanderbilt Memory & Alzheimer's Center
UC Davis Health, Alzheimer's Disease Research Center
OHSU, Layton Aging and Alzheimer's Disease Research Center
School of Medicine, Indiana Alzheimer's Disease Research Center
Cleveland Clinic, Cleveland Clinic Nevada
UCSF Weill Institute for Neurosciences, Memory and Aging Center
Columbia, Taub Institute for Research on Alzheimer's Disease and the Aging Brain
Johns Hopkins School of Medicine, Alzheimer's Disease Research Center
University of Pittsburgh, Alzheimer's Disease Research Center
1Florida ADRC
BU Research, Alzheimer's Disease Research Center
UNM Health
Northwestern Medicine, Feinberg School of Medicine
Sanders-Brown Center on Aging
NYU Langone Health
USC University of Southern California ADRC, Alzheimer Disease Research Center
Michigan ADRC, Alzheimer's Disease Research Center
Washington University School of Medicine in St. Louis, Department of Neurology, Knight Alzheimer Disease Research Center
UAB The University of Alabama at Birmingham, Alzheimer's Disease Center, Heersink School of Medicine
University of Washington ADRC, Alzheimer's Disease Research Center

State with NIA-Designated Center(s)

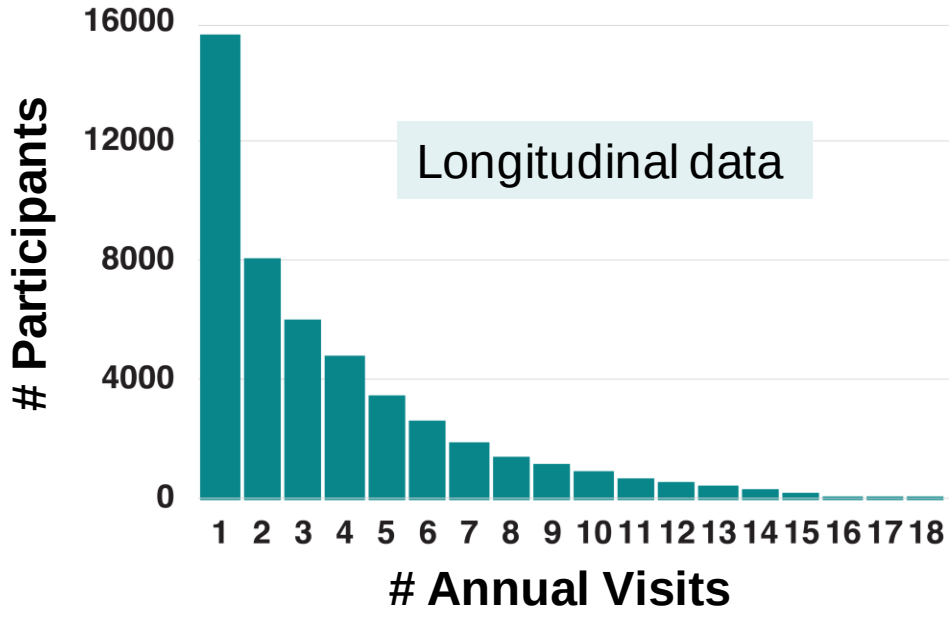
State with Exploratory Center

NACC

UNIVERSITY of WASHINGTON

Independent ADRCs collect standardized longitudinal data

- Centers enroll research participants who are **healthy, at risk,** and **with dementia symptoms**
- Centers collect standardized longitudinal data through annual visits using tools co-developed and provided by NACC



NACC collects, harmonizes, integrates, and shares ADRC data

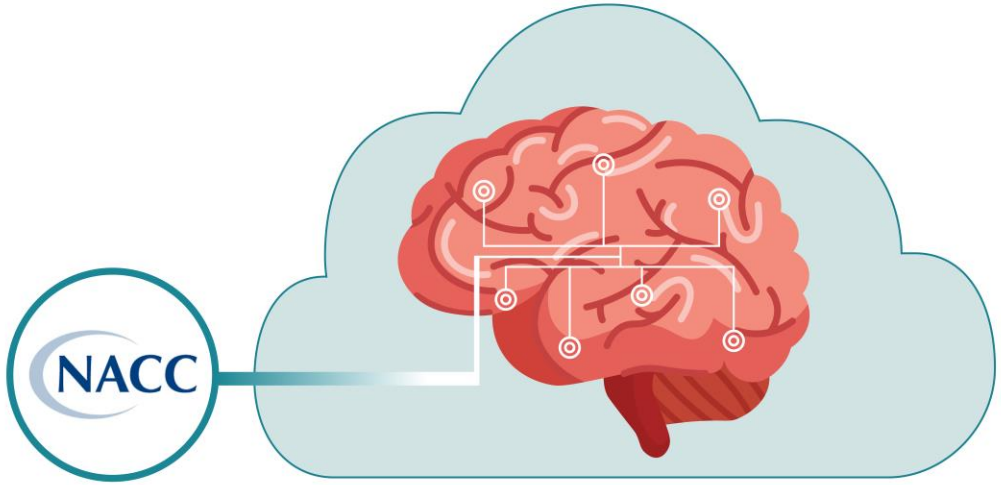
- NACC has been collecting, harmonizing, integrating, and sharing ADRC Data for 23+ years

