

Wearable Sensors and the Future of Health



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Gold Lab Symposium 2023

Disclaimer(s)

Views and ideas are my own, not those of any prior (or future) employers.

Use of genAI tools are referenced accordingly.

BLUF and Outline

BLUF: An “n of 1” approach is needed to link data from digital health tech to useful applications. Wearables as the new “omic.”

- What are DHTs?
- Why do I care?
- Where are we now?
- What could go wrong?
- What is a future vision of health with DHT, and how do we get there?

Key themes



- Data are the **foundation** for discovery and insight
- Technology can enable and is only useful if **people** use it
- Cross-sector **partnerships** (it takes a village)
- Proactive **security** especially for emerging technology

What is it?

What do I mean by DHT?

Digital health technology is the use of digital **devices & technologies** to understand **health, wellness, and physiology**

- Where 1s and 0s meet flesh and blood
- Digital signals that capture health-related signals (digital biomarkers)
- Devices can be wearable devices like watches, implanted, environmental sensors, etc.; could also be software/apps

Data / information from DHTs

Raw

- External sensors
 - heart rhythm, motion/activity, electrodermal activity, temperature, spO2, blood pressure, respiration, sweat, audio, ...
- Implanted sensors
 - Molecules, including glucose, lactate, MBL, O2, ...
- Ingestible sensors
 - smart pills, cameras
- Environmental sensors
 - audio, cough specific signatures, gait
- User-input / data / information
 - diet, weight, water consumption, ...

Processed (inferred)

- Activity
 - Steps (10,000K / day)
- HR summary stats
 - Resting HR
 - HRV
- Cardio anomaly
 - AFib
 - Maybe high BP is next?
- Sleep
- Hydration status
- "Stress"



Why do I care?

Prevent the next pandemic portfolio @ DARPA

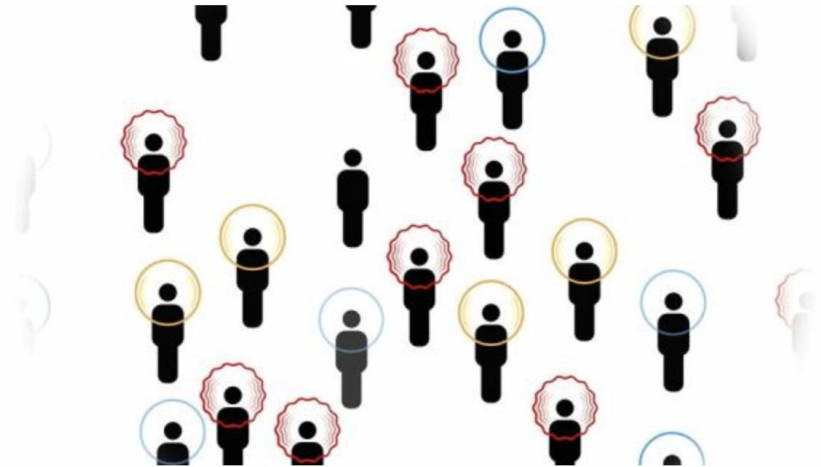
DARPA Prometheus Program

- Multi-omic, multi-pathogen, multi-host
- Telemetry and wearables
- Human challenge for influenza
- Signals of infection as soon as possible (individual level)
- Wearables had earliest signal - resting HR, HR variability, sleep offset

