CRA-I
Computing Research Association
Industry

Sharing Healthcare Data

Washington, DC
October 17-18, 2024

CRA
Computing Research Association

CRA 101

Uniting industry, academia, and government to advance computing research and change the world.

Tracy Camp

Emeritus Professor
Colorado School of Mines

CS@Mines

CRA Computing Association

Board

Co-Chair

CRA-WP
Computing Research Association
Widening Participation

Generation CS:
Computer Science Undergraduate Enrollments Surge Since 2006

Executive Director and CEO
Computing Research Association

What we do

Our **mission** is to catalyze computing research by joining with industry, government, and academia.

- **Lead** the computing research community
- **Inform** policymakers and the public
- **Champion** a diverse, welcoming, equitable, and socially responsible computing research community

CRA

Computing Research Association

Who we are

Our membership spans nearly **300** institutions across industry, government, and academia

Who we are

Industry, Lab, and Center Members

Platinum and Gold

Silver and Bronze

CRA Programmatic Committees

CCC
Computing Community Consortium
Catalyst

CRA-E
Computing Research Association
Education

CRA-I
Computing Research Association
Industry

CERP
Computing Research Association
Evaluation

CRA-WP
Computing Research Association
Widening Participation

CRA
Computing Research Association
Government Affairs

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Government Affairs

CCC

Envision and enable the pursuit of computing research that aligns with national and global challenges

Visioning Workshops and Reports

Help shape the future of computing research

Workshops develop new research visions, spark community interest, and build support.

Cover diverse topics and are held throughout the year.

CCC
Computing Community Consortium
Catalyst

cra.org/ccc/visioning

To do: Propose a CCC visioning workshop!

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Government Affairs

CERP

Increase diversity in computing research through data, evaluation, and community engagement

Develop/Deploy/Analyze Community Surveys

Survey of industry professionals to provide feedback to universities to keep computing curricula up to date.

To do: Complete the P2P survey!

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Computing Research Association

CRA Programmatic Committees

CRA-E

Ensure a continuous supply of computing researchers

CSGrad4US Fellowship Program

The CSGrad4US Mentoring Program supports and mentors recipients of the NSF CSGrad4US Graduate Fellowship returning to graduate school for a PhD in computing

https://cra.org/csgrad4us/

To do: Share CSGrad4US with those interested in earning a PhD!

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CRA-WP

Increase the success and participation of populations minoritized in computing research

Early and Mid-Career Mentoring Workshops

Tailored career guidance for researchers minoritized in computing

- Spans academia, industry, and government labs
- Tracks for those with less than and more than five years of experience

To do: Consider who on your team might benefit from this PD!

CRA-WP
Computing Research Association
Widening Participation

2024 Virtual Workshops

Taking place weekly on Fridays

October 11 - November 15

cra.org/cra-wp/mentoring-workshop

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CRA-I

Convene industry on computing research topics of mutual interest

Bridging the gap between academia and industry

Best Practices for Dual Appointments

Research on dual academic-industry appointments.

To do: Watch for the forthcoming report!

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GOVERNMENT AFFAIRS

Advocate and analyze policy
for the computing research community

Leadership in Science Policy Institute

Learn how federal computing research policy is made

To do: Attend LiSPI in September 2025!

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Best Practices

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NEW CRA BEST PRACTICES REPORT

Conference Submission and Review Policies to Foster Responsible Computing Research

Are you organizing a computing research conference? Interested in promoting ethical and responsible research practices?

CRA
Computing Research Association

NEW CRA BEST PRACTICES REPORT

CRA Report on Minority Serving Institution Engagement in Computing Research

Best Practices for Partnerships of Academia and Industry with Minority Serving Institutions

Looking to build strong, impactful partnerships with Minority Serving Institutions (MSIs) in computing research?

CRA
Computing Research Association

CCC
Computing Community Consortium
Catalyst

CRA BEST PRACTICES DOCUMENT

Catalyzing Interdisciplinary Computing Research

Best Practices for Researchers

July 2024

Attend CRA's Enrichment Programs!

CRA offers a variety of development opportunities for researchers of all career stages

CRA
Computing Research Association

Post your open positions! Actively recruit!

Did you know?

CRA Job Announcements

- Post an ad for your open roles for computing faculty and/or computing researchers
- More than 800 positions posted by nearly 400 universities and companies in 2022

cra.org/ads

CRA Member Discount

CRA PhD Database

- Candidates can upload resumes, research and teaching statements, job objectives, videos, etc.
- Recruiting officers with access can search and contact candidates

cra.org/cv-database

Nominate a team member for a CRA award!

CRA
Computing Research Association

A. Nico Habermann Award

Distinguished Service Award

Outstanding Undergraduate Researcher Award

Service to CRA Award

CRA-E
Computing Research Association
Education

CRA Undergraduate Research Faculty Mentoring Award

CRA-WP
Computing Research Association
Widening Participation

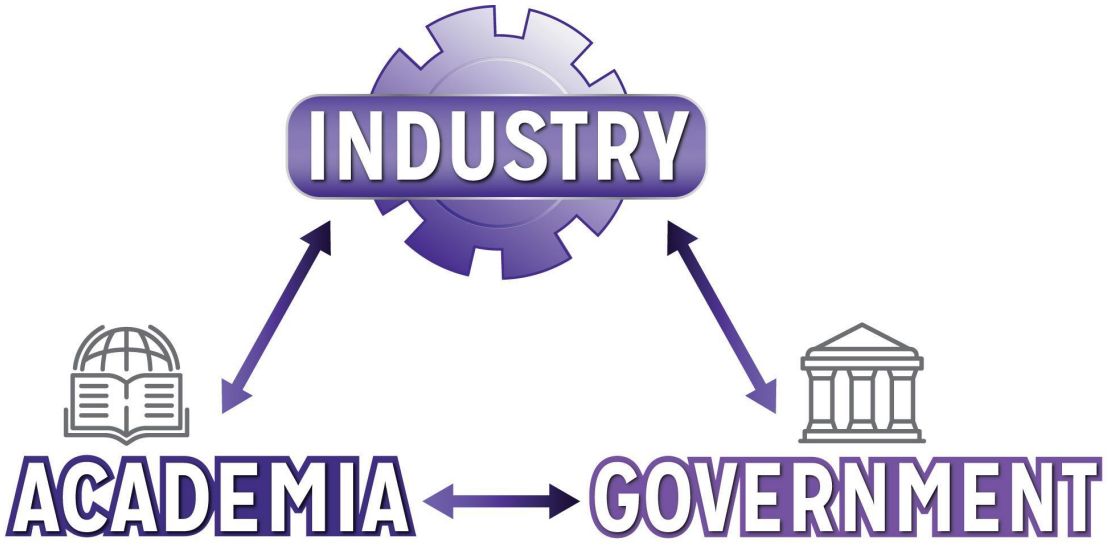
CRA Anita Borg Early Career Award

CRA Skip Ellis Early Career Award

CRA
Computing Research Association

CRA-Industry Overview

Mission: *Convene industry partners on computing research topics and connect them with constituents for mutual benefits and improved societal outcomes.*

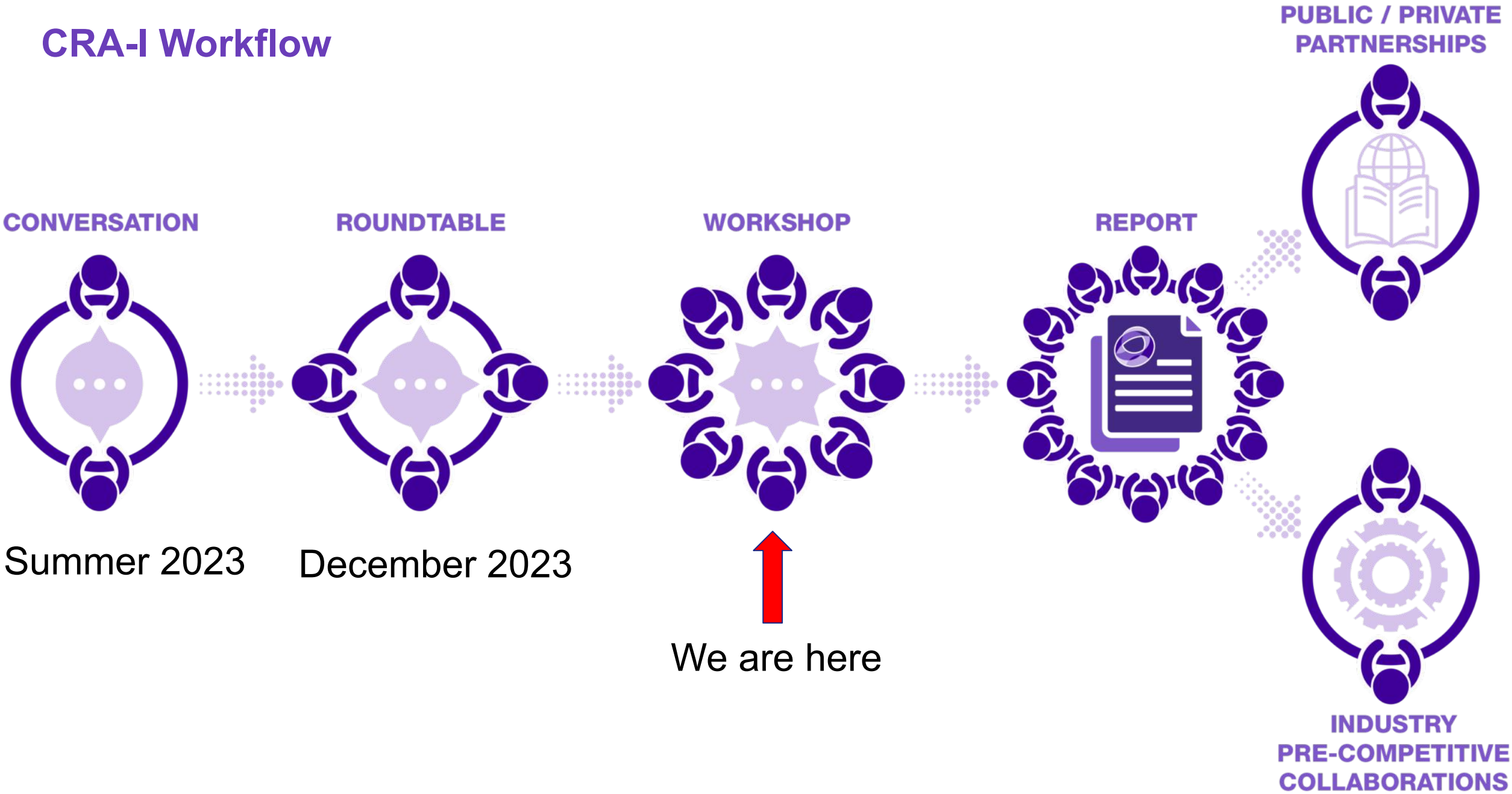


Who

- Companies of all sizes and industries engaged in computing research

- **What**
  - Convene members to share perspectives and form consensus on emerging topics in computing research
  - Coordinate with other CRA stakeholders
- **How**
  - Interview stakeholders
  - Convene roundtables & workshops
  - Produce white papers and reports

CRA-I Workflow



Summer 2023

December 2023

We are here

Steering Committee (SC)

Lisa Amini
IBM

Ron Brachman (Council Chair)
Cornell University

Mary Hall
University of Utah

Fatma Özcan (Co-Chair)
Google

Chris Ramming
VMware

Vivek Sarkar (Past Chair)
Georgia Institute of Technology

Divesh Srivastava (Co-Chair)
AT&T

Ben Zorn (Past Chair)
Microsoft

Helen Wright (Manager)
CRA

Council

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Ron Brachman
Cornell University
(Council Chair)

Elizabeth Bruce
Microsoft

Theo Drane
Intel

Hector Gonzalez
SpiNNcloud Systems

Bruce Hendrickson
LLNL

Jofish Kaye
Wells Fargo

Hank Korth
Lehigh University

Nita Patel
Otis Elevator Co.

Jennifer Rexford
Princeton
University

Eve Schooler
University of Oxford

Mark Segal
NSA

Ronak Shah
NVIDIA

Heather Stephens
Oracle

Tammy Toscos
Parkview Health

Goals of Workshop

- Explore the challenges of data ownership, access, and control, while identifying technological innovations that can overcome these barriers.

- Key objectives include fostering collaboration, advancing the conversation on ethical and regulatory considerations in AI-driven healthcare, and generating actionable insights that can inform future research and policy.

- Put together a report to guide the healthcare data-sharing community forward.

Workshop Planning Team

Shion Guha

Fayika Farhat Nova

Jessica Prater

Divesh Srivastava

Tammy Toscos

Helen Wright

Thursday, October 17

07:30 AM	**BREAKFAST** | Timchenko
08:30 AM	**Welcome and Introductions** | Corning
08:45 AM	**Keynote from Deborah Estrin- Patient-generated data sharing: advancing hybrid, longitudinal, patient care w/digital biomarkers and therapeutics (DBx, DTx)** | Corning
09:30 AM	**Barriers to Sharing Healthcare Data** | Corning • Ronald Emeni (CRISP DC) • Margarita Gonzalez (GTRI) • Peter Margolis (Cincinnati Children's)
11:00 AM	**BREAK** | Timchenko
11:30 AM	**InterAI: Connecting all health models/AI** | Corning • Douglas Horner (MIE) • John Garguilo (NIST) • Beth Mynatt (Northeastern University)
01:00 PM	**LUNCH** | Kingbird Terrace
02:00 PM	**Ethics in Health Data Sharing** | Corning • Andrea Ramirez (NIH) • Katie Siek (Indiana University) • Michael Zimmer (Marquette University)
03:30 PM	**BREAK** | Timchenko
04:00 PM	**Keynote from Tom Kalil- Can AI Save Lives?** | Corning
05:00 PM	**Day 1 Summary / Next Steps** | Corning
06:00 PM	**DINNER** | Library & Foyer

Friday, October 18

08:00 AM	**BREAKFAST** | Timchenko
09:00 AM	**Navigating Regulatory Landscape: AI Compliance in Health Data Sharing** | Corning • Jeffrey Smith (ONC) • Kevin Chaney (AHRQ) • Ranjani Ramamurthy (Global Health Labs) • Ram Sriram (NIST)
10:30 AM	**BREAK** | Timchenko
11:00 AM	**Policy/Agenda Writing Session** | Corning
12:00 PM	**Next Steps** | Corning
12:30 PM	**LUNCH (To Go Box)** | Timchenko
01:00 PM	**ADJOURN** | Corning

CORNELL TECH

JACOBS INSTITUTE

Patient-generated data sharing: advancing hybrid, longitudinal, patient care w/digital biomarkers and therapeutics (DBx, DTx)

Deborah Estrin, Ph.D.