Uniform Data Set Impact

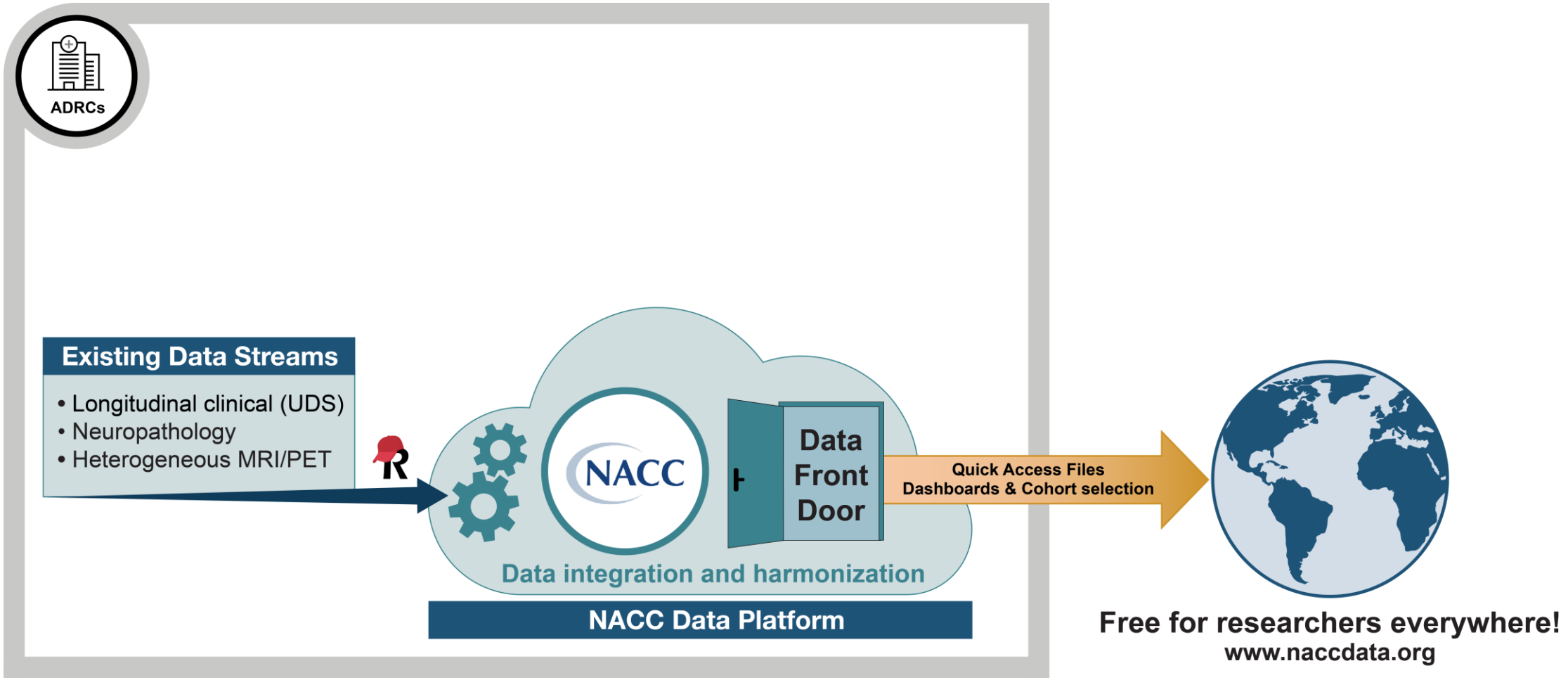
48,605+	Participants with data at NACC (17,000+ active participants)
180,004+	Clinical assessments (1-18 visits per participant; median =3)
7,565+	Neuropathology datasets (From 58% of deceased participants)
1,184+	Published studies using NACC data
33	ADRCs and 4 Exploratory Centers (Across 26 states)

Unique Value of NACC Data

- One of the largest and most comprehensive longitudinal, standardized, clinical and neuropathological datasets in the world
  - Includes participants with normal cognition, MCI, and dementia
  - Data captured for participants prior to and post dementia onset
  - Infrastructure in place for ongoing participant tracking
  - Robust criteria-based diagnoses
- Rich multi-domain neurocognitive data
- Neuropathology data for diverse etiologies



NACC Data Platform: A Modern Cloud-based Multimodal Data Integration and Harmonization Platform



