Patient Generated Health Data

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Director of Participant Platforms

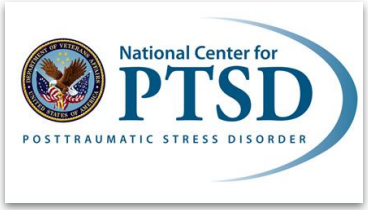
Research for Lyme Infection-Associated Chronic Illnesses Treatment:
Broadening the Lens – Committee Meeting
The National Academies of Sciences, Engineering, & Medicine

July 11, 2024

National Institutes of Health

Brief Background

Director of Participant Platforms
All of Us Research Program
National Institutes of Health



Mobile UX Research Lead
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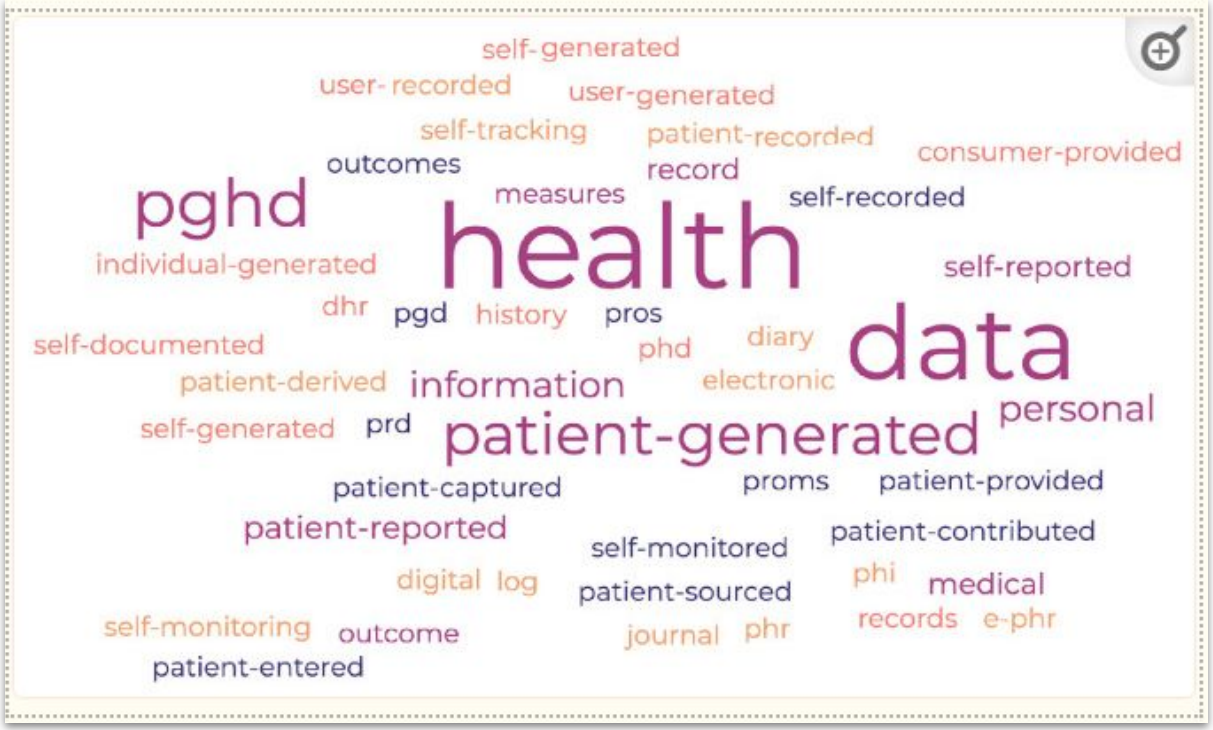
Public Digital Health Innovation Program
National Center for PTSD (NCPTSD)
U.S Department of Veterans Affairs

Overview

1. Brief characterization of patient generated health data
2. Examples of patient generated data from the *All of Us* Research Program
3. Key considerations for research and real-world applications

What is Patient Generated Health Data?