Professor of Computer Science, Cornell Tech

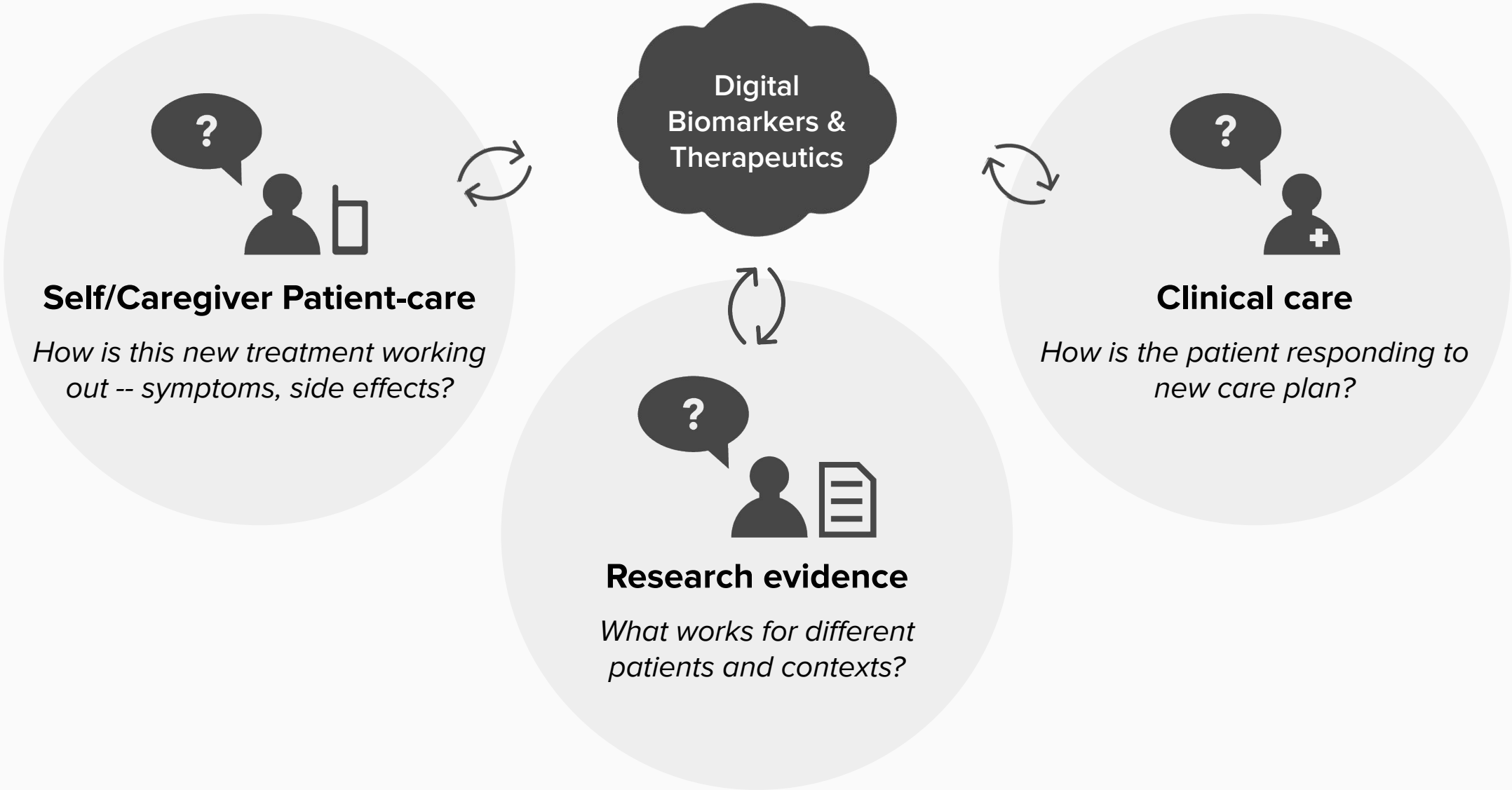
Professor of Population Health Sciences, Weill Cornell Medicine

destrin@cornell.edu @deborahestrin http://destrin.tech.cornell.edu

Conflict disclosure---funders past 5 years:

Federal: NSF, NIH; Foundation: MacArthur, Siegel Family Endowment; Enterprise: Amazon, NYP, Optum

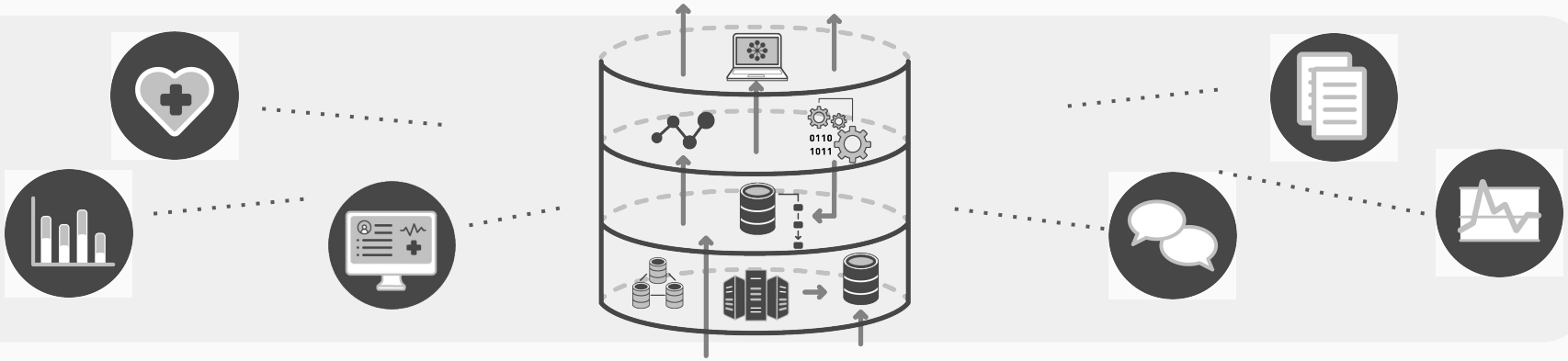
General context: feedback loops of health



Digital Biomarkers & Therapeutics (DBx, DTx) fueled by Patient Generated Data

Hybrid Care Pathways (Digital, Virtual, In-Person)

DBx & DTx models, measures, interventions



Patient Generated Data (PGD)

Wearable-based Digital Biomarkers (DBx) Studies

WATCH

HEALTH TECH

Apple pushes into clinical trials with new FDA nod for Apple Watch

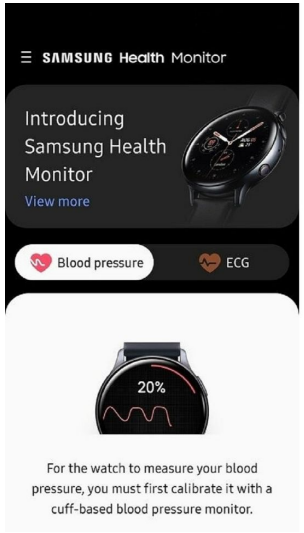
By Mario Aguilar and Lizzy Lawrence May 8, 2024

The Apple Watch has secured a new qualification from the Food and Drug Administration that could make the smartwatch an appealing tool for medical device companies hoping to illustrate the benefits of a common heart procedure.

SAMSUNG

How to use the Samsung Watch 5 series blood pressure feature?

The Galaxy Watch 5 series has the technology to be able to measure the wearer's blood pressure. Using a function called pulse wave analysis, which powers the heart rate sensor, the Galaxy Watch 5 series is not only able to track your heart rate but your blood pressure, too.



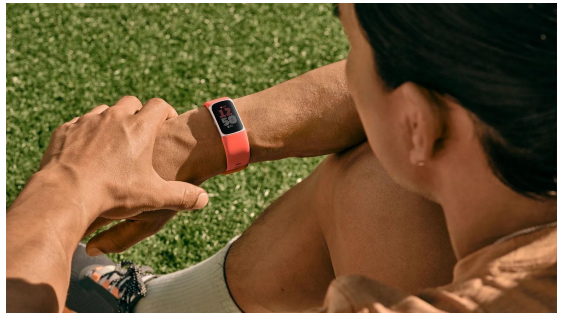
fitbit

New Fitbit study explores metabolic health

Jan 17, 2024 · 3 min read

WEAR-ME Study with Quest Diagnostics will look at how wearables could help people better understand and manage their metabolic health.

Javier L. Prieto
Ph.D. Principal Investigator



ŌURA

Feasibility of Measuring Physiological Responses to Breakthrough Infections and COVID-19 Vaccine Using a Wearable Ring Sensor

Gerald Norman Pho [1], Nina Thigpen [1], Shyamal Patel [1], Hal Tily [1]

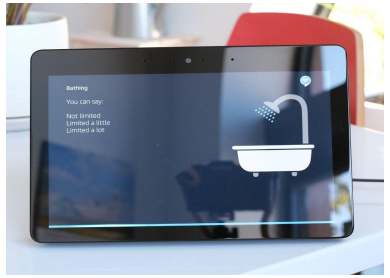
Continuous monitoring using commercial-grade wearable technology was used to quantify the physiological response to reported COVID-19 infections and vaccinations in five biometric measurements. Larger responses were observed following confirmed COVID-19 infection reported by unvaccinated versus vaccinated individuals. Responses following reported vaccination were smaller in both magnitude and duration compared to infection and mediated by both dose number and age.

Exemplar use case history: Parkinson's

mPower Parkinson's Study	A series of mobile research studies for understanding the progression of Parkinson's Disease in individuals *Scientific Data* 3, 160011 (2016). doi: 10.1038/sdata.2016.11	Launched: March, 2015
News From the Food and Drug Administration **Apple Watch Parkinson Disease Symptom Monitor Is Cleared**	Howard D. Larkin *JAMA*. 2022;328(5):416. doi:10.1001/jama.2022.12641	Published: August, 2022
Artificial intelligence-enabled detection and assessment of Parkinson's disease using nocturnal breathing signals	Yuzhe Yang, Yuan Yuan, Guo Zhang, Hao Wang, Ying-Cong Chen, Yingcheng Liu, Christopher G. Tarolli, Daniel Crepeau, Jan Bukartyk, Mithri R. Junna, Aleksandar Videnovic, Terry D. Ellis, Melissa C. Lipford, Ray Dorsey & Dina Katabi *Nature Medicine* 28, 2207–2215. doi: 10.1038/s41591-022-01932-x	Published: August, 2022
Wearable movement-tracking data identify Parkinson's disease years before clinical diagnosis	Ann-Kathrin Schalkamp, Kathryn J. Peall, Neil A. Harrison & Cynthia Sandor Nature Medicine 29, 2048–2056 (2023). doi: 10.1038/s41591-023-02440-2	Published: July, 2023
A Randomized Clinical Trial to Evaluate a Digital Therapeutic to Enhance Gait Function in Individuals With Parkinson's Disease	Jay L. Alberts, Ryan D. Kaya, Amanda L. Penko, Matthew Streicher, Eric M. Zimmerman, Sara Davidson, Benjamin L. Walter and Anson B. Rosenfeldt *https://journals.sagepub.com/doi/epub/10.1177/15459683231184190*	Published: September, 2023

Digital Therapeutics (DTx): where modalities match conditions

- Multimodal assistants for PROs, Tasks. Care Companion



- Wearables trigger intervention, medication

h2o Therapeutics' Apple Watch feature for Parkinson's gets FDA medical device listing

By **Trevor Dermody** | 02:59 pm | April 12, 2024

Turkey-based digital health startup h2o therapeutics announced its new Apple Watch-enabled freezing of

DIGITAL HEALTH

NIH-funded study to test if Apple Watch can prevent strokes, limit blood thinners

By **Heather Landi** · Aug 31, 2022 1:00pm

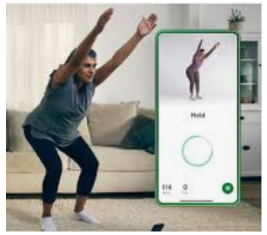
- VR for behavioral health, pain interventions