Predicting Contagiousness to Limit the Spread of Disease

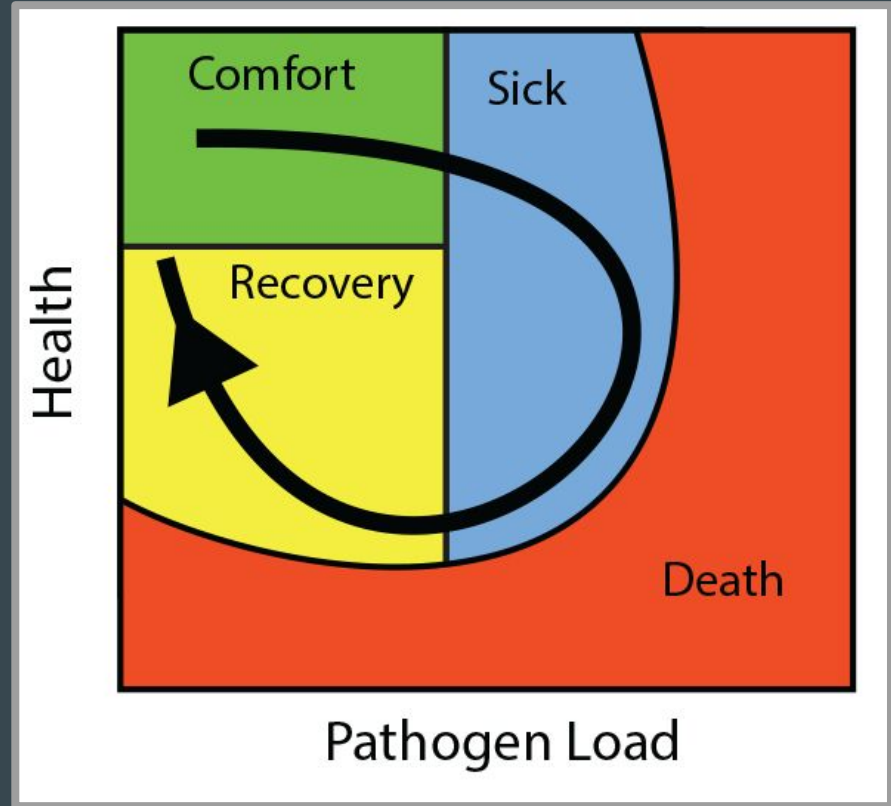
New program aims to identify prognostic biomarkers that indicate contagiousness following infection but before symptoms appear

OUTREACH@DARPA.MIL
6/13/2016



It's all in the data

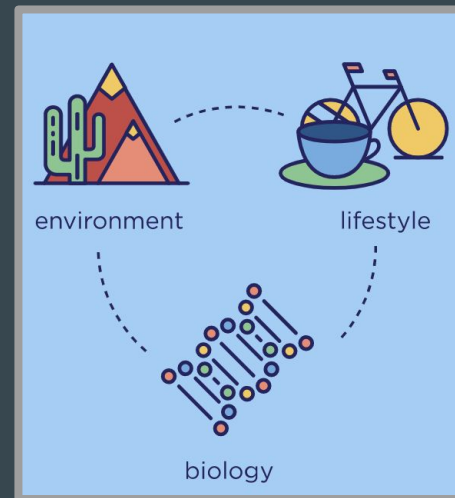
- Systems biology / physiology is dynamic
- Need **continuous vs discrete** data points
- Look at deviations from a baseline / threshold
- Often looping patterns or oscillations
- Can then infer data density that you need to be informative
- Molecular measures are usually invasive and have other challenges



NIH's *All of Us* Research Program



- Goal is 1 million diverse participants
- DHT address environment and lifestyle



The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine

Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH

Data Now Available in the Researcher Workbench



413,350+
Survey Responses



337,500+
Physical Measurements



312,900+
Genotyping Arrays



287,000+
Electronic Health Records



245,350+
Whole Genome Sequences



15,600+
Fitbit Records



1,000+
Long-Read Sequences

Fitbit data in NIH's *All of Us* Research Program



Heart Rate By
Zone Summary



Heart Rate
(Minute-Level)



Activity (Daily
Summary)



Activity Intraday
Steps (Minute-
Level)



912

[Association of **step counts** over time with the risk of chronic disease in the *All of Us* Research Program.](#)

Master, H., Annis, J., Huang, S. et al. (2022) *Nature Medicine*



473

[Association of longitudinal **activity measures** and diabetes risk: an analysis from the NIH *All of Us* Research Program.](#)

Perry, A (2022) *The Journal of Clinical Endocrinology & Metabolism*



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[Revisiting the Latino Epidemiologic Paradox: an analysis of data from the *All of Us* Research Program.](#)

Montanez-Valverde R, et al. (2022) *Journal of General Internal Medicine*



137

[Association of everyday discrimination with depressive symptoms and suicidal ideation during the COVID-19 pandemic in the *All of Us* Research Program.](#)

Lee Younga H, et al. (2022) *JAMA Psychiatry*



117

[Wearable **fitness tracker** use in federally qualified health center patients: strategies to improve the health of all of us using digital health devices.](#)

Holko Michelle, et al. (2022) *NPJ Digital Medicine* (1) 53



AltMetric is an indicator of the volume and type of attention a research publication has received. The donut score reports identify how much and what type of attention a publication received.