Source: Khatiwada, P., Yang, B., Lin, J. C., & Blobel, B. (2024). Patient-Generated Health Data (PGHD): Understanding, Requirements, Challenges, and Existing Techniques for Data Security and Privacy. Journal of personalized medicine, 14(3), 282. https://doi.org/10.3390/jpm14030282

Defining Patient Generated Data

- Patient-generated health data (PGHD) are health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.
- Patients (or proxies), not providers, responsible for capturing
- Patients decide how to share data with providers and additional parties
- PGHD include, but are not limited to:
    - health history
    - treatment history
    - biometric data
    - symptoms
    - lifestyle choices & behaviors

Source: The Office of the National Coordinator for Health Information Technology (ONC). https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-generated-health-data-pghd

Patient Generated Data Types

Source: Khatiwada, P., Yang, B., Lin, J. C., & Blobel, B. (2024). Patient-Generated Health Data (PGHD): Understanding, Requirements, Challenges, and Existing Techniques for Data Security and Privacy. Journal of personalized medicine, 14(3), 282. https://doi.org/10.3390/jpm14030282

Potential Benefits of Patient Generated Health Data in Research & Care

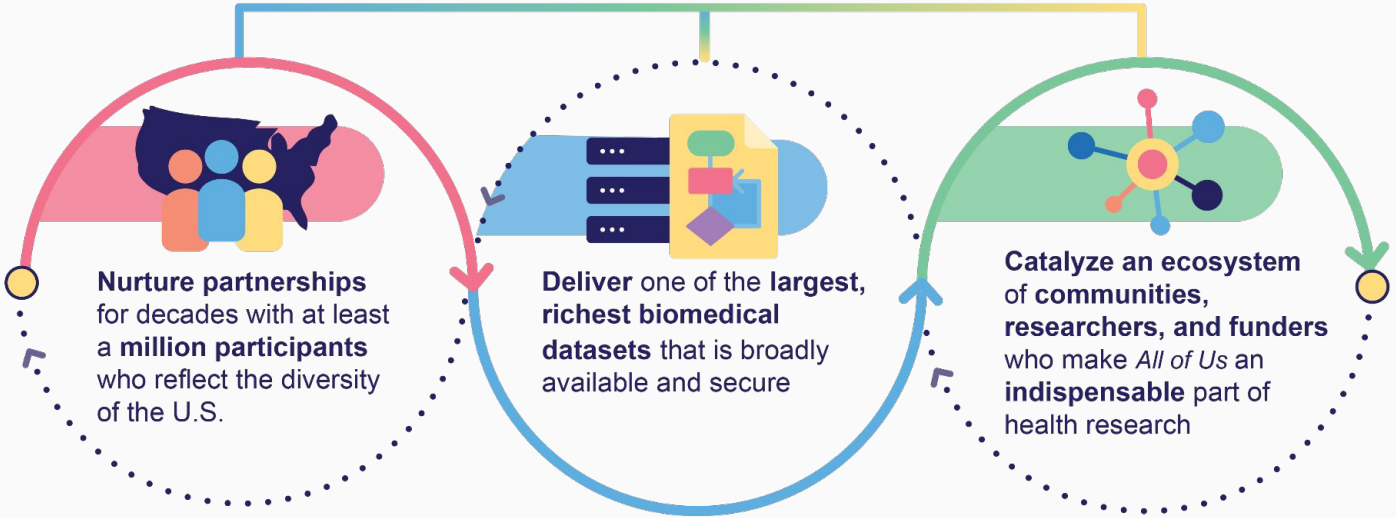
- Gather important information about how patients are doing between medical visits.
- Allow for better patient engagement.
- Provide information for use in shared decision-making about preventive and chronic care management.
- Offer potential cost savings and improvements in quality, care coordination, and patient safety.

Source: Nazi, K.M., Newton, T. & Armstrong, C.M. Unleashing the Potential for Patient-Generated Health Data (PGHD). J GEN INTERN MED 39 (Suppl 1), 9–13 (2024). https://doi.org/10.1007/s11606-023-08461-4