oxfordvr.co

xr.health

www.relievrx.com/

- AR for remote guidance



hingehealth.com

PMC 9694181

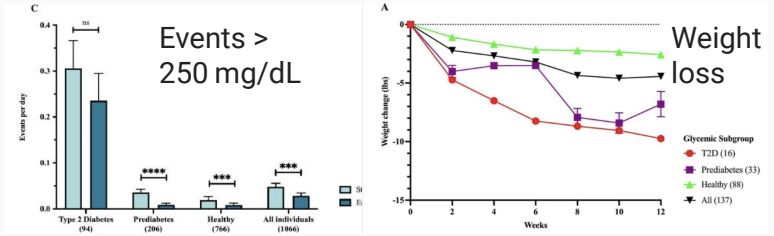
microsoft.com/en-us/hololens

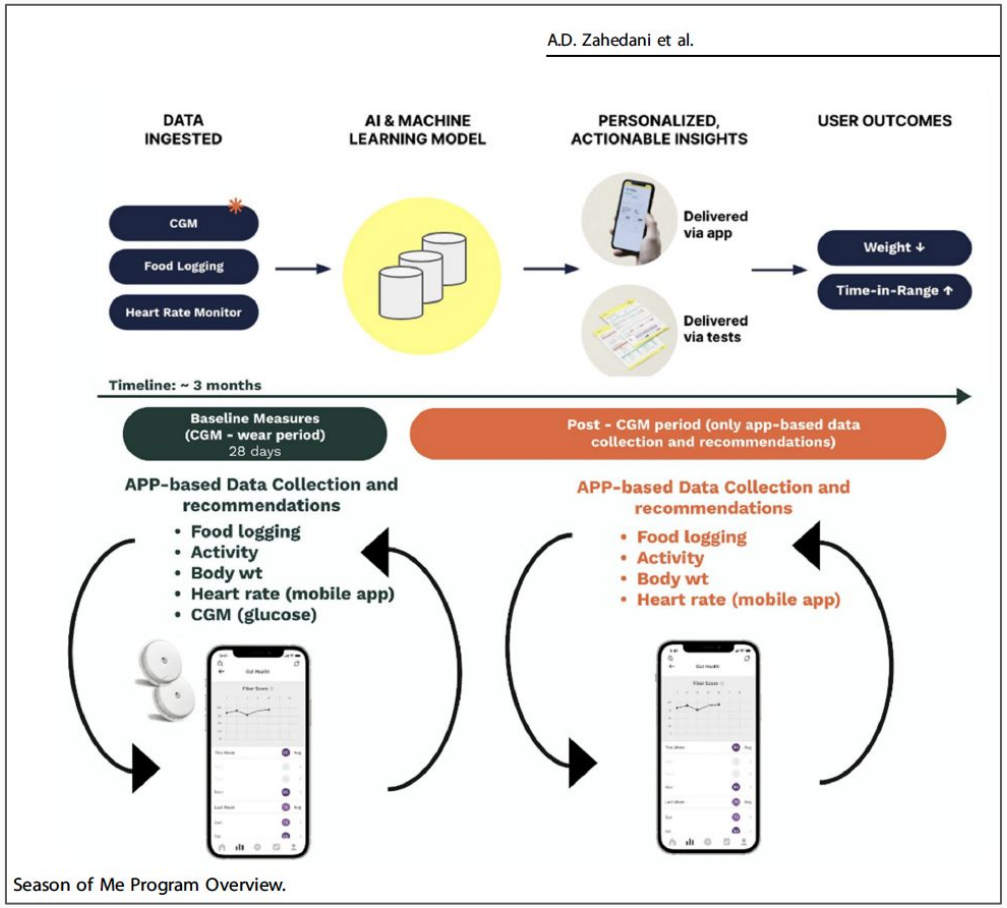
DTx use case: CGMs, Metabolic Health

Article | Open access | Published: 25 November 2023

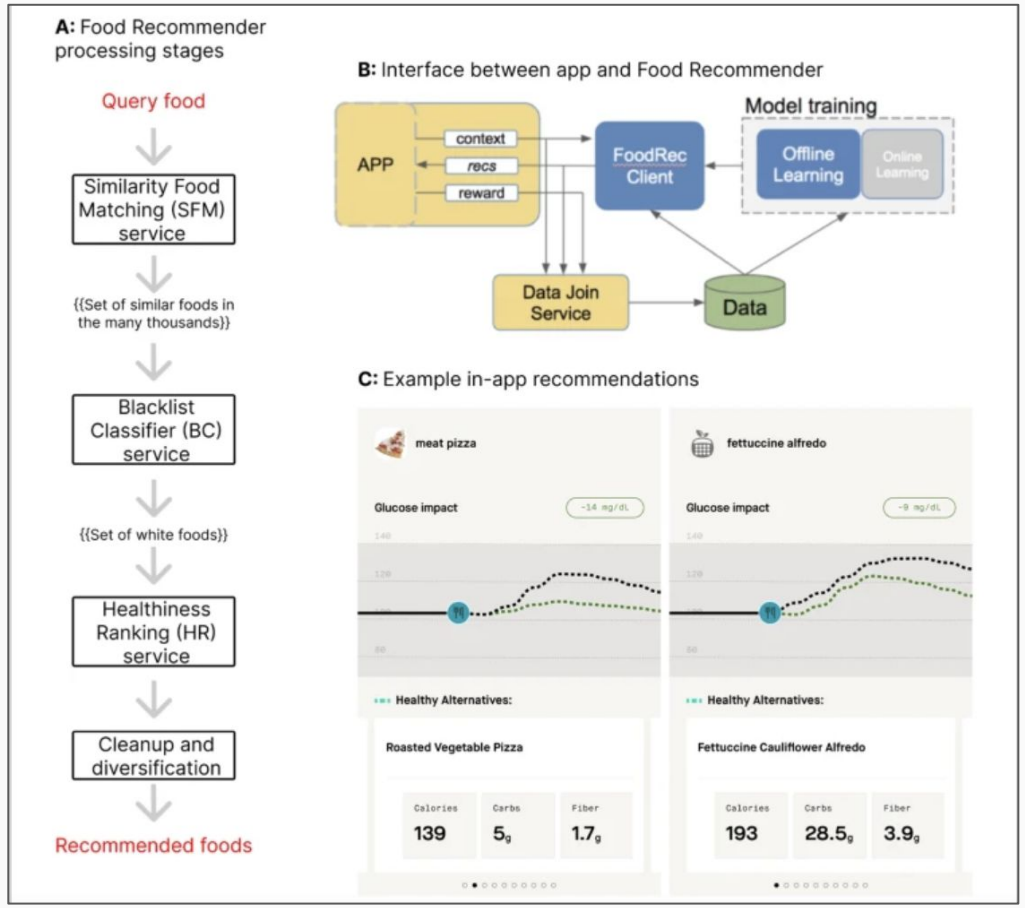
Digital health application integrating wearable data and behavioral patterns improves metabolic health

Ashkan Dehghani Zahedani, Tracey McLaughlin ✉, Arvind Veluvali, Nima Aghaeepour, Amir Hosseinian, Saransh Agarwal, Jingyi Ruan, Shital Tripathi, Mark Woodward, Noosheen Hashemi & Michael Snyder ✉



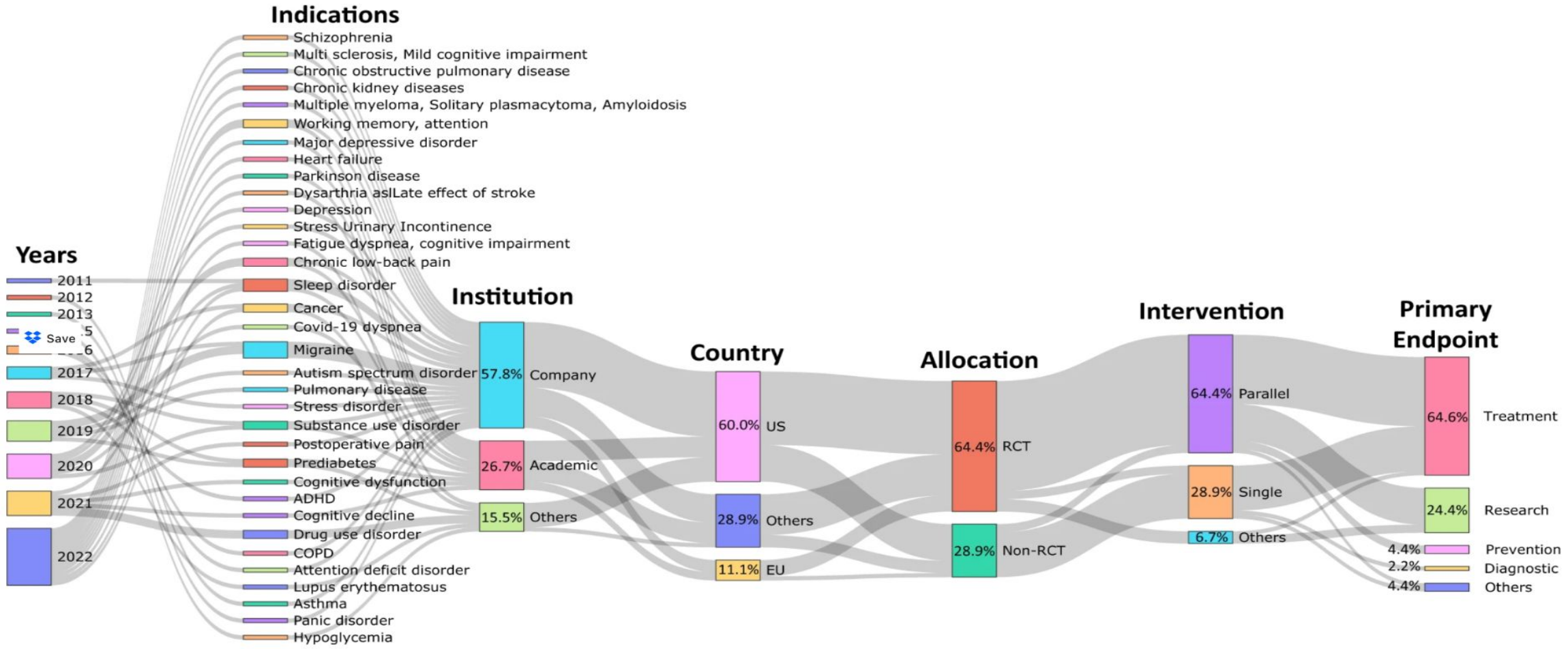


Season of Me Program Overview.



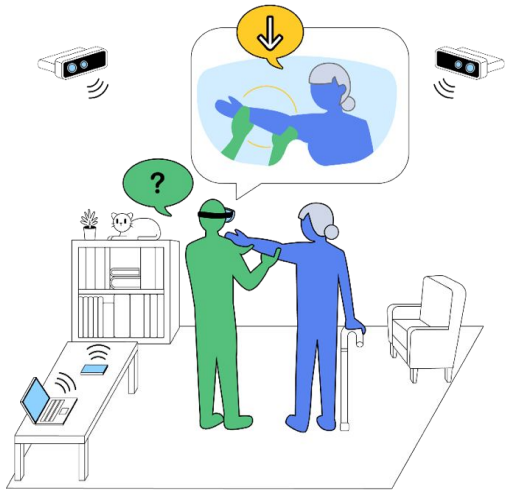
Digital therapeutics related clinical research studies

Wang, C., Lee, C. & Shin, H. Digital therapeutics from bench to bedside. npj Digit. Med. 6, 38 (2023). https://doi.org/10.1038/s41746-023-00777-z



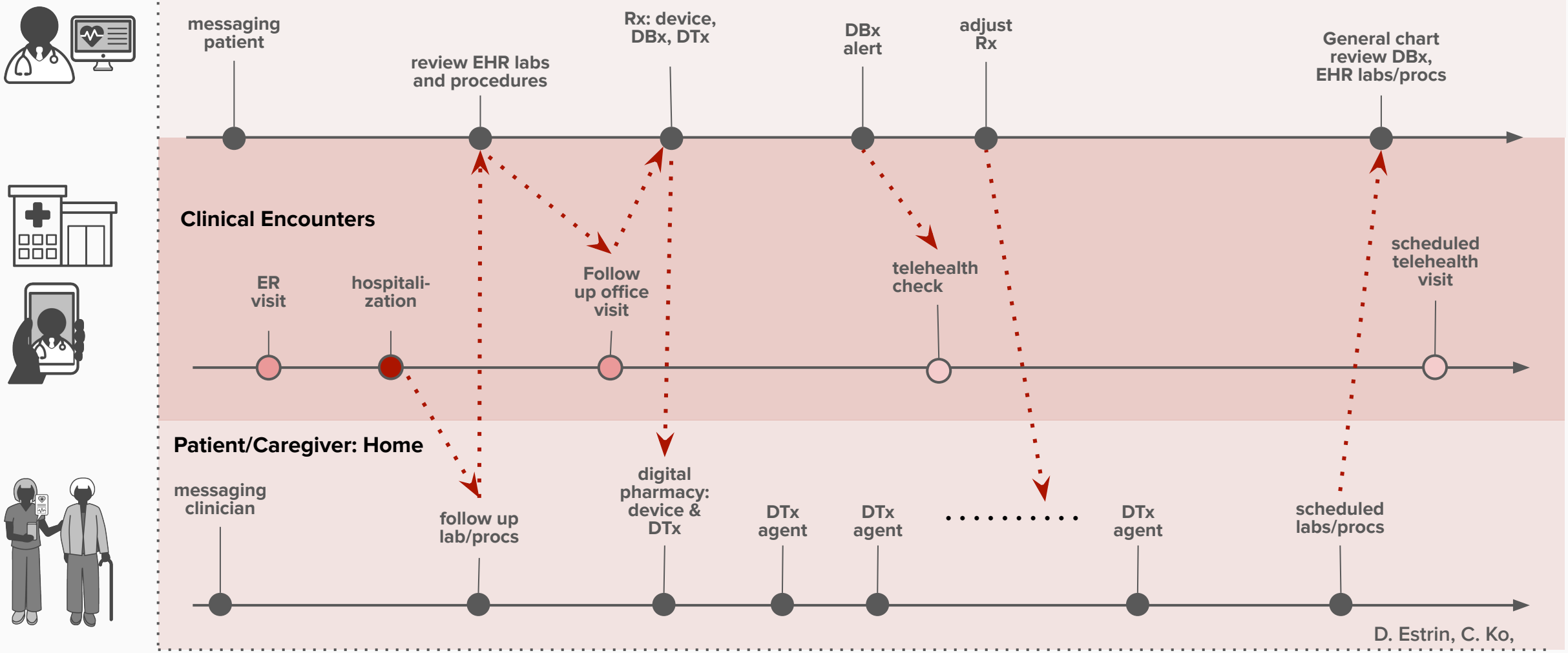
Future: DTx Visual agents to bring caregiver superpowers

- Caregivers in the home as the “last meter of care”
- Visual agents could augment less-trained eyes (and hands) of informal caregivers--manage wound care, rehab, recovery
- Asynchronous interactions for scalable clinical workflow



Local Care Setting

Aspirational Hybrid Longitudinal Care Delivery: with DBx, DTx



I expected a revolution, but we needed time for evolution…

POLICYFORUM

HEALTH CARE DELIVERY

Open mHealth Architecture: An Engine for Health Care Innovation

Standardized interfaces and shared components are critical for realizing the potential of mobile-device–enabled health care delivery and research.

Deborah Estrin[1]* and Ida Sim[2]

Science

November 4, 2010

REVIEW ARTICLE

FRONTIERS IN MEDICINE

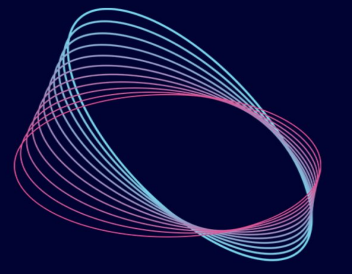
Mobile Devices and Health

Ida Sim, M.D., Ph.D.

The NEW ENGLAND JOURNAL of MEDICINE

September 5, 2019

ARPA-H launches Exploration Topic to improve chatbots for patient-facing applications

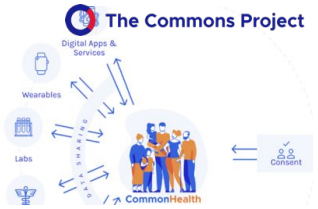


ARPA-H

April 19, 2024

Governance Needs: Standards, Incentives, Infrastructure, Privacy

- Standardized patient-data flow supports care coordination, health communities, research



SMART®

- Misaligned incentives interfere with development and adoption

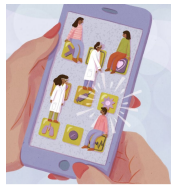
HEALTH

Telehealth startups see an opportunity in long-ignored, complex chronic diseases

STAT+

By Isabella Cueto April 23, 2024

Reprints



- Open modular infrastructure can reduce cost of developing care paths

JupyterHealth

- Unrestricted data sharing risks inappropriate profiling, surveillance, violation of norms

HEALTH TECH

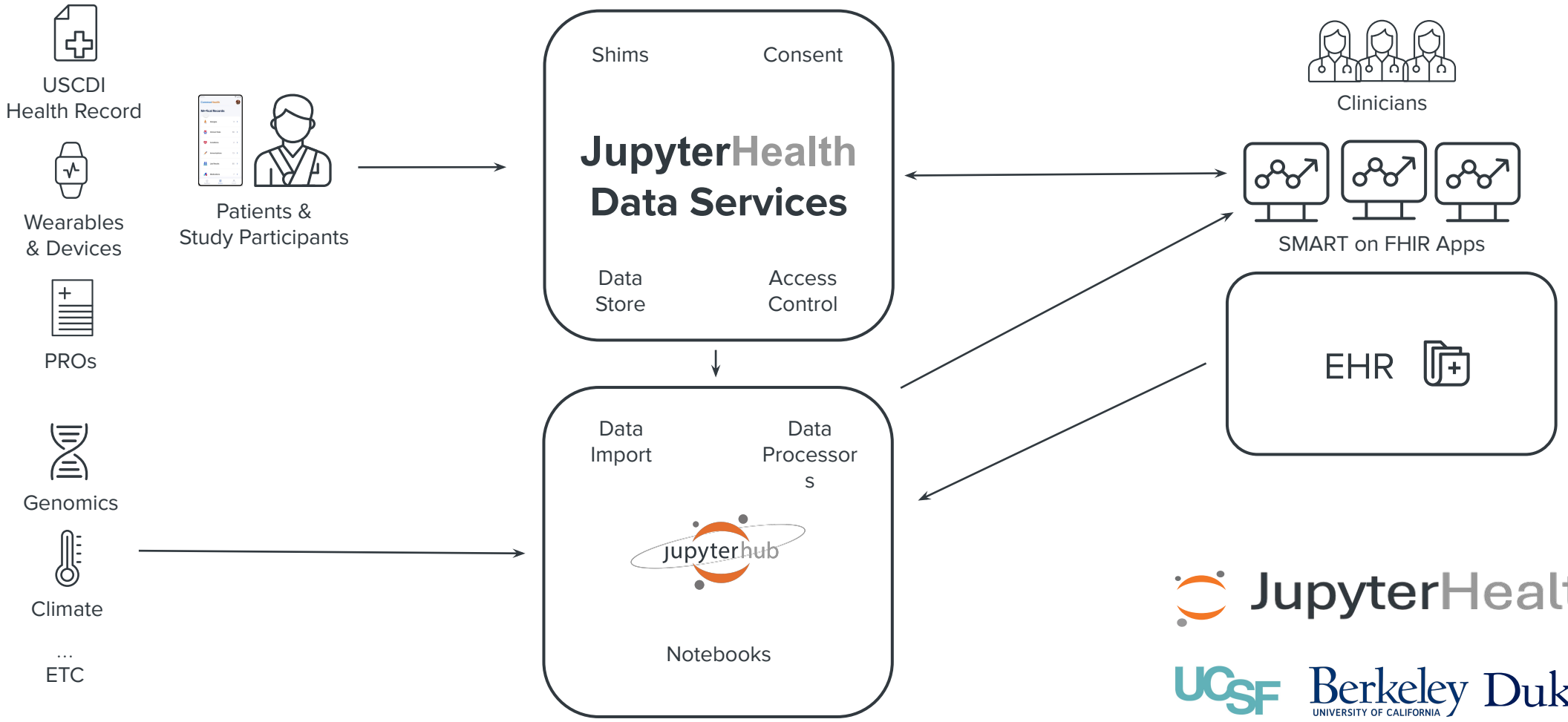
As data sharing ramps up, health insurers wade into patient privacy debate