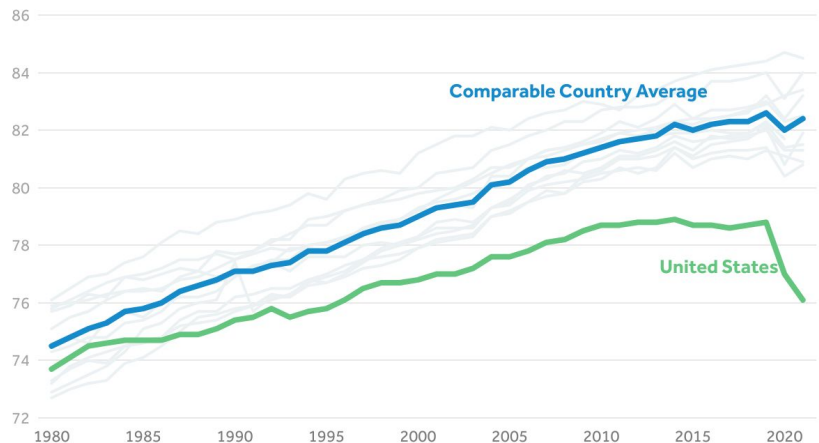
Where are we?

Some context: genomic sequencing tech



Some context: life expectancy in the US is trending down while spending is outsized

Life expectancy at birth in years, 1980-2021



Notes: Comparable countries include: Australia, Austria, Belgium, Canada (except for 2021), France, Germany, Japan, the Netherlands, Sweden, Switzerland, and the U.K. See Methods section of "How does U.S. life expectancy compare to other countries?"

Source: KFF analysis of CDC, OECD, Japanese Ministry of Health, Labour, and Welfare, Australian Bureau of Statistics, and UK Office for Health Improvement and Disparities data

Peterson-KFF
Health System Tracker

Health consumption expenditures per capita, U.S. dollars, PPP adjusted, 2021 or nearest year



Notes: U.S. value obtained from National Health Expenditure data. Data from Australia, Belgium, Japan and Switzerland are from 2020. Data for Austria, Canada, France, Germany, Netherlands, Sweden, and the United Kingdom are provisional. Data from Canada represents a difference in methodology from the prior year. Health consumption does not include investments in structures, equipment, or research.

Source: KFF analysis of [National Health Expenditure \(NHE\)](#) and [OECD data](#) • [Get the data](#) • [PNG](#)

Peterson-KFF
Health System Tracker

Some context: DHT market is growing

Projected size of the global market for wearable devices in the healthcare sector from 2015 to 2021

(in million U.S. dollars)

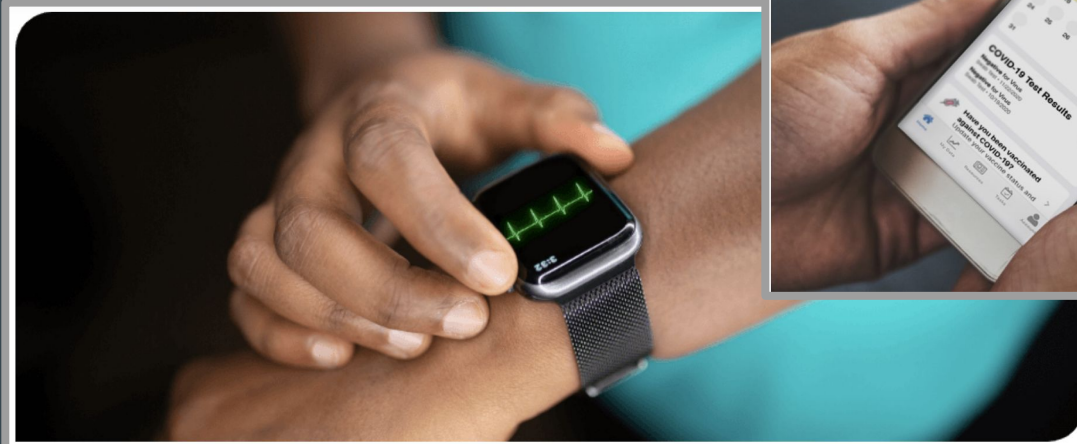


Source: <https://www.statista.com/statistics/607982/healthcare-wearable-device-revenue-worldwide-projection/>