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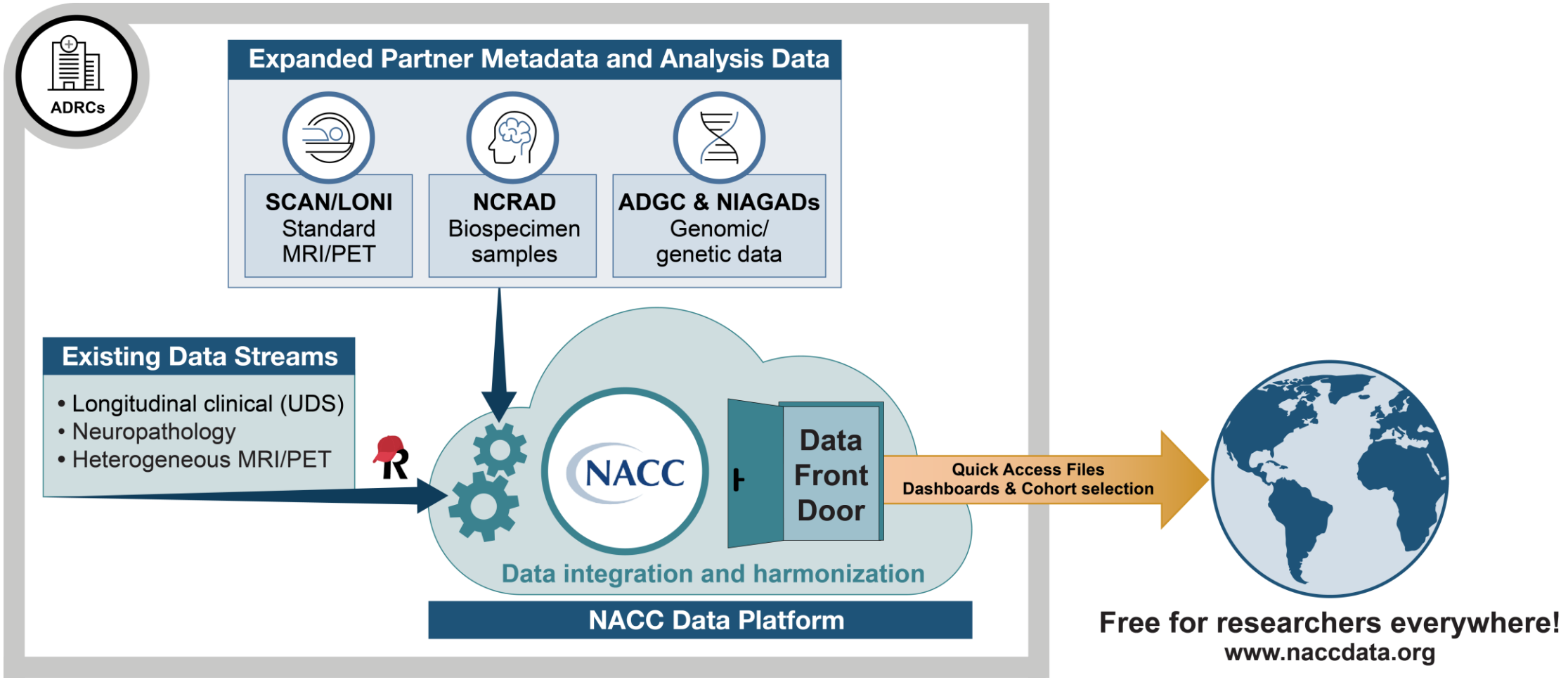

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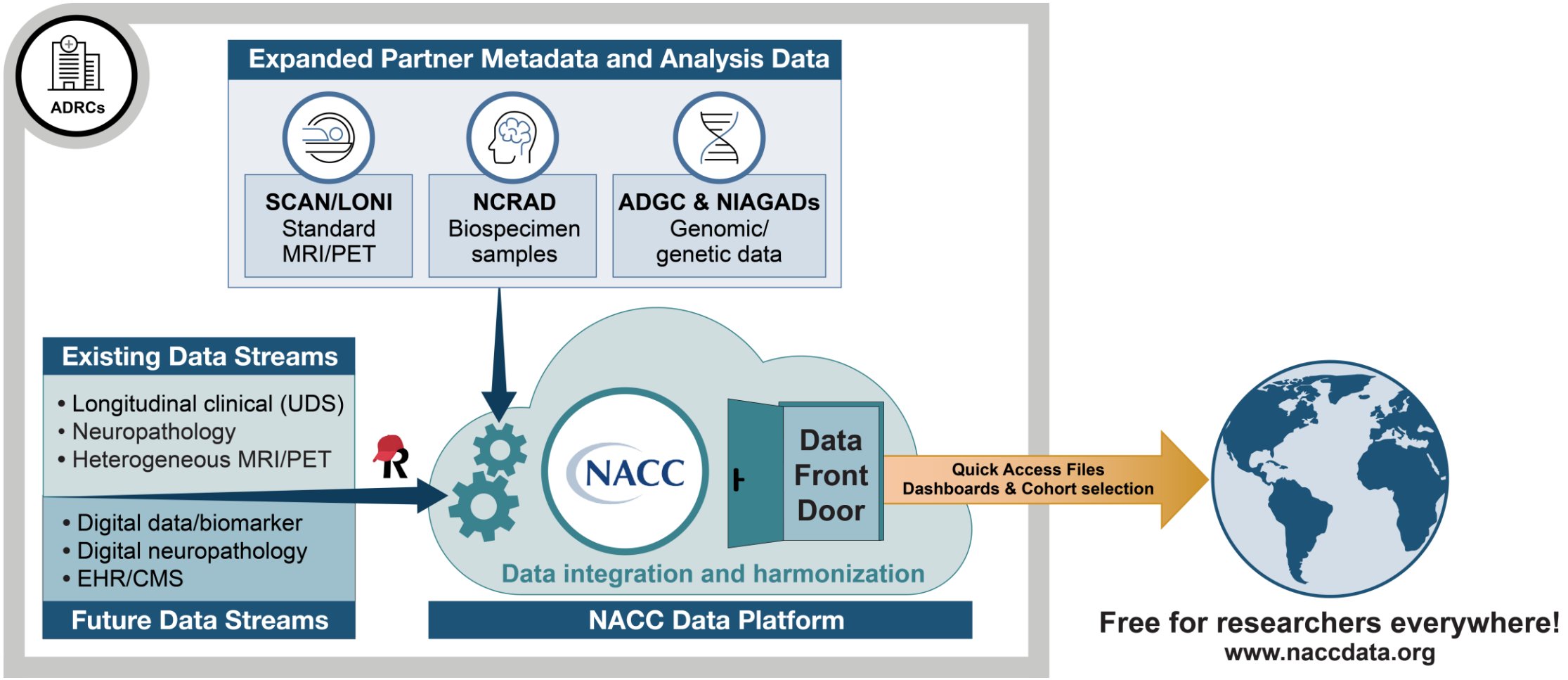