STAT+

By Mohana Ravindranath Feb. 10, 2022

Reprints

Development & Validation w/Open Modular Infrastructure



Open source, modular, vendor-agnostic platform enabling collection and interpretation of health data, based on Project Jupyter

JupyterHealth

UCSF Berkeley Duke UNIVERSITY OF CALIFORNIA

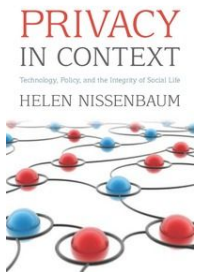
The Commons Project

2i2C

JP Pollak, jp@thecommonsproject.org

When it comes to data sharing, Context is ~~King~~ Queen

Contextual Integrity Framework: Helen Nissenbaum



Privacy in Context Technology, Policy, and the Integrity of Social Life Helen Nissenbaum, *Stanford University Press*, **2009**

Contextual Integrity, Explained: A More Usable Privacy Definition, Nathan Malkin, *IEEE Security & Privacy*, vol. 21, no. 1, pp. 58-65, Jan.-Feb. **2023**

Contextual Integrity Up and Down the Data Food Chain Helen Nissenbaum, *Theoretical Inquiries in Law* 20 (1):221-256. **2019**

- Flow of information is appropriate when it conforms with contextual norms
- A Social Context is defined by its ends, purposes, and values; good norms serve these
- Contextual norms must include values for all the following: data type, data subject, sender, recipient, transmission principle (constraints on flow)
- Good norms serve contextual ends, purpose, and values

ANNALS OF MEDICINE JANUARY 23, 2017 ISSUE

THE HEROISM OF INCREMENTAL CARE

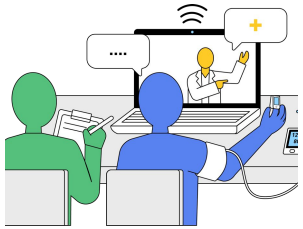
We devote vast resources to intensive, one-off procedures, while starving the kind of steady, intimate care that often helps people more.

By Atul Gawande

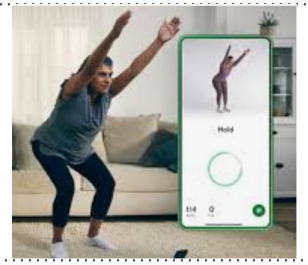
"...shift our focus from rescue medicine to lifelong incremental care. Or ...leave millions of people to suffer .. from conditions that, increasingly, can be predicted and managed. The more capacity we develop to monitor the body and the brain for signs of future breakdown and to correct course along the way...the greater the difference health care can make in people's lives, as well as in reducing future costs."

Summary

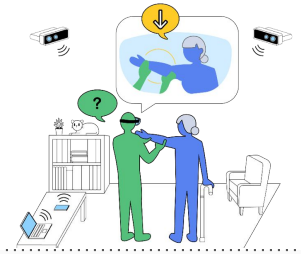
Virtual/Hybrid care as inflection point for DBx -- AI-based to ingest patient generated data volume.



Integrate DBx and DTx interventions into compatible/addressable care paths -- powered by GenAI and visual technologies.



Design and deploy with caregivers in mind to support adoption by aging population.



Invest in shared methods and modular infrastructure -- tall skinny moats risk fragmentation, fragility, inefficiency.

Acknowledgments

- Graduate students, technical faculty, and clinical colleagues.
- Cornell Tech and NYC as platform for innovation and impact.
- Funders: NSF, NIH; MacArthur, Siegel Family Endowment; NYP

Follow up

- **destrin@cornell.edu https://tech.cornell.edu/destrin**

CORNELL TECH
HOME OF THE JACOBS INSTITUTE

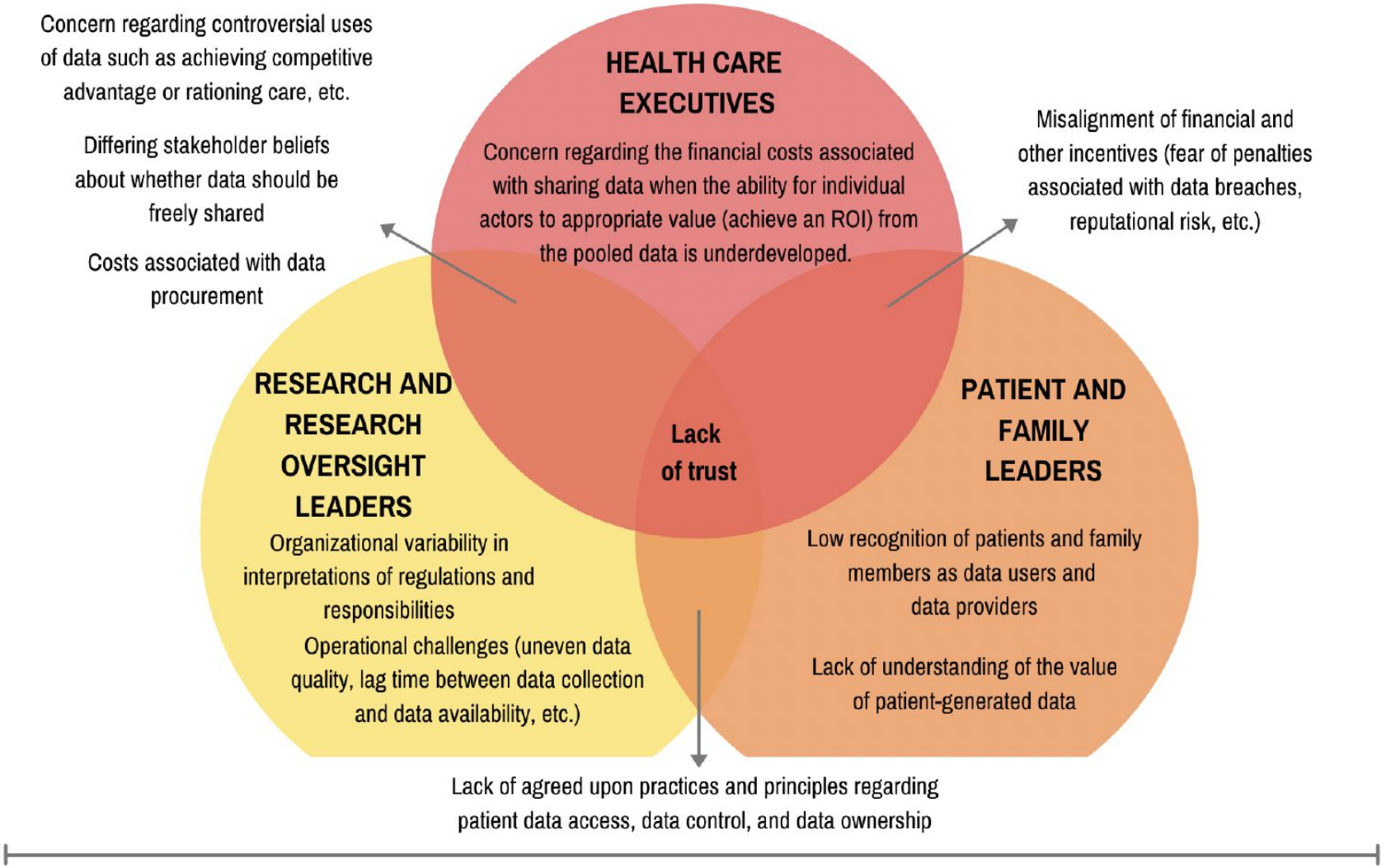
Barriers to Sharing Healthcare Data

CRA-I
Computing Research Association
Industry

- Ronald Emeni (CRISP DC)
- Margarita Gonzalez (GTRI)
- Peter Margolis (Cincinnati Children's)

Moderator: Fayika Farhat Nova

CULTURAL, ETHICAL, REGULATORY, AND FINANCIAL BARRIERS TO DATA SHARING, LINKAGE, AND USE



Source: **Health Data Sharing to Support Better Outcomes Report by NAM**

BREAK

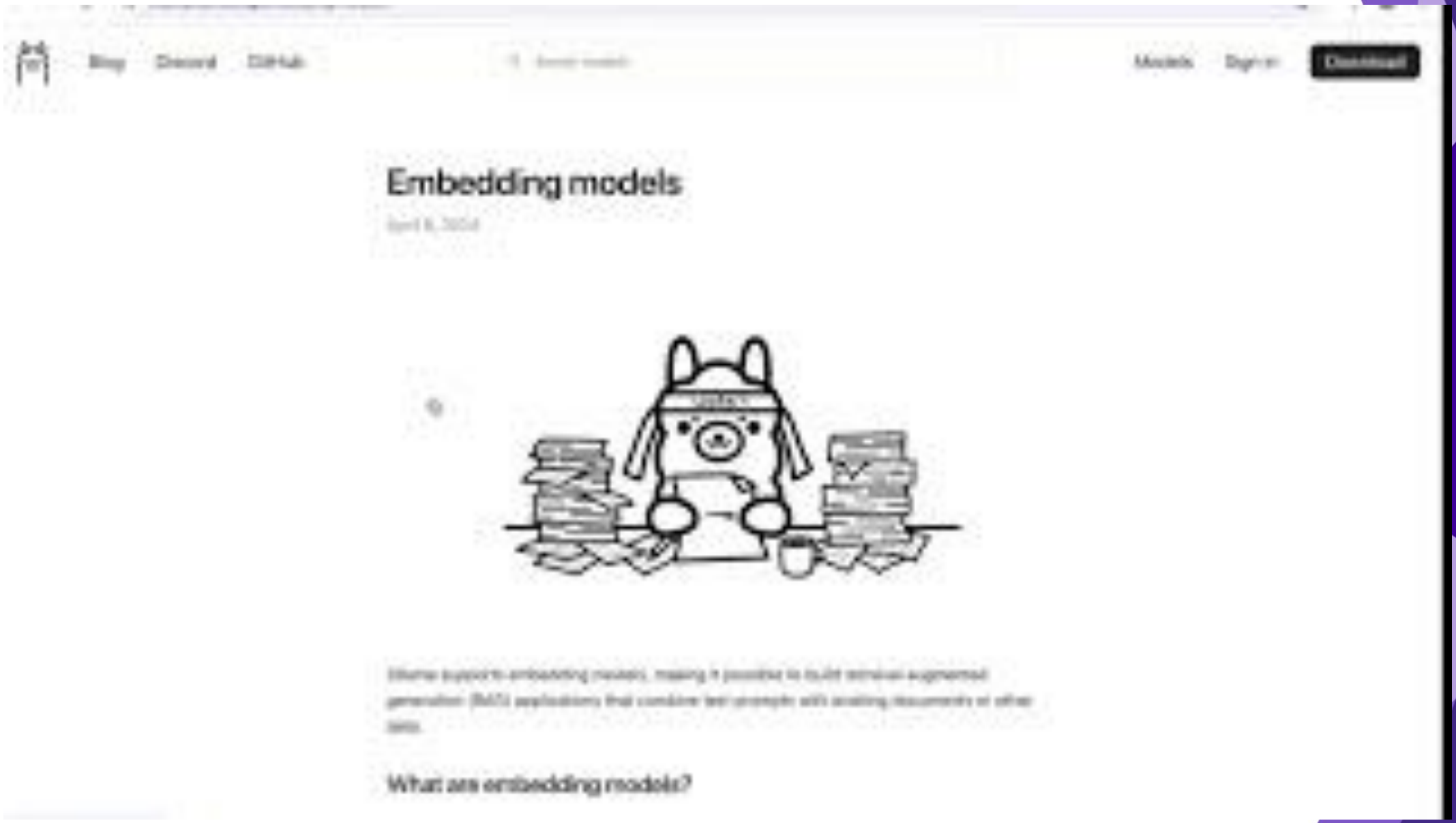
InterAI: Connecting all health models/AI

CRA-I
Computing Research Association
Industry

- Douglas Horner (MIE)
- John Garguilo (NIST)
- Beth Mynatt (Northeastern University)

Moderator: Shion Guha

Doug Horner


Blog
Discord
GitHub
Models
Sign in
Embedding models
What are embedding models?