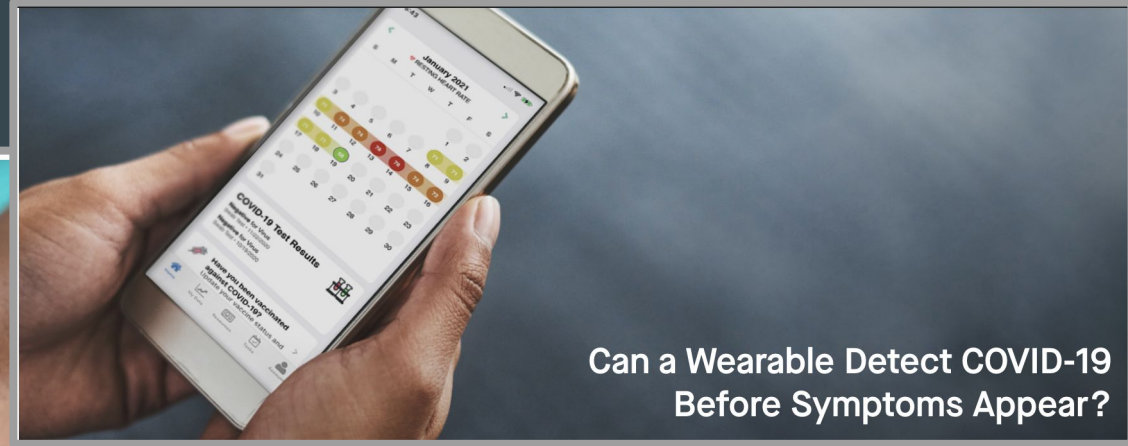
Current DHT research, development, testing, evaluation, application

- Activity monitoring and behavioral health research & applications
- Elite athletes
- Women's health
- Human performance optimization and extreme environments
- Infectious diseases, health security
- Chronic diseases, including long COVID
- Sleep
- Post-surgical monitoring
- Seizure disorders

Scripps DETECT study



Early DETECTION Could Be the Key to Infection Prevention



Can a Wearable Detect COVID-19 Before Symptoms Appear?

Scripps, Care Evolution, Apple, others

<https://www.scripps.edu/science-and-medicine/translational-institute/translational-research/digital-medicine/>

Evidation health

evidation

Our mission is to create new ways to measure and improve health in everyday life.

In 2021 almost 5 million members



**Earned 7 billion
points**



**Took 951 billion
steps**

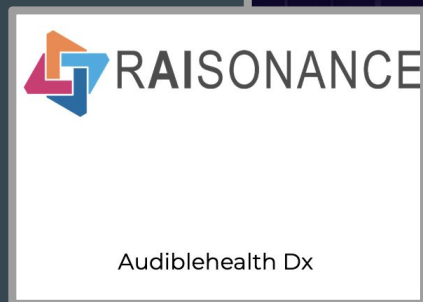
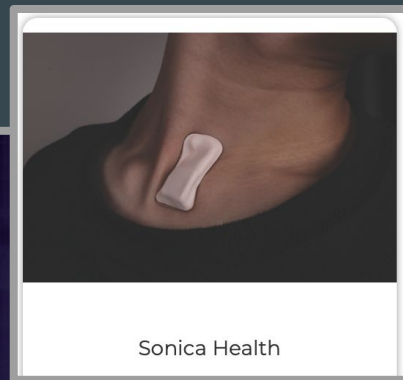
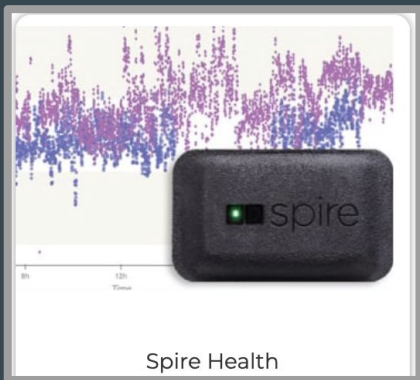