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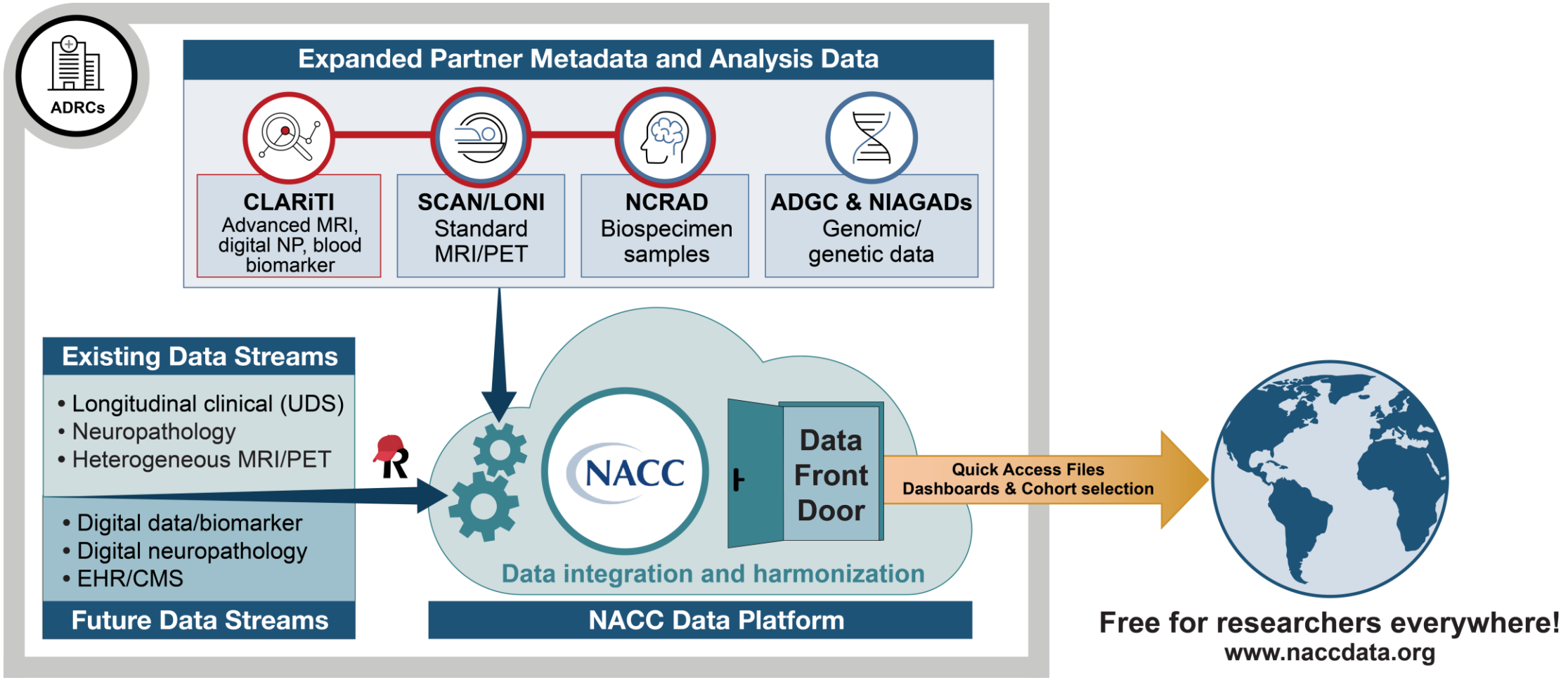