LUNCH
Back at 2pm

Ethics in Health Data Sharing

CRA-I
Computing Research Association
Industry

- Andrea Ramirez (NIH)
- Katie Siek (Indiana University)

Moderator: Jessica Pater

The All of Us Research Program: a platform to transform biomedical research

CRA-I Sharing Health Care Data Workshop, Washington, DC

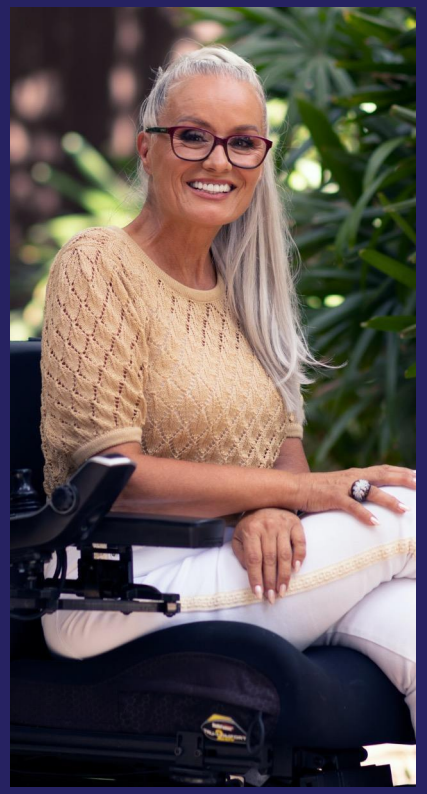
October 17, 2024

Andrea H. Ramirez, M.D., M.S.
Chief Data Officer

National Institutes of Health

All of Us RESEARCH PROGRAM

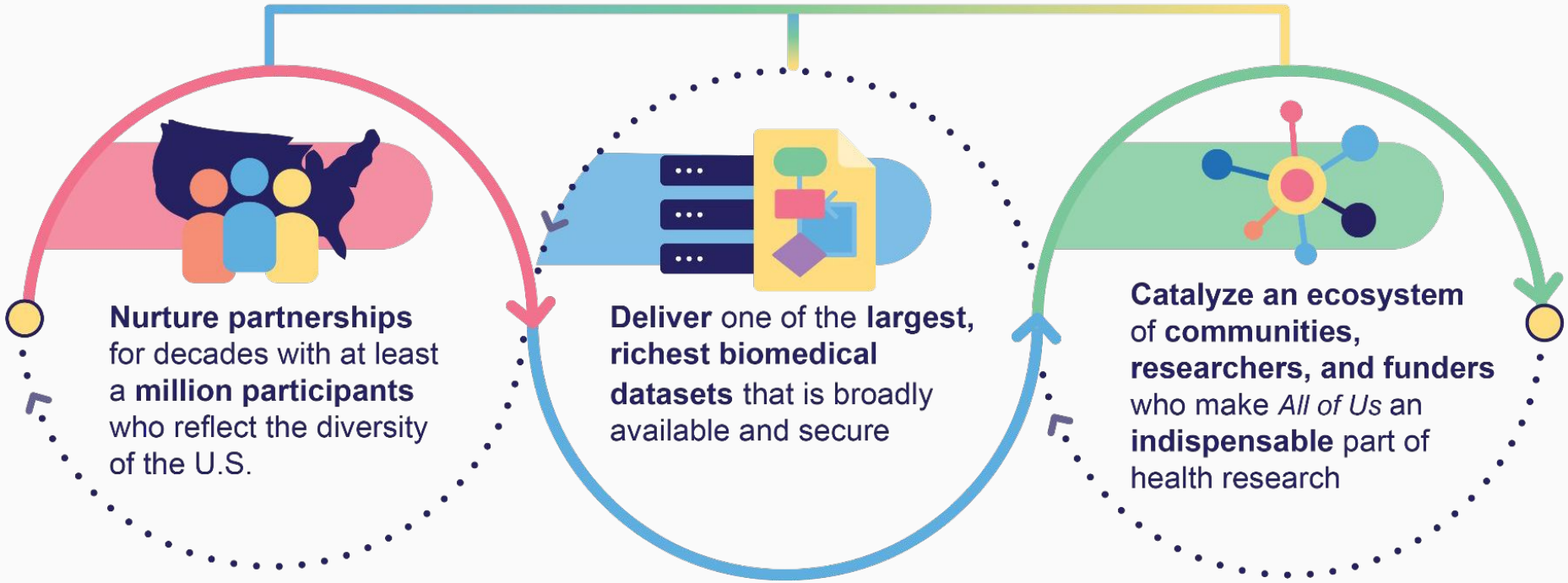
Join *All of Us*






The *All of Us* Research Program Mission

Accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us



Made possible by a team that maintains a culture built around the program's core values

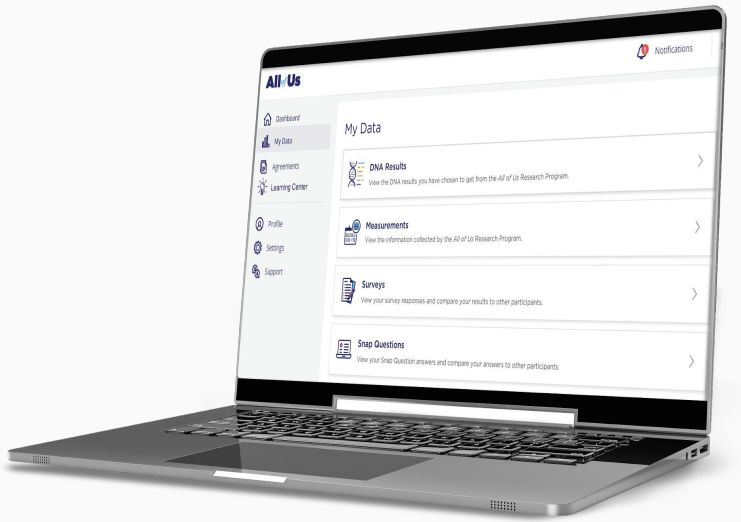
Data Collected and Return of Value to *All of Us* Participants

- Consent and Electronic Health Records
- Participant Surveys
- Physical Measurements
- Biosamples
- Mobile/Wearable Tech

Return of Value for Participants

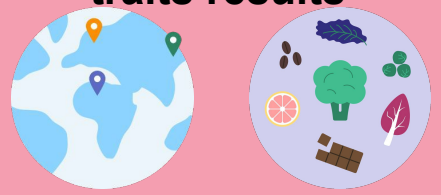
Participants may receive:

- ***Genetic information***
- Survey data (comparative)
- EHR and claims data
- Ongoing study updates
- Aggregate results
- Scientific findings
- Opportunities to be contacted for other research opportunities



Participants Can Receive Four Types of Genetic Research Results

Genetic ancestry and traits results



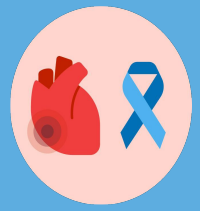
168k *All of Us* Participants have viewed the genetic ancestry report, which includes 7 regions and 20 subregions:

- Sub-Saharan Africa
- Europe
- Oceania
- Southern Asia
- Eastern and northern Asia
- The Middle East and North Africa
- The Americas

153k participants have viewed the genetic traits report, which includes 4 traits:

- Ear wax
- Bitter taste perception
- Cilantro preference
- Lactose intolerance

Hereditary Disease Risk (HDR) Report



106k *All of Us* Participants have viewed this report, which looks for genetic variants in 59 genes associated with serious health conditions, including:

- Breast cancer
- Ovarian cancer
- Uterine cancer
- Colorectal cancer
- Prostate cancer
- Melanoma
- Brain cancer
- Pancreatic cancer
- Stomach cancer
- Neurofibromatosis type 2
- Familial hypercholesterolemia
- Cardiomyopathies
- Arrhythmias
- Arteriopathies

~3% (>2,600) of participants who received their hereditary disease risk report have **a potentially life-changing genetic variant.**

Medicine and Your DNA Report

102k *All of Us* Participants have viewed this report, which analyzes seven genes that can affect how bodies process medicine and impacts which medication or what dosage you take. This report includes 50+ different medicines that may be impacted by your genetics, including:

- Citalopram (Celexa®)
- Clopidogrel (Plavix®)
- Escitalopram (Lexapro®)
- Sertraline (Zoloft®)
- Lidocaine
- Glimepiride (Amaryl®)
- Sulfamethoxazole/ trimethoprim (Bactrim®)
- Simvastatin (Zocor®)
- Amitriptyline (Elavil®)

89% (>91,000) of participants who received this report have **a result that could impact how their body processes a medication within this report.**