**Joined 200+
research studies**



**Exercised
1.4 million days**

BARDA's portfolio of health security applications



ENACT

Early Notification to Act, Control, and Treat

Athlete-focused devices



WHOOP's key advantage over other fitness bands is the amount of data this it collects and pushes into the cloud for processing. With five sensors that collect data 100 times per second, the wearable sucks up 100 megabytes of data per user, per day. By comparison, the Apple Watch's sensors generally turn on just once per minute. But even with all that information, WHOOP's strength is in its simplicity. After crunching all the numbers (including next-level stats like heart rate variability and sleep), WHOOP helps athletes judge themselves against: st



 **WATCH**
ULTRA



 **NIX**



DOD invests in DHT

Profusa awarded \$7.5M DARPA grant to work on implantable biosensors

By Alyssa Huntley • Jul 12, 2016 02:23pm

DoD Investing in Wearable Technology That Could Rapidly Predict Disease



[Military News](#)

Why 300 Sailors and Marines Deployed on an Amphibious Ship with Smart Rings

VA distributes wearables to veterans

VA » Office of Public and Intergovernmental Affairs » News Releases

Office of Public and Intergovernmental Affairs

VA, Fitbit help support Veteran health and wellness during COVID-19 pandemic

Jan. 11, 2021, 11:00:00 AM



Another interesting device / application for kiddos



Owlet

<https://www.owletcare.com/>

What could go wrong?

Basic security issues with information systems

- CIA triad
- Privacy
- Data-type specific regulatory concerns (HIPAA)
- Emerging (new) data types
- Attack space
- Threat vectors



New technology present new risks

DIGITAL HEALTH

Fitbit, Apple user data exposed in breach impacting 61M fitness tracker records

By Heather Landi • Sep 13, 2021 04:21pm

Medical devices are a weak link in hospital cyber defenses, putting patients in the crossfire: study

By Annie Burky • Aug 18, 2022 03:05pm



Strava data outlines military bases

Fitness tracking app Strava gives away location of secret US army bases

Data about exercise routes shared online by soldiers can be used to pinpoint overseas facilities

**The
Guardian**



All of Us Research Program participants

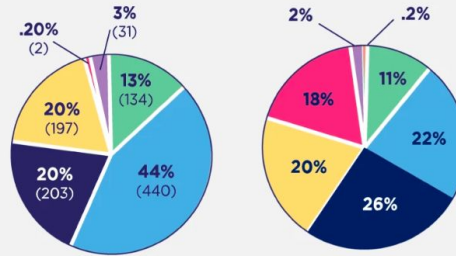
Inequity

- Fitbit (BYOD) participant demographics vs. all participants
- Clear difference in diversity of participants
- Surveyed FQHC patients to learn more about interest and awareness of DHT devices

	Fitbit participants	all AoU participants
White	78.43%	47.80%
Black or African American	5.41%	20.69%
Hispanic or Latino	4.41%	16.08%
Asian	3.04%	2.94%
female	70.10%	59.60%
male	29.01%	39.02%
Advanced degree	36.18%	17.68%
College graduate	32.82%	19.93%
1-3 years of college	23.20%	25.63%
high school only	6.34%	20.92%
income >\$25K/yr	85.34%	49.97%
income <\$25K/yr	8.50%	31.16%
live in an urban area	90.38%	94.03%
live in a rural area	9.16%	5.97%

Wearable fitness tracker use in federally qualified health center patients: strategies to improve the health of all of us using digital health devices