Examples of Patient Generated Data: The *All of Us* Research Program

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

818K+ Participants Enrolled Across the Country

Participant Enrollment

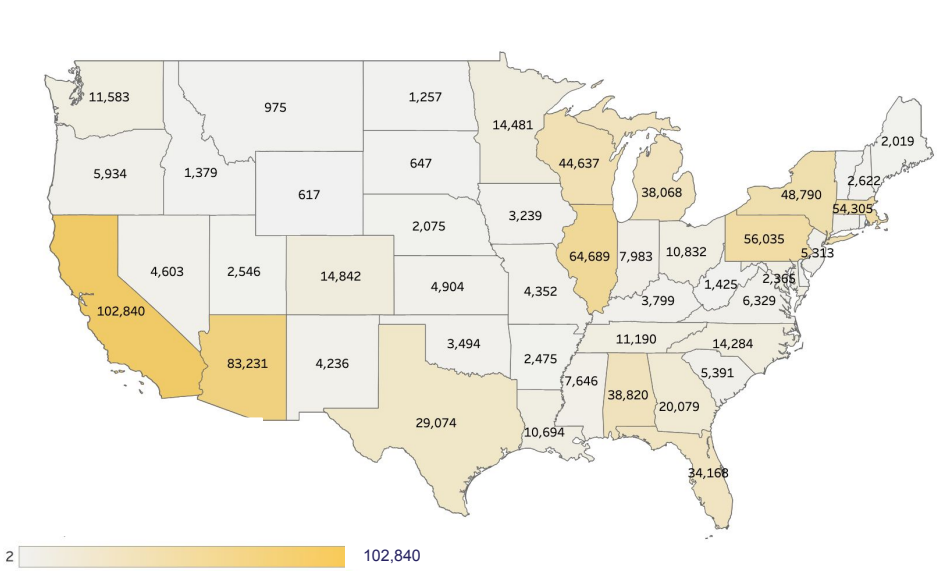
818,000+
Participants

451,000+
Electronic Health Records

559,000+
Participants who have completed initial steps of the program

578,000+
Biosamples

Map of Consented Participants



Hawaii
1,420

Alaska
686

Puerto Rico
5,384

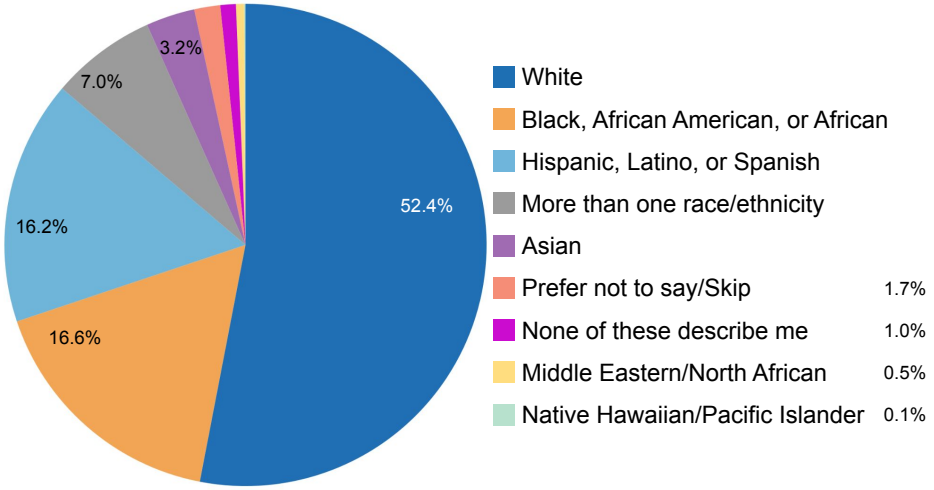
Guam
59

Plus >5,610 consented participants across U.S. territories