Enrolled 802K+ Participants With Continued Growth

Participant Enrollment

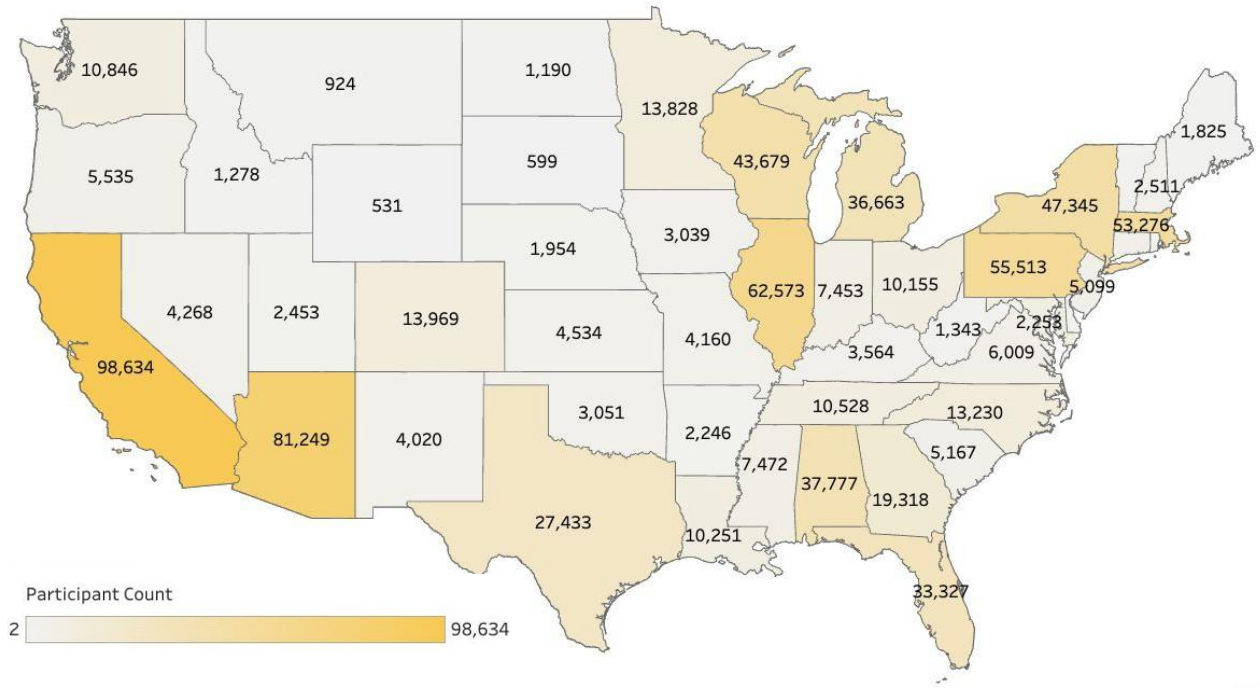
802,000+
Participants

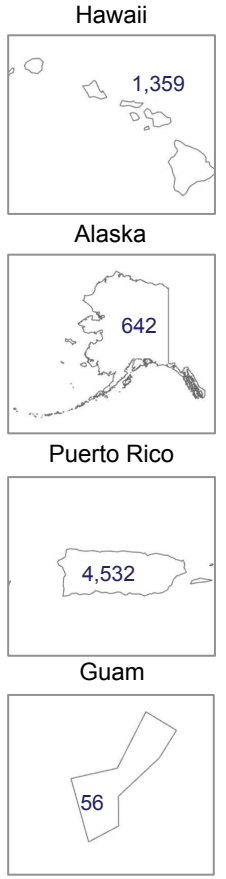
438,000+
Electronic Health Records

548,000+
Participants who have completed initial steps of the program

567,000+
Biosamples

Map of Consented Participants



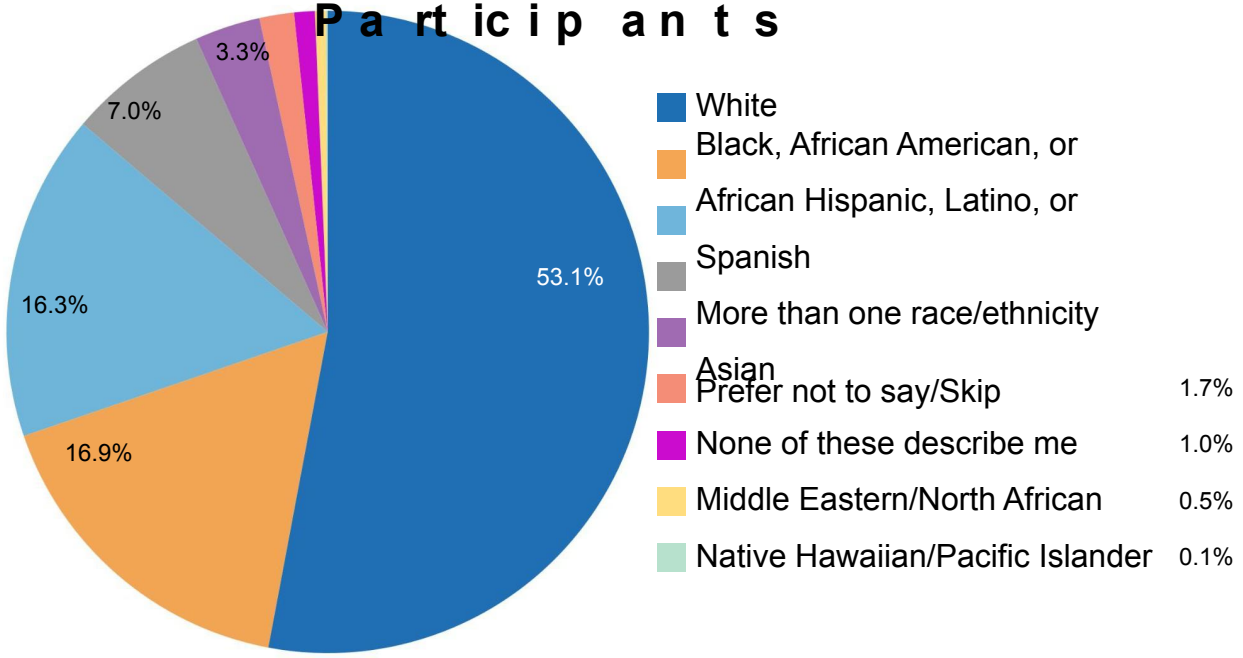


Plus >4,700 consented participants across U.S. territories

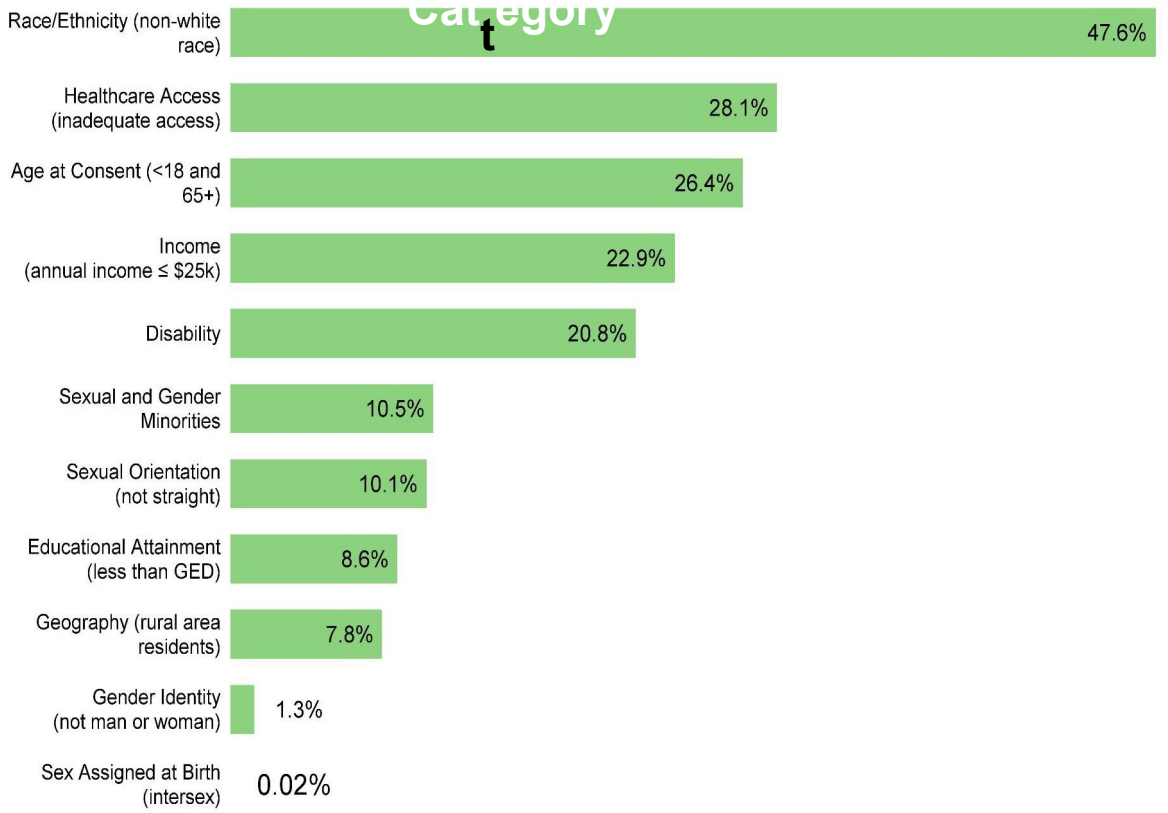
Numbers current as of Sept 3, 2024

Participant Diversity

Race & Ethnicity of Participants



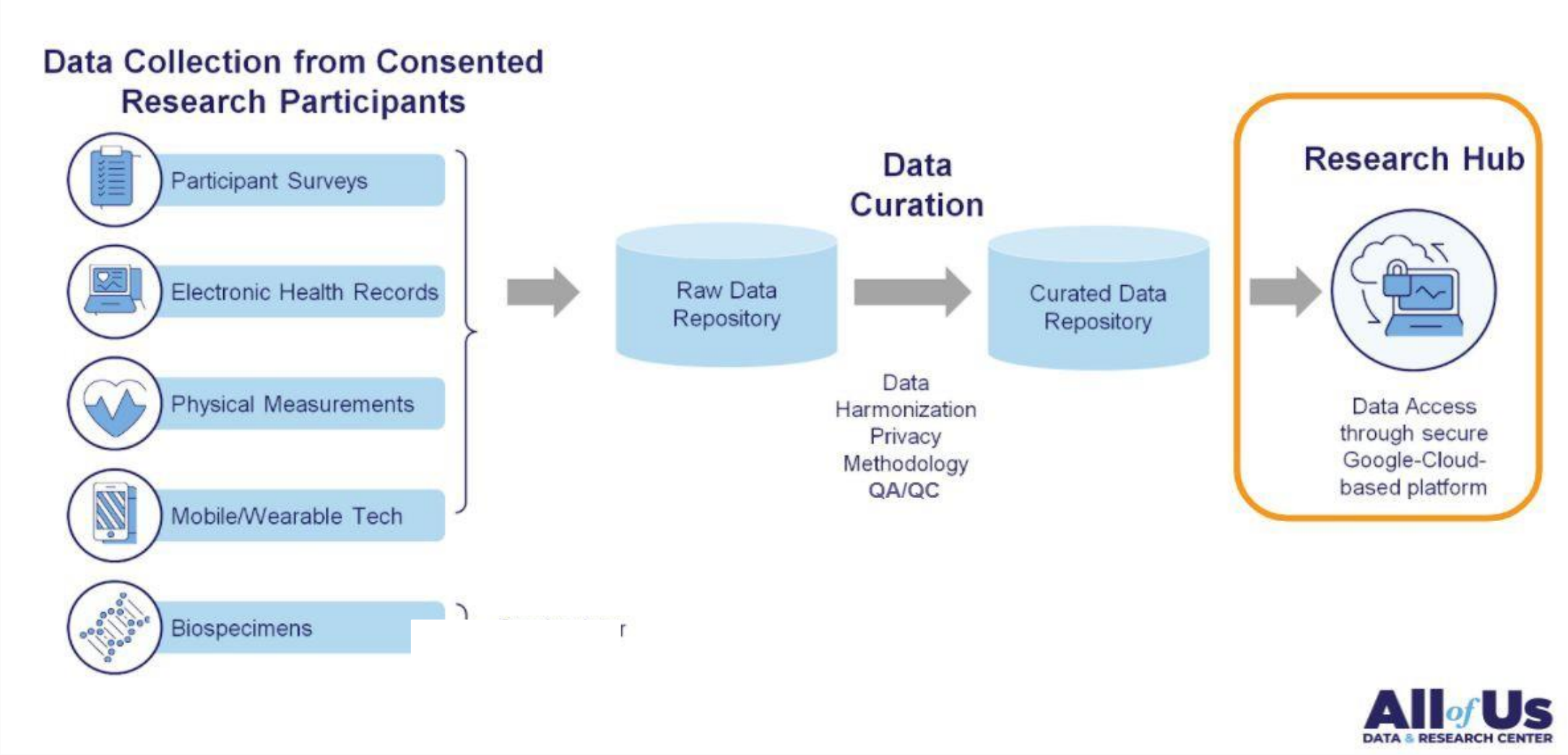
UBR



Over 87% of *All of Us* participants are underrepresented in biomedical research

Numbers current as of Sept 3, 2024

All of Us Research Data Pipeline



Bringing Researchers to Data Facilitates Collaboration

Traditional Approach

Bring Data to Researchers

Discourages Shared Research

"Weakest link" security

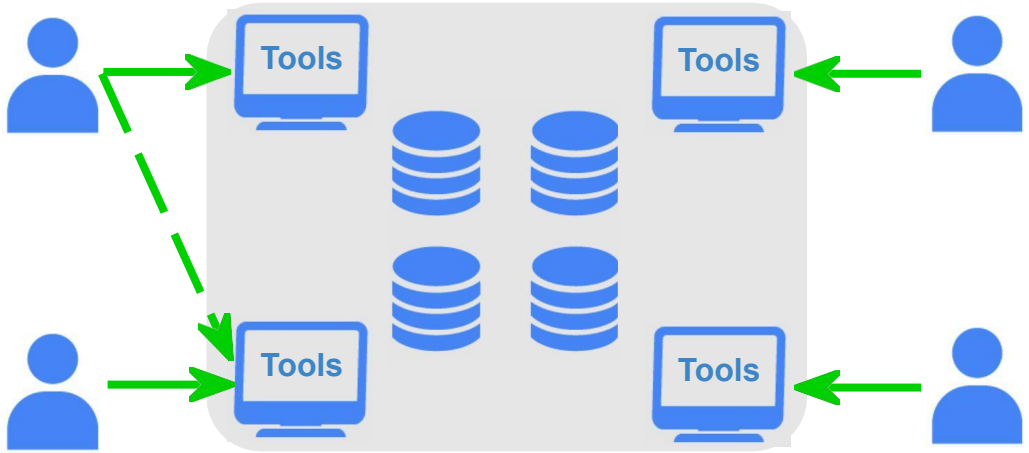
Huge infrastructure needed

Pay for multiple copies

Bespoke & unsupported tools

Cloud-Centric Approach

Bring Researchers to Data



Facilitates Collaboration

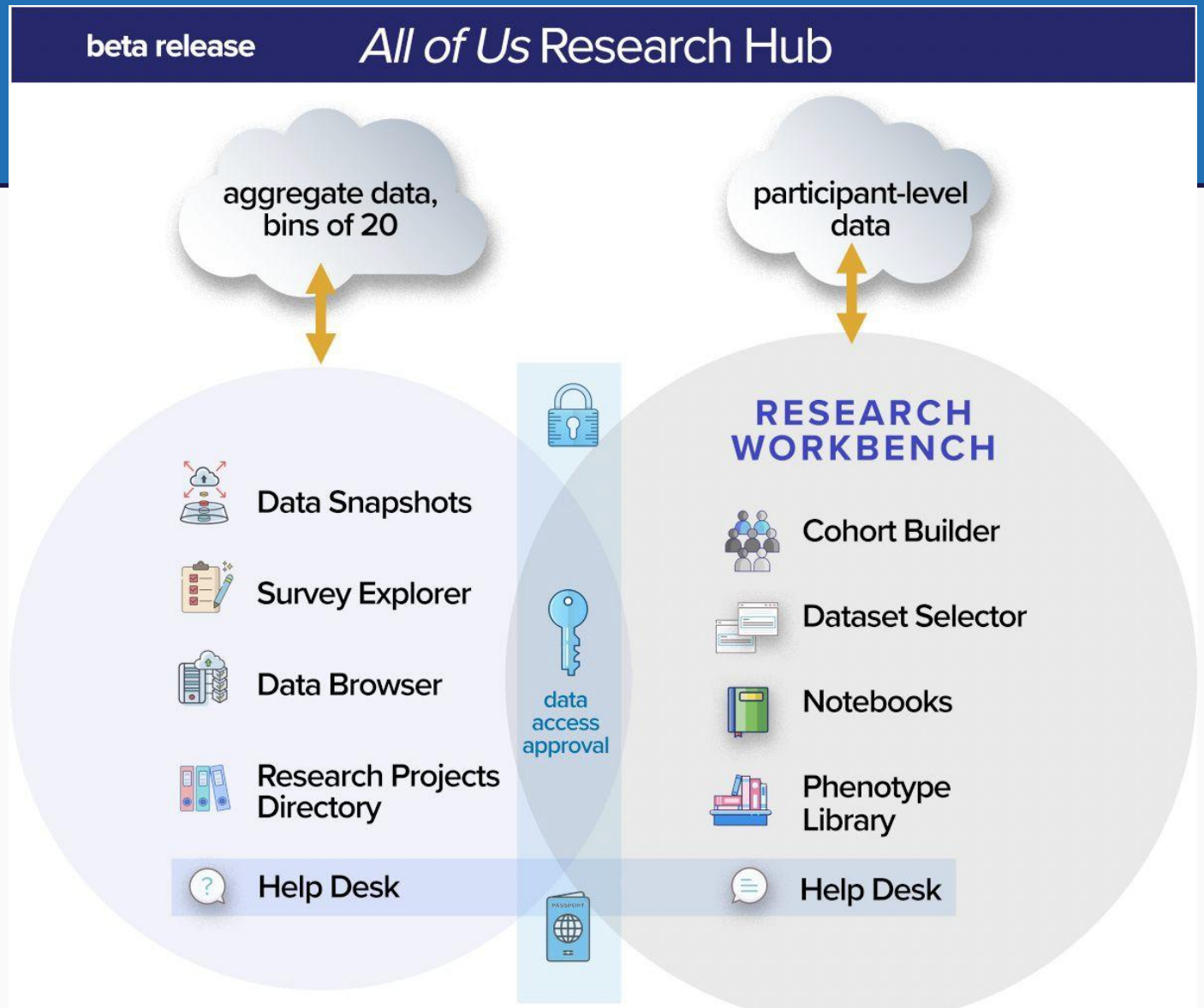
Centralized security controls

Accessible to all researchers

Decreased cost of storage

Shared tool ecosystem

Public and registered Passport access options



Viewpoint

June 11, 2021

Progress With the All of Us Research Program
Opening Access for Researchers

Andrea H. Ramirez, MD, MS[1,5]; Kelly A. Gebo, MD, MPH[2,3]; Paul A. Harris, PhD[4]

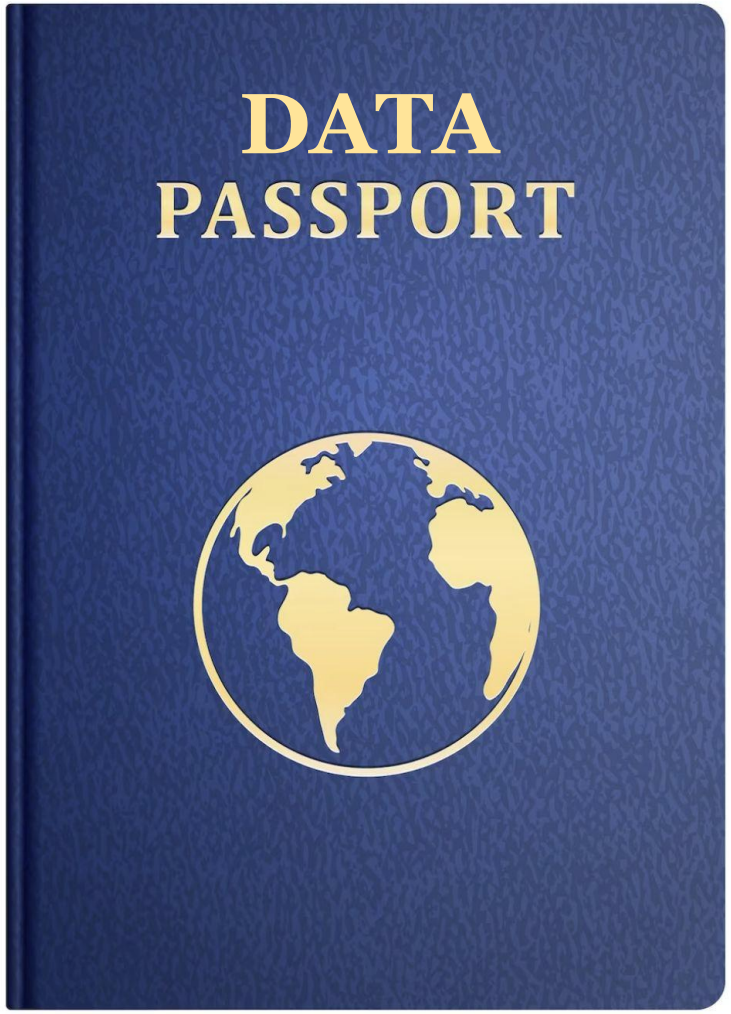
» Author Affiliations | Article Information

JAMA. 2021;325(24):2441-2442. doi:10.1001/jama.2021.7702

https://jamanetwork.com/journals/jama/fullarticle/2781166

Enabling Discoveries Through Broad Access to Data

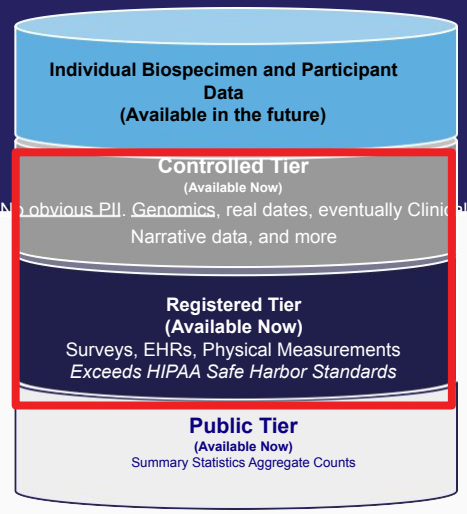
The *All of Us* Researcher Workbench uses a "data passport" model to give registered researchers broad access to the Researcher Workbench rather than granting data access on a **project-by-project** or **question-by-question** basis.



How It Works:

- Registered researchers typically **do not need** institutional IRB approval for their research projects because most researchers will not be conducting human subjects research
- Researchers can register once their institution has signed a Data Use and Registration Agreement (DURA) (see next slide for details).
    - Once registered, researchers can access the Registered and/or Controlled Tiers
- When researchers set up their workspaces, they are required to provide publicly-facing project descriptions on the platform
- Researchers must ensure that their research complies with the program's data use policies

All of Us Researcher Workbench: Access to Row-Level Data for Analysis



STEP 1

CONFIRM YOUR INSTITUTION'S AGREEMENT

Before you can create an account, your institution must have a Data Use and Registration Agreement (DURA) in place with *All of Us*. **Confirm DURA**.

STEP 2

CREATE AN ACCOUNT AND VERIFY IDENTITY

After creating your Researcher Workbench account, you will be asked to verify your identity through login.gov. **Learn more**.

STEP 3

COMPLETE THE MANDATORY TRAINING

The training focuses on conducting responsible and ethical research using the Researcher Workbench. Additional training is required to access the Controlled Tier. **Learn more**.