Education

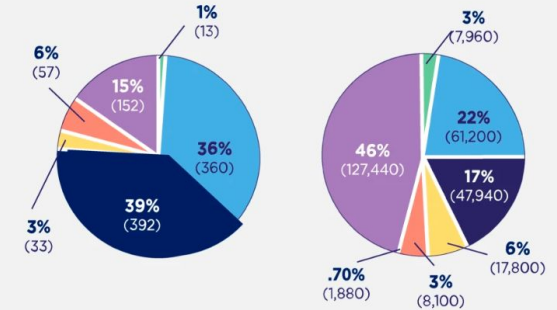


Fitness Tracker Study

All of Us Participants

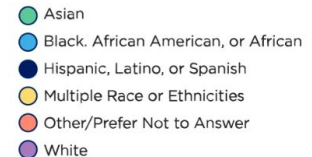


Race and Ethnicity

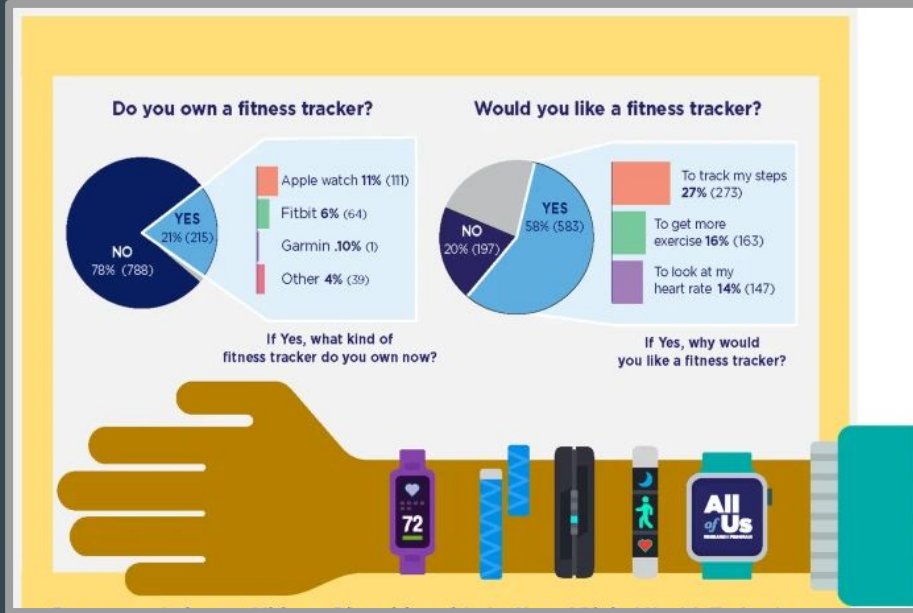


Fitness Tracker Study

All of Us Participants



Inequity



Recommendations to Mitigate Disparities with the Use of Digital Health Technology

Hindering factors

- 1 **Awareness** of fitness trackers
- 2 **Cost** is a barrier
- 3 **Language** may be a barrier
- 4 Most would like more **knowledge** and high touch support, including pamphlets, informational sessions and training
- 5 Many requested over the phone **assistance** from research staff versus completing the survey independently

Helping factors

- 1 Majority would like to **have and use** a device
- 2 Most would **share data** for research
- 3 Most have a **smartphone** and know how to **download** and use apps
- 4 Most believe that the devices could provide **relevant health information**
- 5 Most would like to **learn more** about how **devices could be useful** for obtaining personalized health information
- 6 Most would like to **get reminders** about their device (via text)

What is a future vision of DHT in health, and how do we get there (safely & equitably)?

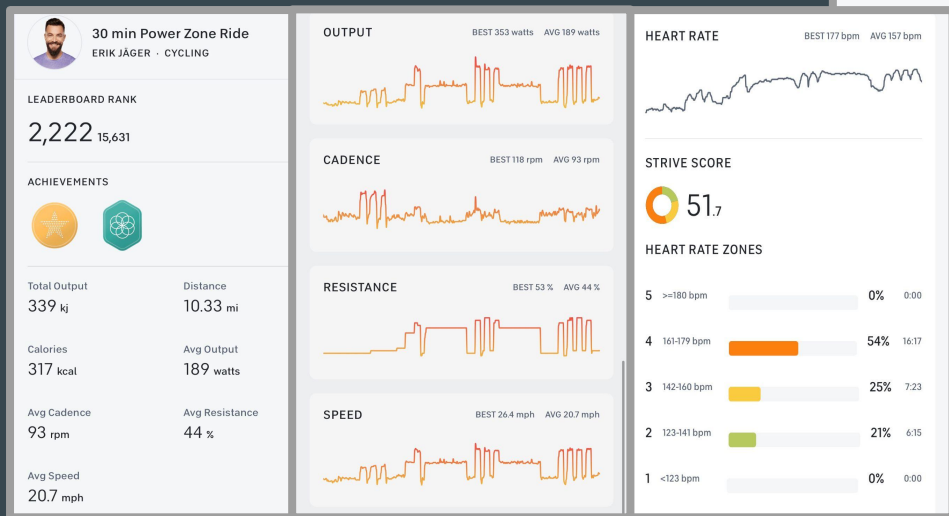
What do I even mean by health, and how can DHTs inform?