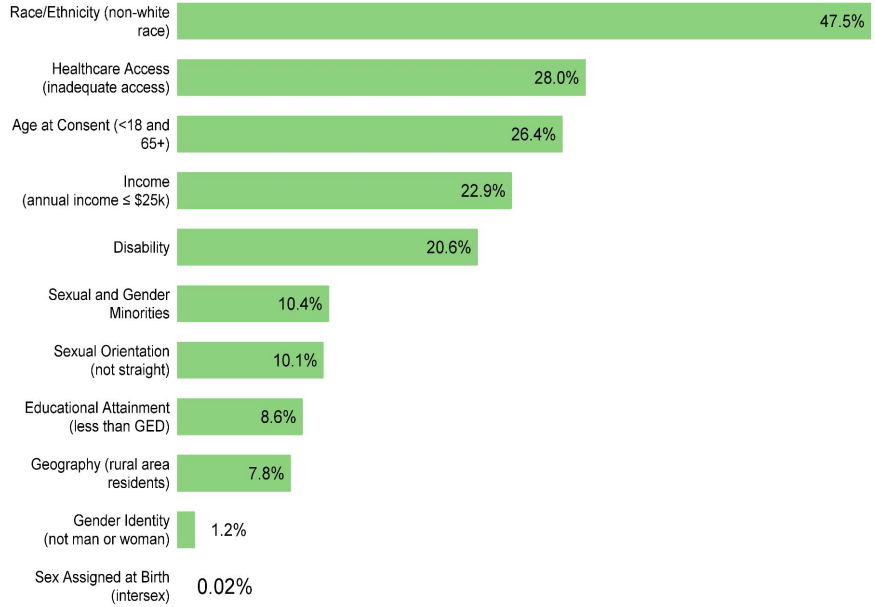
Numbers as of July 2, 2024

Participant Diversity

Race & Ethnicity of Participants



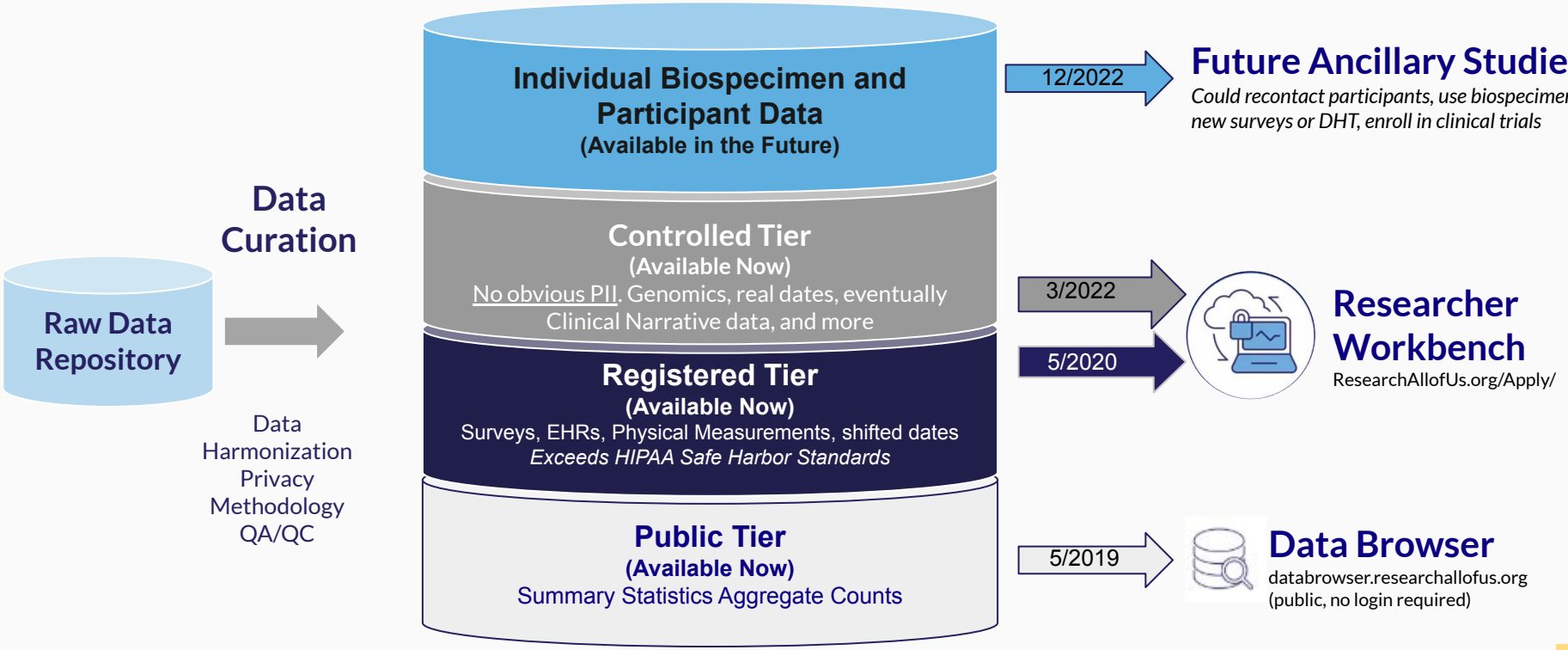
UBR Category



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

Numbers current as of July 2, 2024

Researcher Data Access

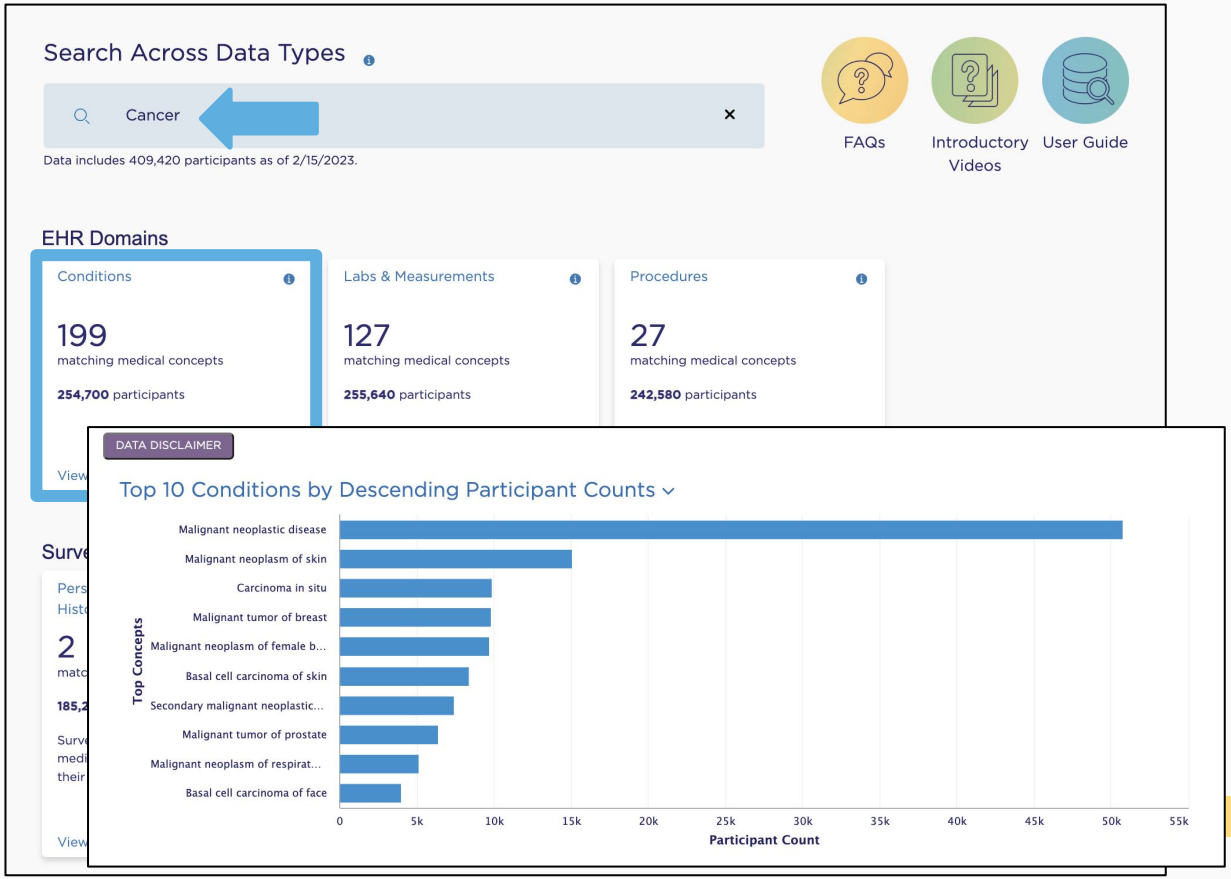


All of Us Research Hub: Public Data Browser

Summary statistics of:

- EHR Data (Conditions, Drug Exposures, Lab & Measurements, Procedures)
- Genomic Variants
- Survey Questions (including COVID-19 surveys)
- Physical Measurements
- **Open Access (no login required)**

Data Browser



Public Data Browser: Fitbit Data

Home > Data Browser

Data Browser

Browse aggregate-level data contributed by *All of Us* research participants. Data are derived from multiple data sources. To protect participant privacy, we have removed personal identifiers, rounded aggregate data to counts of 20, and only included summary demographic information. Individual-level data are available for analysis in the Researcher Workbench.

Search Across Data Types

Keyword Search

Data includes 409,420 participants as of 2/15/2023.