STEP 4

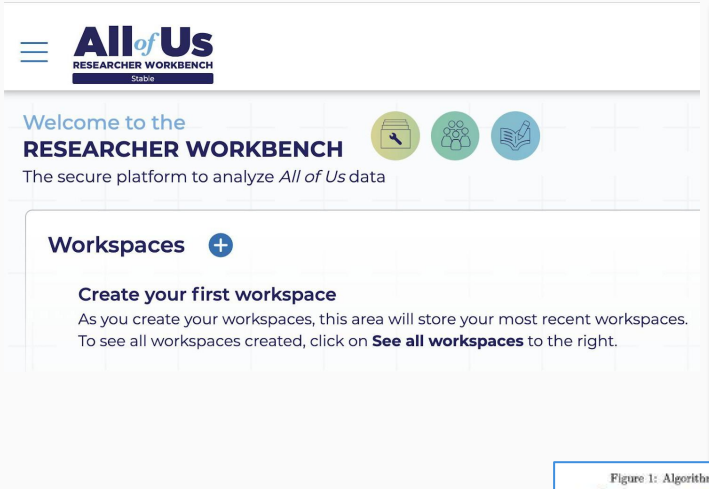
SIGN THE DATA USER CODE OF CONDUCT (DUCC)

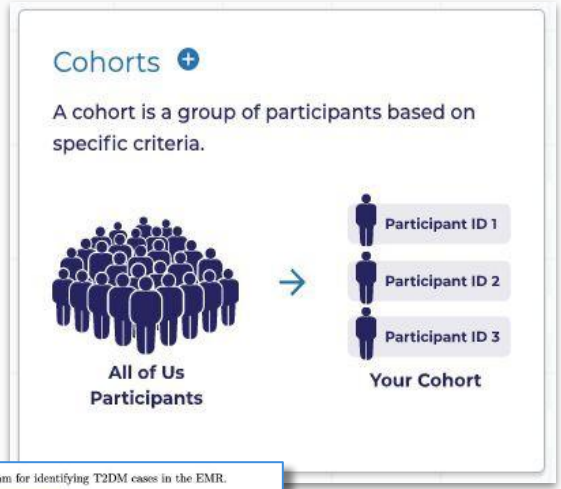
This agreement outlines the program's expectations for researchers who use the Researcher Workbench and describes how program data may be used. **View the DUCC**.

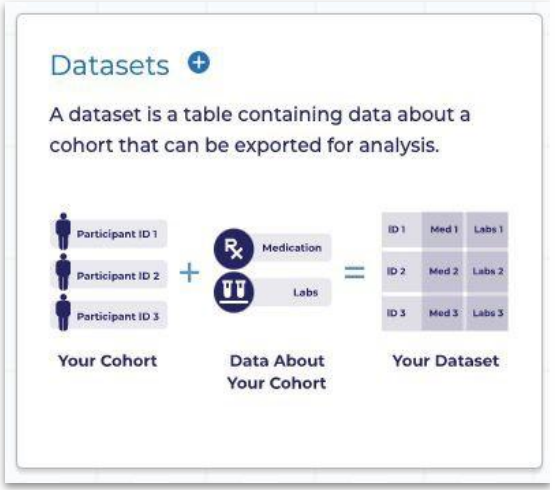
Researcher Workbench

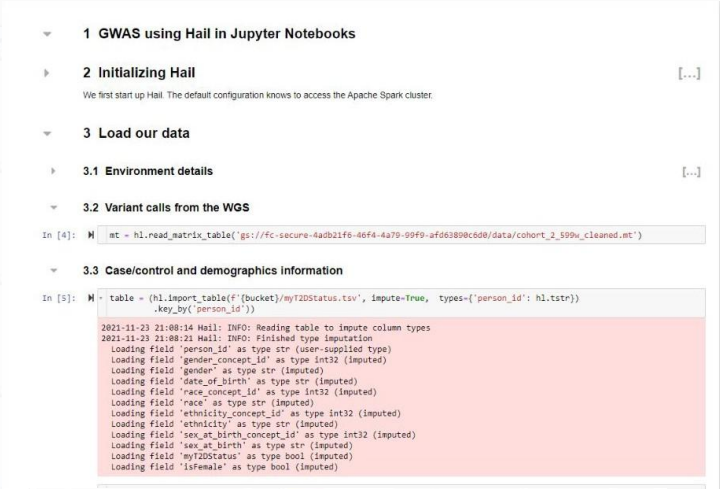
What Does It Look Like To Do an Analysis in *All of Us*?
A Genome Wide Association Study (GWAS) of Type 2 Diabetes

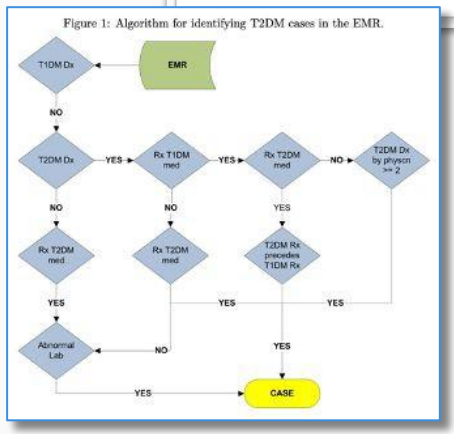
Workspace → **Cohort Builder** → **Concept Set Selector** → **Dataset Builder** → **Jupyter Notebook**



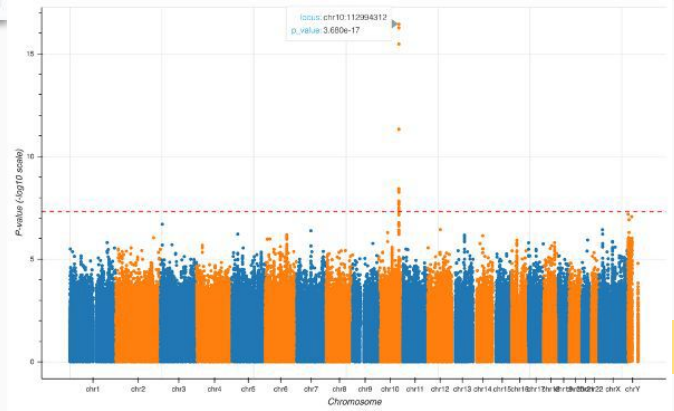








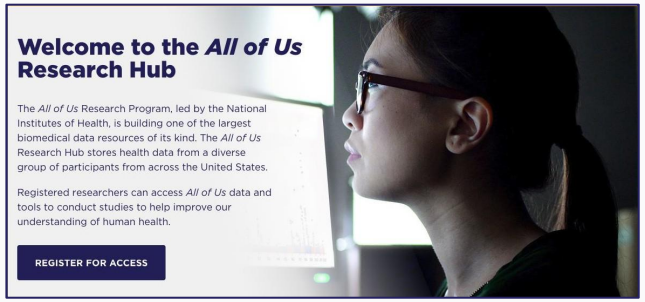
- ~23M SNPs
- ~20k participants
- GWAS runtime of ~20 minutes
- Cost $37



Just a Sampling of Scientific Findings Using *All of Us* Data

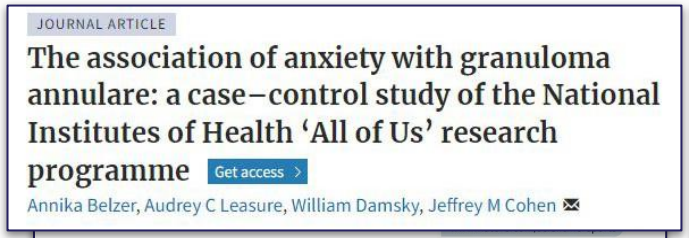
Research Highlights

Researcher Workbench Workspaces



- Stress and Prostate Cancer Among African American Men
- Genetics of Neurodegeneration and Parkinson's Disease
- Diabetes Mellitus, Eye Care, and Neighborhood SDOH
- Predicting Major Adverse Cardiac Events in Heart Failure Patients with COVID-19
- Characteristics Associated with Cervical Cancer Screening by AANHPI Ethnicities
- Classification of Mental Health Disorders and Social Determinants of Health

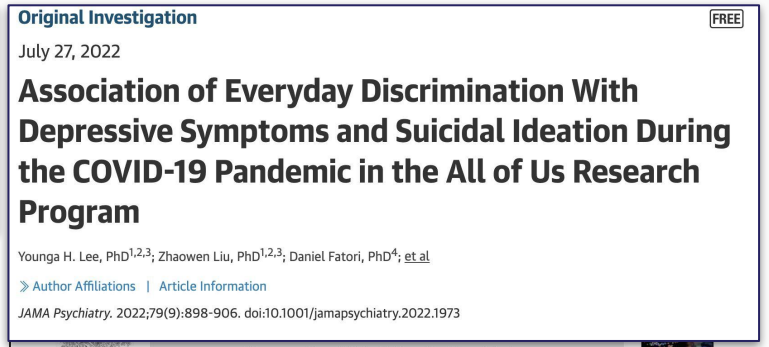
600+ Publications


JOURNAL ARTICLE

The association of anxiety with granuloma annulare: a case–control study of the National Institutes of Health 'All of Us' research programme

Get access

Annika Belzer, Audrey C Leasure, William Damsky, Jeffrey M Cohen


Original Investigation

FREE

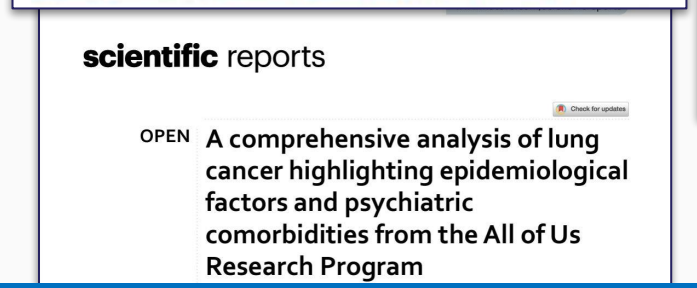
July 27, 2022

Association of Everyday Discrimination With Depressive Symptoms and Suicidal Ideation During the COVID-19 Pandemic in the All of Us Research Program

Younga H. Lee, PhD[1,2,3]; Zhaowen Liu, PhD[1,2,3]; Daniel Fatori, PhD[4]; et al

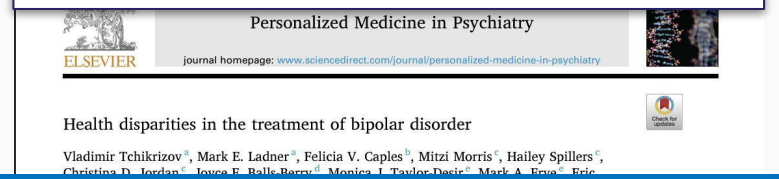
Author Affiliations | Article Information

JAMA Psychiatry. 2022;79(9):898-906. doi:10.1001/jamapsychiatry.2022.1973


scientific reports

OPEN

A comprehensive analysis of lung cancer highlighting epidemiological factors and psychiatric comorbidities from the All of Us Research Program


Personalized Medicine in Psychiatry

ELSEVIER

journal homepage: www.sciencedirect.com/journal/personalized-medicine-in-psychiatry

Health disparities in the treatment of bipolar disorder

Vladimir Tchikrizov[a], Mark E. Ladner[a], Felicia V. Caples[b], Mitzi Morris[c], Hailey Spillers[c], Christina D. Jordan[c], Joyce E. Balls-Berry[d], Monica J. Taylor-Desir[e], Mark A. Frye[e], Eric


Article | Published: 08 June 2023

Social support and depression during a global crisis

Karmel W. Choi, Younga H. Lee, Zhaowen Liu, Daniel Fatori, Joshua R. Bauermeister, Rebecca A. Luh, Cheryl R. Clark, André R. Brunoni, Sarah Bauermeister & Jordan W. Smoller

Nature Mental Health 1, 428–435 (2023) | Cite this article

3166 Accesses | 33 Altmetric | Metrics

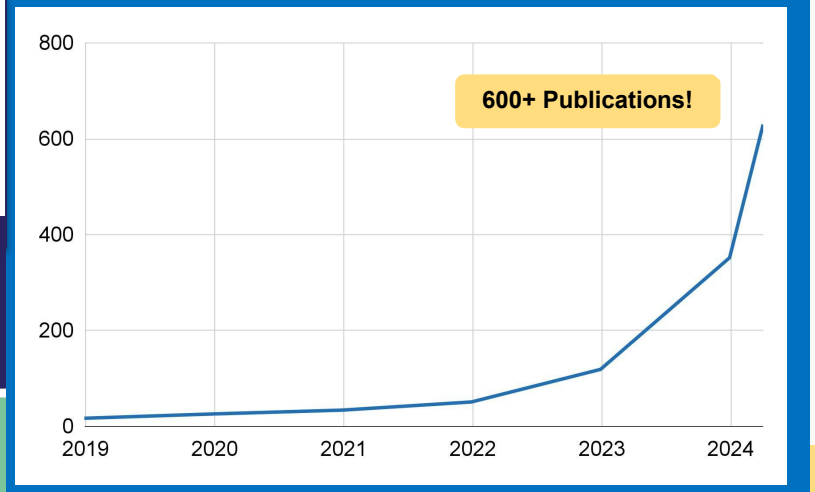
Having any type of social support prevented feelings of depression. Having all three was the most protective.

All of Us RESEARCH PROGRAM

Tangible Support

Positive Social Interactions

Emotional & Informational Support



Examples of the Scientific Impact of *All of Us*

Open Access | Article

Race, Ethnicity, and Pharmacogenomic Variation in the United States and the United Kingdom

by Shivam Sharma [1,2], Leonardo Mariño-Ramírez [2] and I. King Jordan [1,*]

Pharmaceutics **2023**, *15*(7), 1923; https://doi.org/10.3390/pharmaceutics15071923

Received: 12 June 2023 / Revised: 30 June 2023 / Accepted: 5 July 2023 / Published: 11 July 2023

medRxiv — THE PREPRINT SERVER FOR HEALTH SCIENCES

Multi-ancestry genome-wide study in >2.5 million individuals reveals heterogeneity in mechanistic pathways of type 2 diabetes and complications

Ken Suzuki, Konstantinos Hatzikotoulas, Lorraine Southam, Henry J. Taylor, Xianyong Yin, Kim M. Lorenz, Ravi Mandla, Alicia Huerta-Chagoya, Nigel W. Rayner, Ozvan Bocher, S. V. Arruda Ana Luiza de, Kyuto Sonehara, Shinichi Namba, Simon S. K. Lee, Michael H. Preuss, Lauren E. Petty, Philip Schroeder, Brett Vanderwerff, Mart Kals,

Article | Open Access | Published: 10 October 2022

Association of step counts over time with the risk of chronic disease in the *All of Us* Research Program

Hiral Master, Jeffrey Annis, Shi Huang, Joshua A. Beckman, Francis Ratsimbazafy, Kayla Marginean, Robert Carroll, Karthik Natarajan, Frank E. Harrell, Dan M. Roden, Paul Harris & Evan L. Brittain

Nature Medicine **28**, 2301–2308 (2022) | Cite this article

AJHG — Supports open access

ARTICLE | VOLUME 110, ISSUE 2, P228-239, FEBRUARY 02, 2023 | Download Full Issue

Functional interpretation, cataloging, and analysis of 1,341 glucose-6-phosphate dehydrogenase variants

Renee C. Geck • Nicholas R. Powell • Maitreya J. Dunham

Open Access • Published: January 20, 2023 • DOI: https://doi.org/10

Research Square — Search preprints

Brief Communication

Quantifying physical activity needed to mitigate genetic risk for obesity

Iide Han, Jeffrey Annis, Hiral Master, Andrew Hughes, Dan Roden, and 3 more

Research article | Open Access | Published: 11 June 2023

Using machine learning to develop a clinical prediction model for SSRI-associated bleeding: a feasibility study