- Meet you where you are in everyday life, not just clinical encounters
- Continuous data stream helps establish a baseline for physiological parameters
- Signal to test
- Precision medicine
- Real-world evidence
- Health decision making with YOU at the center



An example from my life

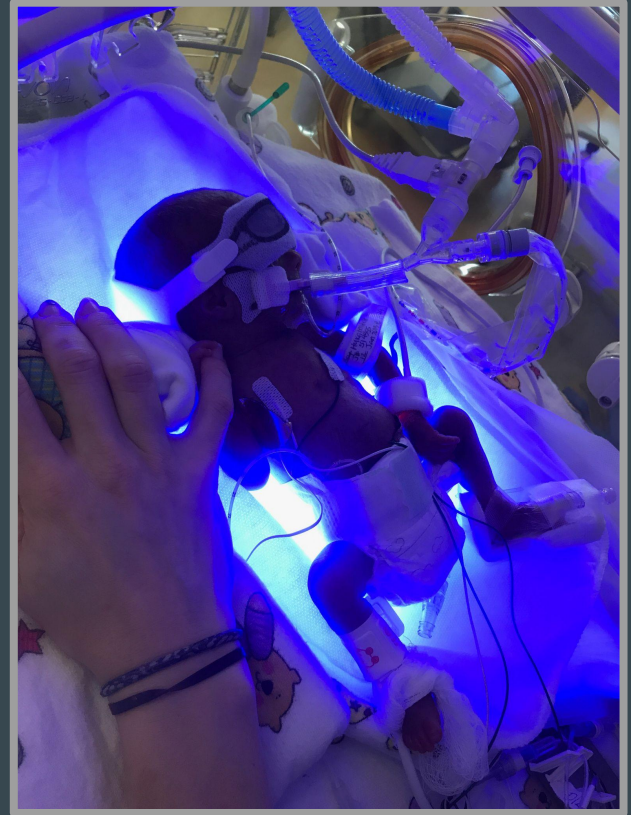
- Power Zone training
- Functional Threshold Power



- Opportunity to think rationally about life choices
- Access to personal training at scale

Another example from my life

- First trimester Cytomegalovirus (CMV)
- Absent end diastolic flow
- 28w, 1lb 10oz



How do we realize the potential?

- Expand use of of data beyond clinical applications
 - Real world evidence generation
- Expand access to data
 - AoU but need others
- Share standards/frameworks
- Innovation in tools & methods
- Ripe for innovation:
 - Sleep study
 - Women's health
 - Cardiovascular diseases
 - Public health



How do we do it safely?

- Build technology with unintended use in mind
- Zero trust
- API strategy for JIT right-sized data access with audit logs

Framework for the Use of Digital Health Technologies in Drug and Biological Product Development

INNOVATION PREDICTABILITY ACCESS



Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on April 3, 2023.

How do we do it equitably?

- **Human-centered design**
- Collaborate with **communities**
 - Honor history and culture
- Improve access to the **basics**
 - e.g. healthcare, broadband, health literacy
- Public-private **partnerships**
 - Robin-hood models for companies