FAQs | Introductory Videos | User Guide

EHR Domains

Conditions
25,638 medical concepts
254,700 participants
View Conditions

Drug Exposures
29,865 medical concepts
239,740 participants
View Drug Exposures

Labs & Measurements
16,216 medical concepts
252,980 participants
View Labs & Measurements

Procedures
30,328 medical concepts
242,580 participants
View Procedures

Genomics

SNP/Indel Variants
245,400 Participants in Short-Read Whole Genome Sequencing (WGS) dataset
1,074,881,214 SNP/Indel Variants
View SNP/Indel Variants

Genomic data only in Researcher Workbench
1,040 participants in the Long-Read WGS dataset
11,400 participants in the Short-Read WGS Structural Variants dataset
312,940 participants in the Genotyping Arrays dataset
Register for access

Measurements and Wearables

Physical Measurements
8 Physical Measurements
337,540 participants
Participants have the option to provide a standard set of physical measurements.
View Physical Measurements

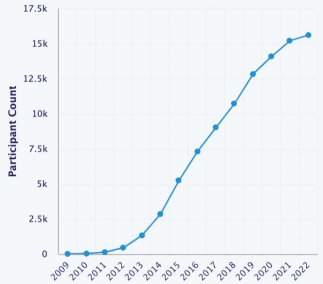
Fitbit
6 Fitbit Measurements
15,620 participants
Fitbit data includes heart rate and activity summaries.
View Fitbit

Fitbit Data

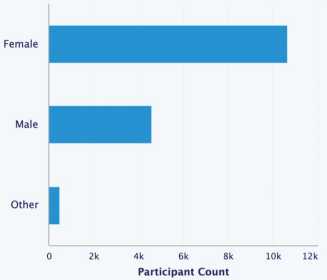
- **Any Fitbit Data**
- Heart Rate By Zone Summary
- Heart Rate (Minute-Level)
- Activity (Daily Summary)
- Activity Intraday Steps (Minute-Level)
- Sleep Daily Summary
- Sleep Level (Sequence By Level)