Jatin Goyal, Ding Quan Ng, Kevin Zhang, Alexandre Chan, Joyce Lee, Kai Zheng, Keri Hurley-Kim, Lee Nguyen, Lu He, Megan Nguyen, Sarah McBane, Wei Li & Christine Luu Cadiz

BMC Medical Informatics and Decision Making **23**, Article number: 105 (2023) | Cite this article

Original Investigation | Equity, Diversity, and Inclusion

July 31, 2023

Prevalence of 12 Common Health Conditions in Sexual and Gender Minority Participants in the All of Us Research Program

Nguyen K. Tran, PhD, MPH[1,2]; Mitchell R. Lunn, MD, MAS[1,2,3]; Claire E. Schulkey, PhD[4]; Samantha Tesfaye, BA; Siddhartha Nambiar, PhD[5]; Snigdhansu Chatterjee, PhD[6]; Dawn Kozlowski, MEd[7]; Paula Lozano, PhD[8,9]; Fornessa T. Randal, MCRP[8,9]; Yicklun Mo, MSW[8,9]; Siya Qi, MS[8,9]; Ell Hundertmark, BS[1,10]; Chloe Eastburn, BA[1,11]; Anthony T. Pho, PhD[1,2]; Zubin Dastur, MS, MPH[1,10]; Micah E. Lubensky, PhD[1,12]; Annesa Flentje, PhD[1,12,13]; Juno Obedin-Maliver, MD, MPH, MAS[1,3,10]

Otolaryngology–Head and Neck Surgery — American Academy of Otolaryngology–Head and Neck Surgery Foundation

Original Research

Hearing Loss and Sociodemographic Barriers to Health Care Access Using the *All of Us* Research Program

Luis E. Cortina BS, Andrew Amini BS, Jalen Benson BS, Victoria W. Huang MD, James G. Naples MD

Original Investigation | Oncology

August 10, 2023

JAMA Network

Alcohol Consumption Among Adults With a Cancer Diagnosis in the All of Us Research Program

Mengyao Shi, MBBS, MPH[1]; Chongliang Luo, PhD[1]; Oluseye K. Oduyale, MD[1]; et al

Nuclear genetic control of mtDNA copy number and heteroplasmy in humans

Rahul Gupta, Masahiro Kanai, Timothy J. Durham, Kristin Tsuo, Jason G. McCoy, Anna V. Kotrys, Wei Zhou, Patrick F. Chinnery, Konrad J. Karczewski, Sarah E. Calvo, Benjamin M. Neale & Vamsi K. Mootha

Nature **620**, 839–848 (2023) | Cite this article

nature

International Journal of Dermatology

Correspondence

The association of cutaneous squamous cell carcinoma and basal cell carcinoma with solid organ transplantation: a cross-sectional study of the *All Of Us* Research Program

Annika Belzer BS, Audrey C. Leasure MD, MHS, Jeffrey M. Cohen MD, Sara H. Perkins MD

First published: 05 May 2023 | https://doi.org/10.1111/ijd.16700

Higher Hospital Frailty Risk Score Is Associated With Increased Risk of Stroke: Observational and Genetic Analyses

Daniela Renedo, Julián N. Acosta, Andrew B. Koo, Cyprien Rivier, Nanthiya Sujijantarat, Adam de Havenon, Richa Sharma, Thomas M. Gill, Kevin N. Sheth, Guido J. Falcone and Charles C. Matouk

Originally published 22 May 2023 | https://doi.org/10.1161/STROKEAHA.122.041891 | Stroke. 2023;54:1538–1547

PLOS ONE

Family and personal history of cancer in the *All of Us* research program for precision medicine

Lauryn Keeler Bruce, Paulina Paul, Katherine K. Kim, Jihoon Kim, Theresa H. M. Keegan, Robert A. Hiatt, Lucila Ohno-Machado, On behalf of the All of Us Research Program Investigators

Published: July 17, 2023 • https://doi.org/10.1371/journal.pone.0288496

Clinical Pharmacology & Therapeutics

Article

Drug-Induced Liver Injury with Commonly Used Antibiotics in the *All of Us* Research Program

Shaopeng Gu, Govarthanan Rajendiran, Kennedy Forest, Tam C. Tran, Joshua C. Denny, Eric A. Larson, Russell A. Wilke

First published: 07 May 2023 | https://doi.org/10.1002/cpt.2930

researchallofus.org/publications/

Estimates of data in CDR v8, being prepared for release.

Data types	Count (and %) of participants in CDR		Participant count change (%)
	CDRv7 (Previous)	CDRv8 (Current)	
Any Survey	413,376 (99.98%)	633,547 (100.0%)	▲ 53.26%
PM	337,540 (81.6%)	509,001 (80.3%)	▲ 50.80%
EHR	287,012 (69.4%)	393,596 (62.1%)	▲ 37.14%
Fitbit	**15,607 (3.8%)**	**59,018 (9.3%)**	**▲ 278.15%**
Genomics - Short Read WGS	245,388 (59.4%)	414,830 (65.5%)	▲ 69.05%
Genomics - Array	312,925 (75.7%)	447,278 (70.6%)	▲ 42.94%
Genomics - Long read WGS	1,027 (0.25%)	2,778 (0.44%)	▲ 170.50%
Genomics - Structural Variant	11,390 (2.8%)	97,061 (15.3%)	▲ 752.16%
Total Genomics (WGS OR Array)	312,925 (75.7%)	447,281 (70.7%)	▲ 42.94%
Both Genomics (WGS & Array)	245,388 (59.4%)	414,830 (65.5%)	▲ 69.05%
Total participants	413,457	633,547	▲ 53.23%

(Red = percentage of the dataset went down from prior release)

Curated Genomic Data Overview

One of the biggest genomic releases of short read WGS (srWGS)!

- 414,830 samples in srWGS joint callset (DRAGEN 3.7) with over one billion variant sites in both blood and saliva samples → 40% to 1M participants!
- Now including AI/AN participants
- Save effort for researchers by offering common slicing of the genomic region:
  - Exome, AC/AF threshold (common), and ClinVar variants
  - New!: Challenging Medically Relevant Genes (small) callset: contains improved variant calling in a subset of clinically relevant genes to improve accuracy

Ongoing quality control efforts

- Report of no appreciable batch effects across blood vs saliva
- Updated auxiliary, QC, and variant annotation files

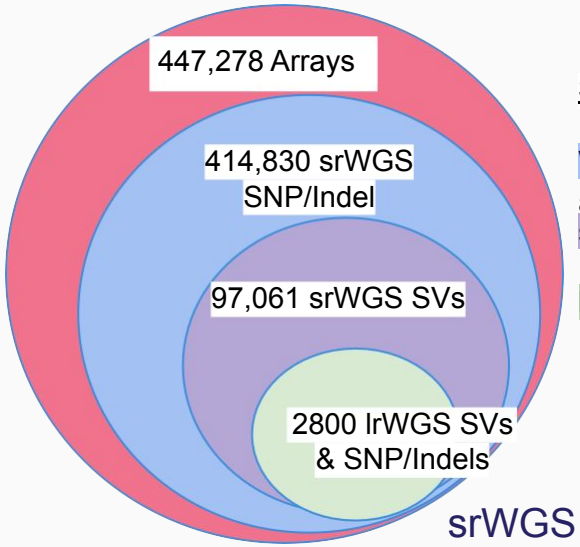
New additional auxiliary data for all srWGS samples

- Pharmacogenomics (PGx) - identify genetic markers associated with drug efficacy or toxicity
- Admixture estimation - improve methods using continuous ancestry estimates, instead of categorical.

Additional structural variants and long reads!

- Structural variants on 97,061 short read WGS (VCFs)
- 2800 long read samples (BAMs, and VCFs for SNP, Indel, and Structural

Data Types	SNP/Indel	Structural Variants	Raw data
Short Read WGS	Hail VDS, Joint VCFs/MT/bgen/ PLINK for subsets of genome (n=415k)	Joint VCF (n=97k) (v8 refresh of off cycle release in Q2 2024)	Aligned reads (cram) (n=415k)
Long Read WGS	Joint VCF, ssVCF (n=2860)	ssVCF (n=2860)	Aligned reads (bam) (n=2860)
Array	VCF, Hail, PLINK (n=447k)	None	Intensity (iDat) (n=447k)



Subset Structure Data Corpus

WGS are subset of array.

srWGS SVs is a subset of srWGS SNP/Indel.

lrWGS is a subset of srWGS SVs.

srWGS SNP/Indel (**+67% from v7**)
srWGS SV (**+790% from v7**)
lrWGS (**+150%**)
Arrays (**+41%**)

All of Us Data Roadmap

In the coming years, *All of Us* expects to enroll **at least one million people** from across the United States, adding new data and data types to the Workbench.

https://allof-us.org/DataRoadmap

Data availability and access timelines are estimates and subject to change.

Data Roadmap

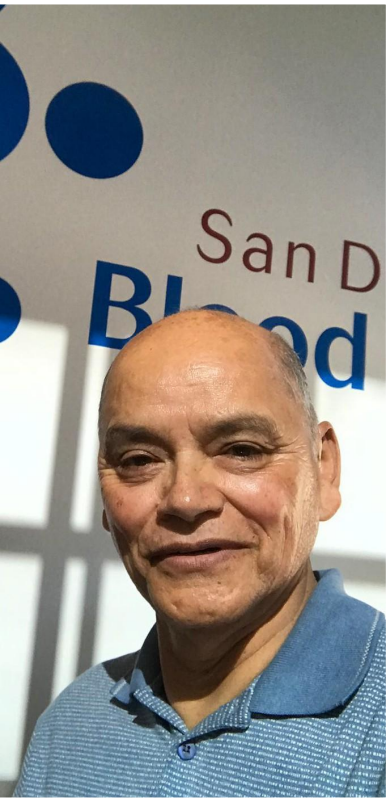
In the coming years, *All of Us* will enroll more participants and make more types of data available, as funding allows. Data availability and access timelines are estimates and subject to change.

	Available as of early 2024	Planned for late 2024	Under consideration for future years
Surveys	• 410k+ participants with data from The Basics • Additional data from: » Overall Health » Lifestyle » Health Care Access and Utilization » Personal and Family Health History* » Social Determinants of Health » COVID-19 Participant Experience (COPE) (responses closed) » Minute Survey on COVID-19 Vaccines (responses closed)	• 630k+ participants with data from The Basics • Questions about life functioning incorporated into The Basics • More granular participant-reported population descriptors	• Initial data from Emotional Health History and Well-Being • Initial data from Behavioral Health and Personality
Physical Measurements	• 328k+ physical measurements collected at health care provider organizations as part of enrollment: » Height » Weight » BMI » Hip circumference » Waist circumference » Blood pressure » Heart rate • Physical measurements recorded in EHR data	• Participant-reported height and weight	⋯→
Genomics	• 312k+ participants with array data • 245k participants with short-read whole genome sequencing data (srWGS)** » 98k+ participants with structural variant data » All by All tables (genome- and phenome-wide analysis) • 1k+ participants with long-read whole genome sequencing data (lrWGS)	• 440k+ participants with array data • 410k+ participants with srWGS data including updated auxiliary data: » Admixture estimates » Pharmacogenomics: Star allele calling » PGEN format • 2.5k+ participants with lrWGS data	• 500k+ srWGS • 10k+ participants with mult-omics data, including: » RNA sequencing » Proteomics » lrWGS
Data Linkages	• American Community Survey data linked at 3-digit ZIP code level	⋯→	• Mortality • Environmental Justice Index • Claims • Imaging
Electronic Health Records (EHR)	• Health care provider organization-provided EHR	• Participant-provided EHR	• Extracted notes
Digital Health Technologies	• Fitbit (participant-provided devices): » Heart rate (zone summary and minute-level) » Activity (daily summary) » Activity (intraday steps, minute-level) » Sleep (daily summary) » Device data (e.g., device type, battery level, and date last synced, and more)	• Fitbit (program-distributed devices): » Same data elements as participant-provided devices	• Apple HealthKit data
Ancillary Studies	• COVID-19 serology data	⋯→	• Exploring the Mind task data • Initial data from Nutrition for Precision Health • Exposomics

All of Us

AllofUs.NIH.gov
JoinAllofUs.org

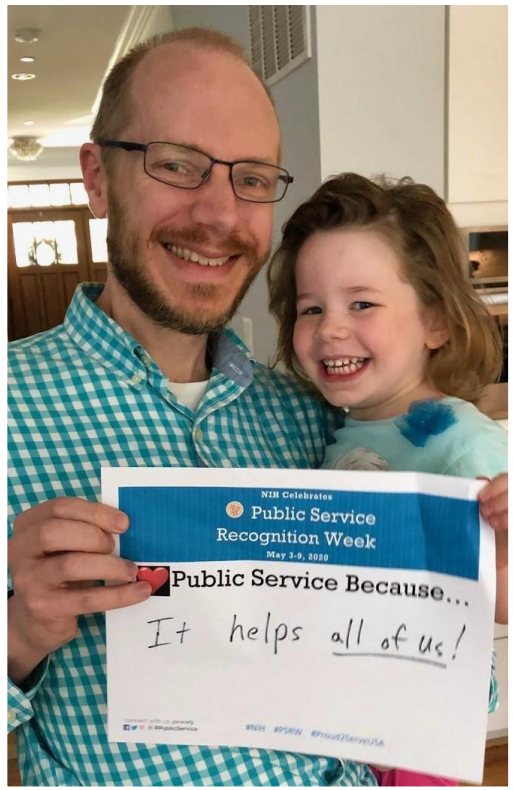
ResearchAllofUs.org



Thank you!

- Andrea Ramirez, MD, MS, Chief Data Officer

@AllofUsResearch
#JoinAllofUs



Thank you to our 802,000+ participants!

BREAK
Back at 4pm

Keynote- Can AI Save Lives?

Tom Kalil is the CEO of Renaissance Philanthropy. Tom served in the White House for two presidents (Obama and Clinton) and in collaboration with his team worked with the Senate to give every federal agency the authority to support incentive prizes for up to $50 million.

Day 1 Summary / Next Steps

DINNER

Friday, October 18

08:00 AM	**BREAKFAST** | Timchenko
09:00 AM	**Navigating Regulatory Landscape: AI Compliance in Health Data Sharing** | Corning • Jeffrey Smith (ONC) • Kevin Chaney (AHRQ) • Ranjani Ramamurthy (Global Health Labs) • Ram Sriram (NIST)
10:30 AM	**BREAK** | Timchenko
11:00 AM	**Policy/Agenda Writing Session** | Corning
12:00 PM	**Next Steps** | Corning
12:30 PM	**LUNCH (To Go Box)** | Timchenko
01:00 PM	**ADJOURN** | Corning

What to Expect This Morning

Final Panel on Navigating Regulatory Landscape

Collaborative work time for report generation content & report out to the group

Next Steps and Goodbyes!

Navigating Regulatory Landscape: AI Compliance in Health Data Sharing

CRA-I
Computing Research Association
Industry

- Jeffrey Smith (ONC)
- Kevin Chaney (AHRQ)
- Ranjani Ramamurthy (Global Health Labs)
- Ram Sriram (NIST)

Moderator: Jessica Pater

BREAK

Policy/Agenda Writing Session

Next Steps

Lunch & Adjourn

CRA-I
Computing Research Association
Industry

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