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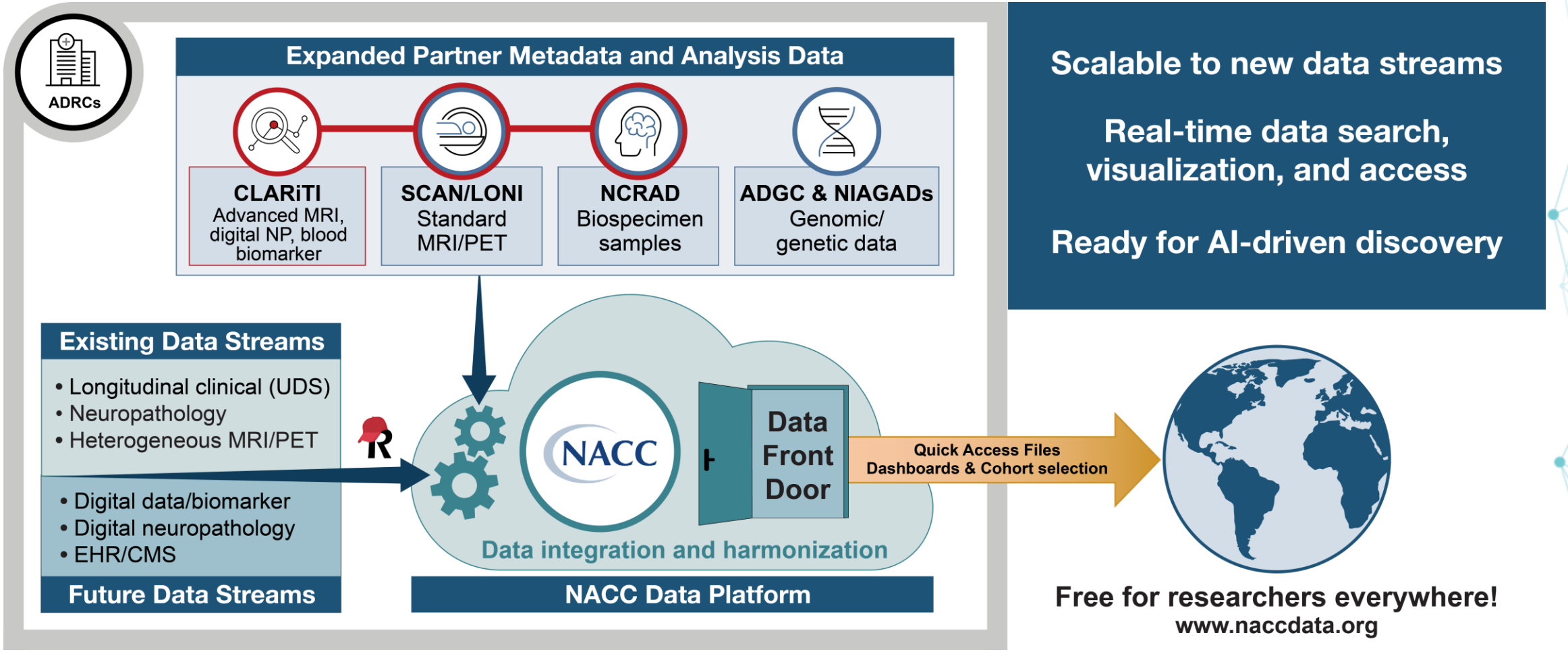
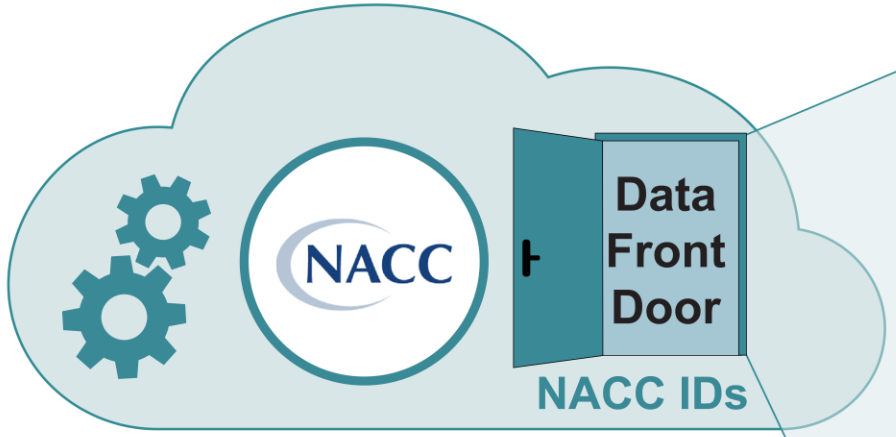


Data Front Door - Advanced Data Search and Access

One-Stop-Shop for All ADRC Data



ADRC Data & Metadata Modalities

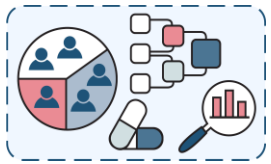
- Socio-demographic
- Neurocognitive tests
- Neuropathology
- Imaging (MRI/PET)
- Genetic and genomic
- Biomarker
- Electronic Health Record (EHR)
- Digital biomarker

Quick Access Files

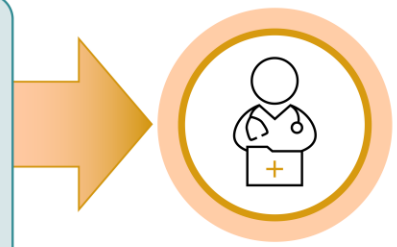
Dashboards

SCAN imaging data and more!

Cohort Selection



Build your own multimodal dataset!



Investigators everywhere

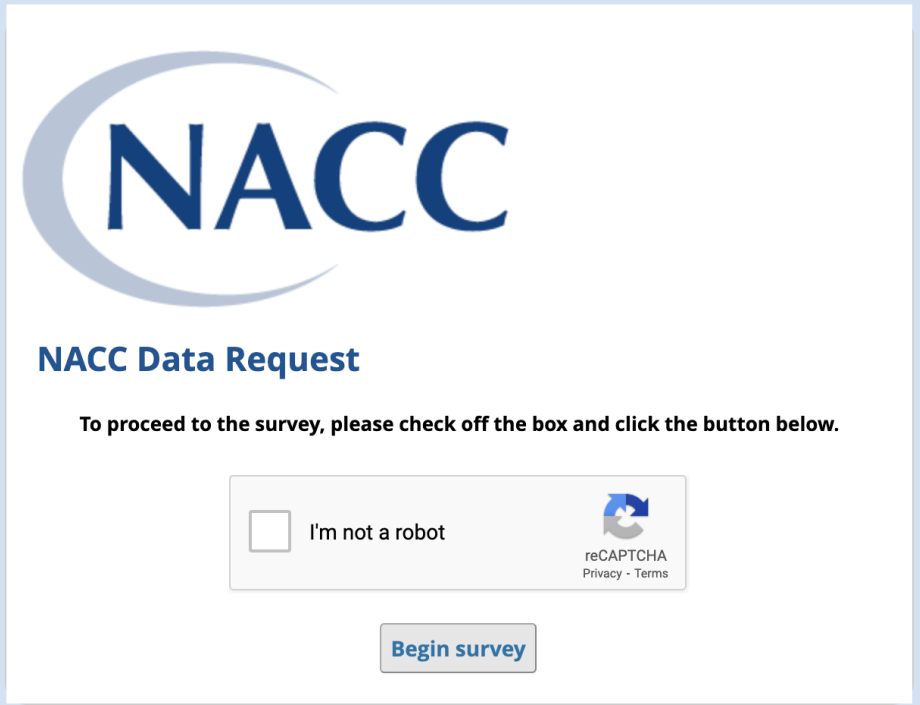
NACC Data Request System: Quick Access File