Any Fitbit Data

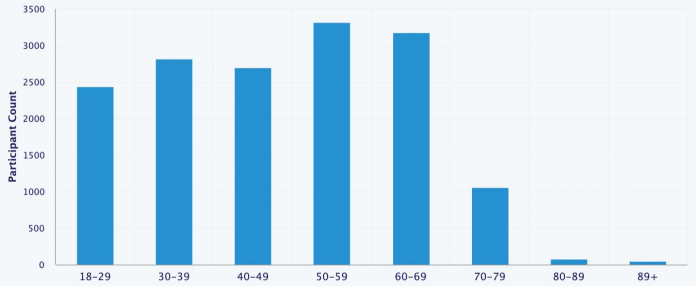
Participants with any Fitbit data



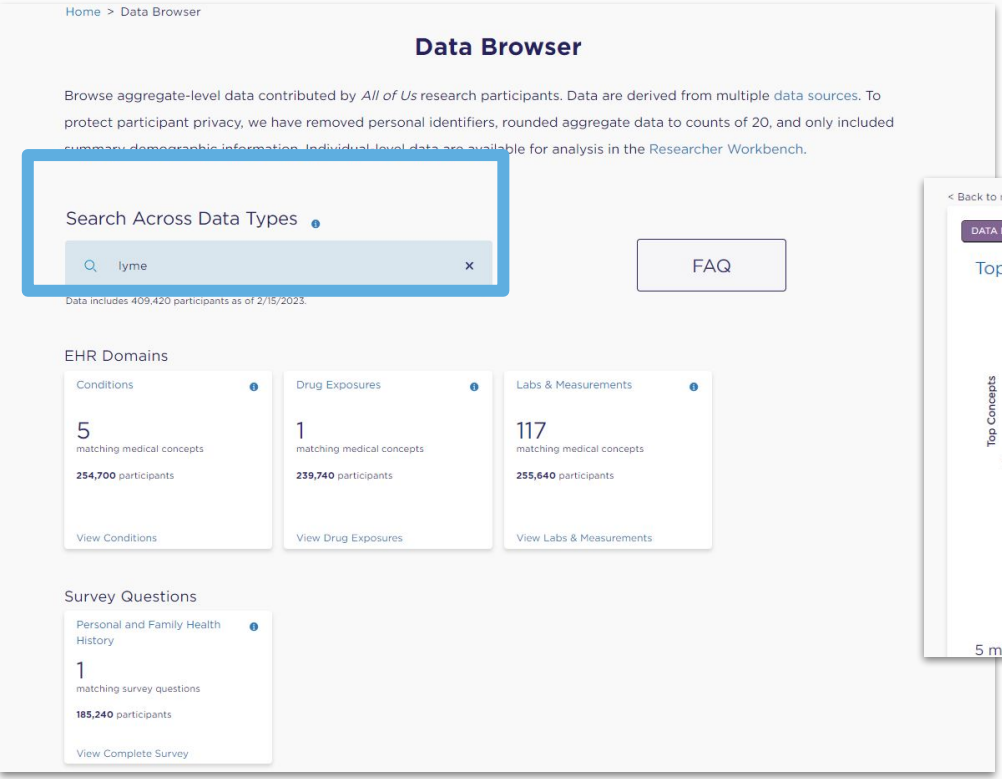
Sex assigned at birth

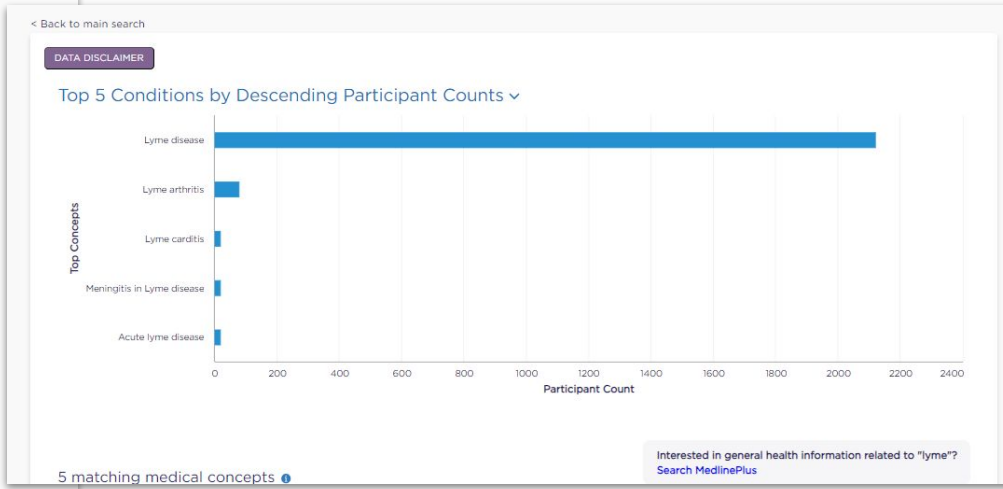


Age at data collection



Public Data Browser: Lyme Disease-Related Data





Key Considerations for Leveraging Patient Generated Health Data

Consideration 1: Centrality of Health Equity and Access

- Cannot be an afterthought - must be by design
- Research teams & all partners should be mission-aligned
- Accessibility of products and tools for data capture should go beyond the bare minimum
  - Must be designed to promote health literacy & engagement
  - Meeting Americans with Disabilities Act (ADA) Compliance and Web Content Accessibility Guidelines (WCAG) necessary but not sufficient for digital

Consideration 2: Create and Iterate via Participatory Methodologies

- Co-design: Diverse voices included directly in all aspects of the the design process (e.g., defining the problem space, possible solutions, strategies for implementation)
- Iterate early and often

Consideration 3: Cultivate Multidisciplinary Teams

- Greater variety of disciplines, the better
  - Increased likelihood of better data & real-world integrations
- Will likely need to spend time creating shared language & understanding

Consideration 4: Ethical Approaches to Data Collection and Uses

- Informed consent is key, especially among historically underserved and/or vulnerable populations
- Focus on the six Vs (Wesson et al., 2022)
  - virtuosity (equity and ethics of big data)
  - volume (size of data)
  - veracity (trustworthiness of data)
  - variety (types of data)
  - value (usefulness of data for decision-making)
  - velocity (speed with which data are collected/processed)

Concluding Thoughts

- Patient generated health data has great potential - but hasn't been fully leveraged yet
- Existing, diverse, data sets are available to researchers
- Key considerations to guide the use of PGHD include:
  - Centrality of health equity
  - Role of participatory methodologies & iteration
  - Need for multidisciplinary teams
  - Ethical collection and uses of the data

Thank You!

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All of Us RESEARCH PROGRAM

NIH National Institutes of Health

AllofUs.nih.gov

@AllofUsResearch
#JoinAllofUs