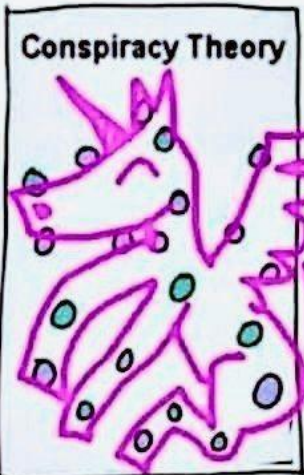
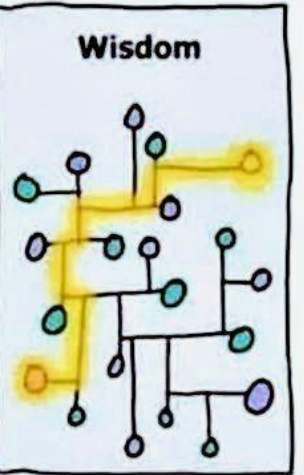
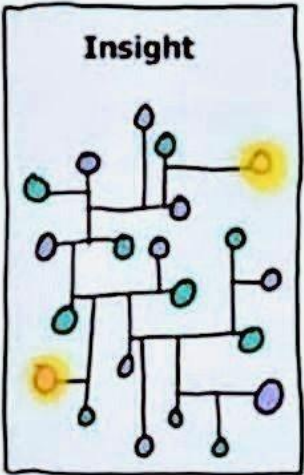
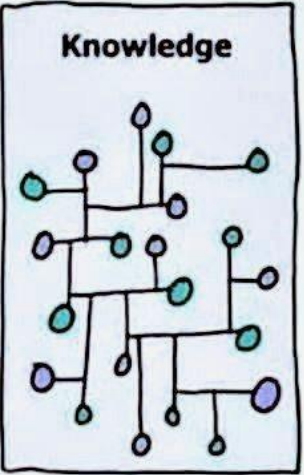
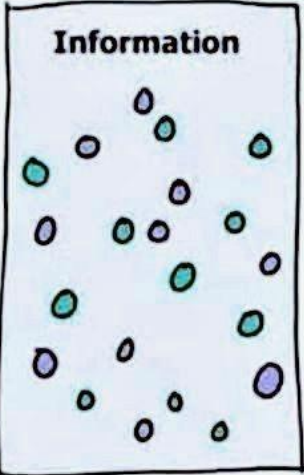
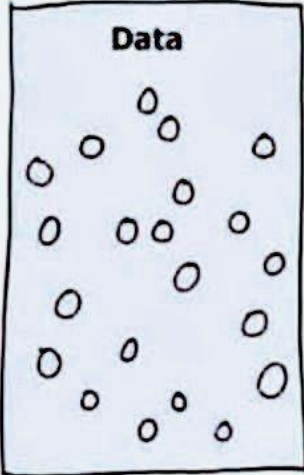


Key themes to close



- Data are the **foundation** for discovery and insight
- Technology can enable and is only useful if **people** use it
- Cross-sector **partnerships** (it takes a village)
- Proactive **security** especially for emerging technology
- **Curiosity** about ourselves

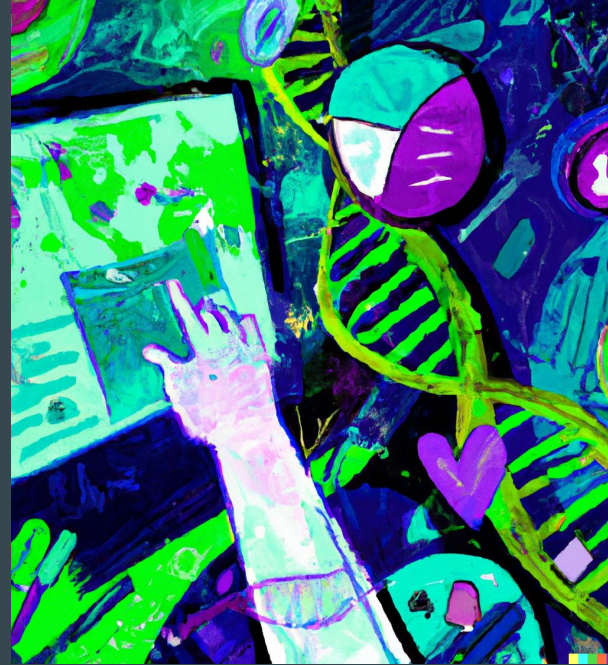
BLUF: An “n of 1” approach is needed to link data from digital health tech to useful applications. Wearables as the new “omic.”



Thank you!!



Getting visual inspiration from DAL-E



draw a modern art painting of the ecosystem of digital health technology