Submit a data request (15 min)

Step 1. Sign a Data Use Agreement and submit a title with specific aims.

Step 2. NACC reviews request.

Step 3. Approved requests typically receive datasets in 48 hours.



Login into the existing data request system:
https://naccdata.org/requesting-data/data-request-process

Why Digital Data?

Digital Data Opportunities

Enormous unmet need in AD/ADRD research for high-resolution, high-value, and objective measures that can be captured frequently over time

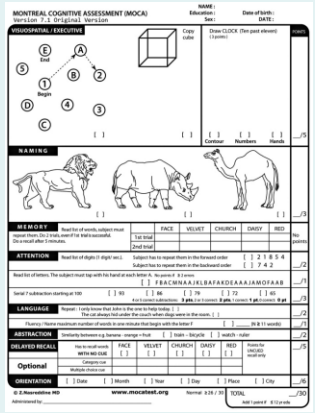
Digital measures/tools hold promise for:

- Supporting earlier detection/diagnosis
- Defining disease phenotypes
- Predicting prognosis
- Monitoring disease progression and treatments (longitudinal)
- Reducing participant burden (passive collection)
- Optimizing clinical trials

Digital Data and Phenotyping

Clinically meaningful data collected through digital technologies (active or passive)

Clinically Administered



MOCA, Balance and Gait

Remotely Administered

Remote Cognitive Assessments

Out of Clinic Collection

Heart Rate, Mobility, Gait, Steps, Accidental Falls, Sleep, Cognitive Testing, Home Monitoring

Overview

Digital data collection covers a lot of concepts and is very heterogenous

Many are collecting data and there are few, if any, standards or standardization

Slide borrowed from Sean Mooney

Bringing Some Harmonization

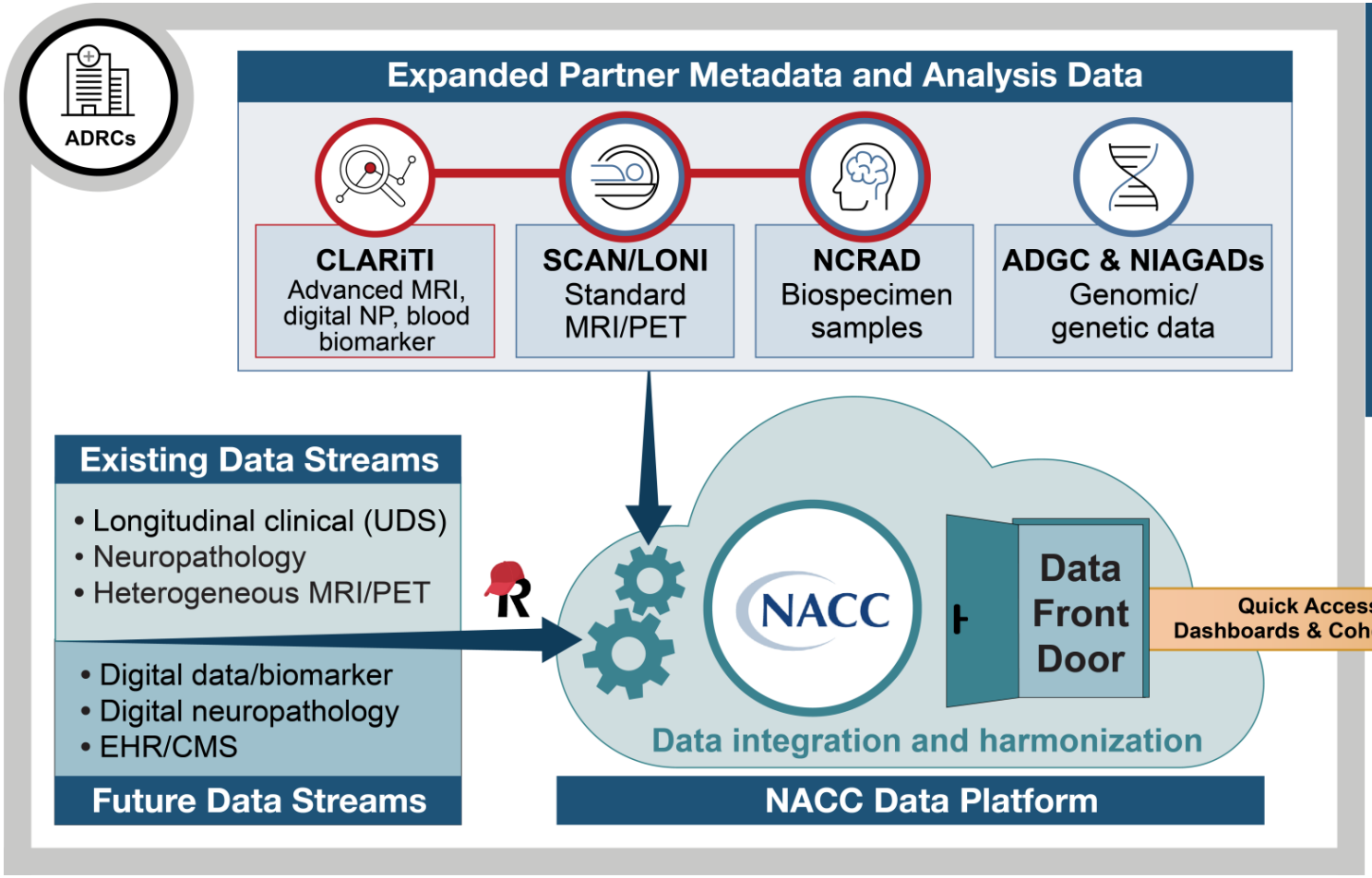
At NACC, we feel that we should help standardize, harmonize, ensure efficacy, and collect established instruments

… And …

Facilitate discovery using new technologies that have research and clinical value that are very likely to be unharmonized

Digital Data Collection, Integration, and Sharing

NACC Data Platform: A Modern Cloud-based Multimodal Data Integration and Harmonization Platform



Scalable to new data streams

Real-time data search, visualization, and access

Ready for AI-driven discovery

Free for researchers everywhere!
www.naccdata.org

Digital Tools Enable AI-Based Decision Support

Human interpretation takes time, is variable, and could potentially be replaced by supervised machine learning algorithms

Ultimate Goal

Standardized and clinically-validated digital biomarkers for AD/ADRD

These will:

- Support earlier diagnosis
- Define disease phenotypes
- Predict prognosis
- Monitor disease progression and treatments (longitudinal)
- Optimize clinical trials

Gates/NACC Digital Pilot Program

AD/ADRD Digital Biomarker Pilot Program

- **Goals:**
  - Accelerate impactful digital data collection and sharing across the ADRC Program to advance AD/ADRD research and discovery
  - Leverage technology to capture richer and more objective data with less burden for participants and ADRCs
  - Advance the development and/or validation of digital biomarkers for early detection, diagnosis, prognosis, or monitoring.
- **Budget:** 1-3 pilots ranging from $250K to $1M (direct costs), 15% indirect cap
- **Pilot length:** 1-2 years

AD/ADRD Digital Biomarker Pilot Program

- **Goals:**
  - Accelerate impactful digital data collection and sharing across the ADRC Program to advance AD/ADRD research and discovery
  - Leverage technology to capture richer and more objective data with less burden for participants and ADRCs
  - Advance the development and/or validation of digital biomarkers for early detection, diagnosis, prognosis, or monitoring.
- **Budget:** 1-3 pilots ranging from $250K to $1M (direct costs), 15% indirect cap
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Gates Ventures NACC

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**Instruments can be from a variety of sources and offered in kind*

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- **Review Committee:** Expertise in scalable digital technologies from across academia, industry, and government

AD/ADRD Digital Biomarker Pilot Program

Pilot Requirements:

- Adds research value and enhances metrics
- Reduces burden (participant or staff)
- Expands accessibility/reach and addresses diversity
- Involves multiple ADRCs
- Demonstrates scalability (ADRCs and beyond)
- Amenable to a data challenge down the line
- Partnering companies must provide the raw digital files to NACC

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- **April 2024:** Select 1-3 winners
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Potential Follow-Up Support :

- Funded Data Challenge using data collected from the pilot
- Promising digital pilots may be scaled to the full ADRC Program via NACC's U24 renewal
- NIA SBIR/STTR
- AD Diagnostic Accelerator

NIA Small Business Programs (SBIR & STTR)

Non-dilutive Funding for Healthy Aging Innovations

https://www.nia.nih.gov/research/sbir

Alzheimer's Drug Discovery Foundation

https://www.alzdiscovery.org/research-and-grants/diagnostics-accelerator

AD/ADRD Digital Biomarker Pilot Program

Proposals will be scored based on the following selection criteria:

1. **Significance:**
   - How does the proposed digital data collection contribute critical data needed in the Alzheimer's Disease field?
   - Is the team addressing a real problem/need in AD/ADRD research or healthcare?

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2. **Innovation/Impact:**
   - Does the proposal demonstrate how this data will open the door to better early detection/diagnosis, phenotypes, predicting prognosis, monitoring disease progression and/or treatment (longitudinal), and optimizing clinical trials in AD/ADRD?
   - Could this project lead to the development of a validated digital biomarker (biomarkers can include diagnostic, monitoring, predictive, prognostic, and susceptibility/risk factors) in research and clinical settings?

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5. **Accessibility and Equity:**
   - Does this project enable AD/ADRD research and discovery to be more inclusive?

Q&A Session

Informational Webinar | January 22, 2024

Gates Ventures

NACC

NIH National Institute on Aging (NIA)
Alzheimer's Disease Research Center Program

FAQs

- **Are applicants' budgets held to the NIH salary cap?**
  - As this grant is not funded by NIH, there is no requirement to adhere to the NIH salary caps.
- **Are non-US based companies eligible for funding?**
  - Yes! Non-US companies are eligible for funding as long as they have at least two Alzheimer's Disease Research Center (ADRC) Program collaborators.
  - All data generated or used in each pilot project must be made accessible to the research community through the National Alzheimer's Coordinating Center (NACC) Data Platform.
- **Are sites under the requirement to adhere to the single-site IRB?**
  - There is no requirement to adhere to the single-site IRB – IRB requirements are met so long as each site is clear to collect the data described in the proposal and share this data with NACC.
- **Can the institutions involved in an application submit the budgets separately for the proposal?**
  - Each of the four institutions as well as any technology partners on your application can submit a separated budget for your application. NACC would then setup subawards for each institution to maximize the amount of funding that goes towards the actual research.

FAQs available at:

FAQs

- **Are postdocs eligible to be the PI on the application?**
  - If the PI on the application is a postdoc, most institutions will ask for a faculty sponsor when they submit and go through their internal approval process.
  - If that is the case for your institution and your proposal is awarded funding, that award may need to be listed under the faculty sponsor's name.
- **The requirements for the RFA state that "industry partnerships are strongly encouraged" - should we interpret this statement to mean that we should not apply for the program if we are not currently partnered with a wearable device company?**
  - This statement is meant to encourage those applying to have a strong plan for how their pilot proposal will be implemented across several piloting sites. An industry partnership or plan that supports this would make for a stronger application.
- **Are there any system requirements for sharing data in NACC's cloud?**
  - NACCID must be affiliated with data
  - Documentation on datatype, metadata descriptors, etc.
  - Tooling & code necessary for QC/processing of data
  - All data generated or used in each pilot project must be made accessible to the research community through the National Alzheimer's Coordinating Center (NACC) Data Platform.

FAQs available at:

bit.ly/DGP_Awards

Q&A Format

1. Please raise your hand and the moderator will call on you to ask your question
2. You may also add your question to the Q&A box at the bottom of the screen
3. If we do not get to your question, please reach out to naccmail@uw.edu

Panelists:

- **Niranjan Bose, PhD –** Gates Ventures, Managing Director
- **Nina Silverberg, PhD –** NIA, ADRC Program Director
- **Rhoda Au, PhD, MBA –** Boston University, Professor
- **Sarah Biber, PhD –** NACC, Executive Director

Thank you!

Learn more at:

bit.ly/DGP_Awards

Connect with NACC

Have questions?

Contact us at:
NACCmail@uw.edu

NACC | UNIVERSITY of WASHINGTON

Digital Biomarker Pilot: RFA Eligibility

Funding is open to researchers and clinicians worldwide at:

- Academic institutions or nonprofits
- For profit companies; existing companies and new spinouts are both eligible
- Industry partnerships are strongly encouraged

NOTE: Pilot Principal Investigators can come from any institution, but proposal submitters must have multiple (two or more) ADRC collaborators to be considered for funding.

Digital Biomarker Pilot: RFA Modalities and Tools

Example modalities or data sources include but are not limited to: *(Examples of clinical measures of interest in parenthesis)*

- **Sleep** *(e.g. biological measures such as heart rate, time sleeping, sleep interruptions, body temperature, etc.)*
- **Movement and/or Phone gyroscope measures** *(e.g. gait measures and disorders, motor and physical functioning)*
- **Fall detection** *(e.g. motor and physical functioning)*
- **Mood State**
- **Speech** *(e.g. cognition, mood state)*
- **Video** *(e.g. movement characteristics, cognition, mood state)*
- **Language** *(e.g. cognition, mood state)*
- **Eye tracking** *(e.g. eye movement characteristics)*
- **Digitized UDS (Uniform Data Set) and non-UDS**
- **Diet** *(e.g. biological measures, cognition, mood state)*
- **Driving** *(e.g. cognition, motor and physical functioning)*
- **Keystrokes** *(e.g. cognition, motor and physical functioning)*

Examples of digital tools include, but are not limited to:

- Wearable devices (e.g. smart watch)
- Single and/or Multi-sensors
- Mobile/tablet apps
- Smart home systems
- Virtual and augmented reality platforms
- Desktop/web apps
- Deep machine learning-AI-driven Algorithms
- Single Digital Modality Processing Software
- Multi-Digital Modality Processing Software
- Large Language Models

Digital Biomarker Pilot: RFA Requirements

The proposed pilot project should:

- Add research value and increase accuracy and/or objectivity of measures
- Reduce burden: projects must demonstrate how they will reduce burden on patients and/or providers and medical center staff
- Expand and address diversity
- Involve multiple ADRCs
- Demonstrate scalability
- Be amenable to open science experiments that include broad data sharing (such as data challenges) down the line
- Funded projects, including for-profit companies, must agree to broad, raw, data sharing.

Data sharing: All data generated or used in each pilot project must be made accessible to the research community through the National Alzheimer's Coordinating Center (NACC) Data Platform.

Open Science on Digital Data

Data Science 'Community Challenges' are a popular way to do science

They pose questions that data scientists can answer and the answers are only known by the organizers

These challenges have facilitated unbiased improvement in machine learning in many fields

My group (Mooney) has been leading, participating, and advising these challenges for decades

DREAM CHALLENGES
powered by Sage Bionetworks

Open Science on Digital Data

Collection of digital data opens the possibility of doing new approaches to facilitate open science

DREAM Challenges and Kaggle, have platforms for building and evaluating machine learning

We are strategizing a potential challenge around data on the most technical forefront of potential markers of disease or treatment response such as Digital Recordings of clinics