

Digital Tools in Trials for Monitoring: What you need to know about validating novel digital measures



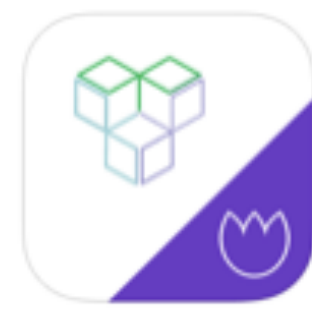
We believe that we can learn more by learning from each other....We advance biomedicine by making science more open, collaborative, and inclusive.

Involved with mHealth/Digital Health research since the 2014

> 450,000 study participants



Psoriasis



Parkinsons



Cardiovascular



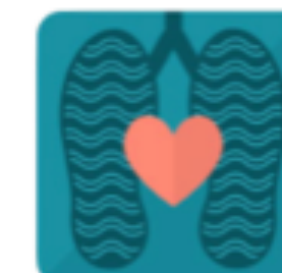
MoleMapper



Asthma



Multiple
Sclerosis



AllofUS
CRF



Samsung
my BP lab

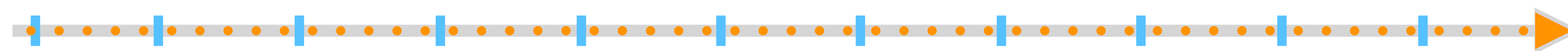


Mobile
Toolbox

<https://sagebionetworks.org/digital-health-expertise/>



Digital Tools provide an opportunity



Research Protocol



Frequent Tasks

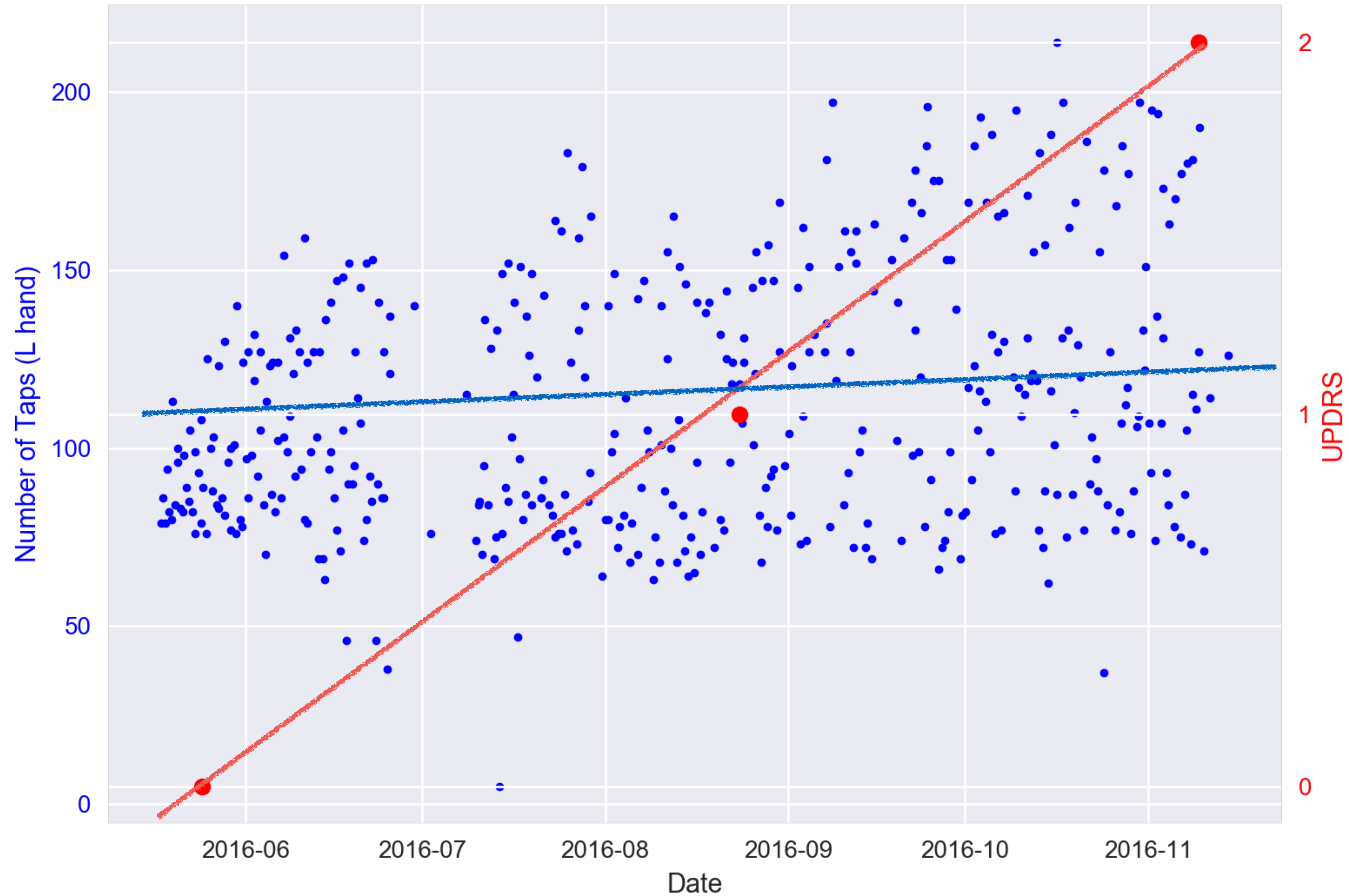


SageBionetworks
Better Science Together



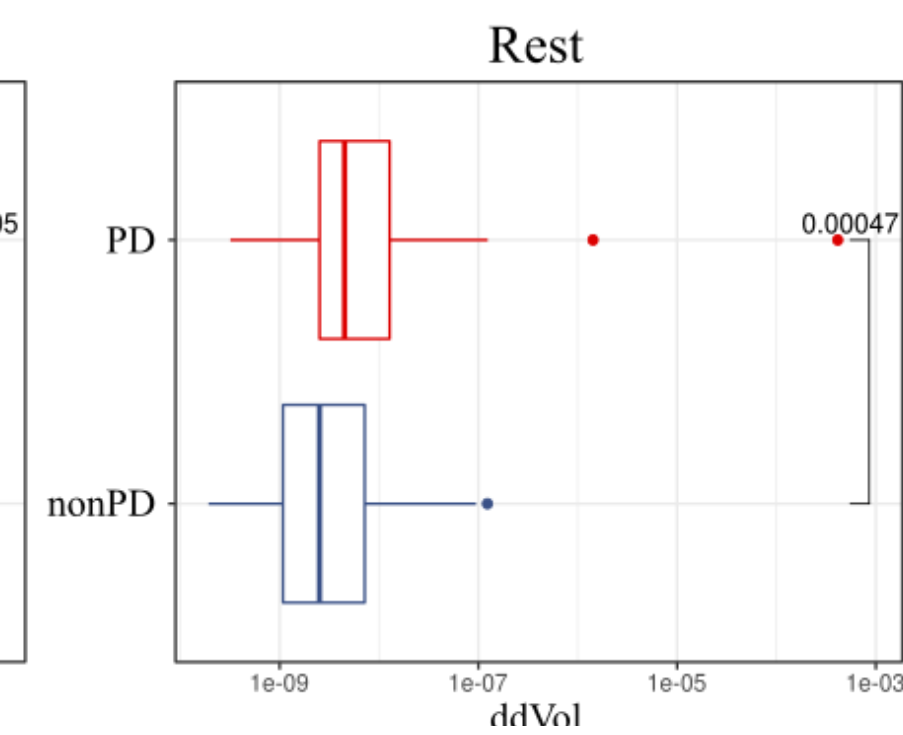
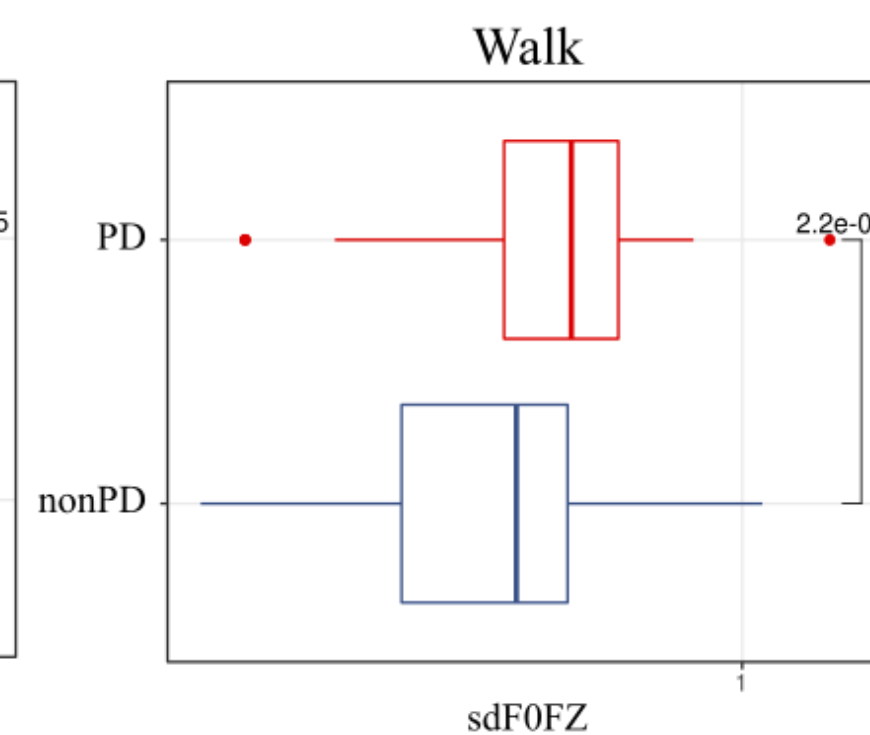
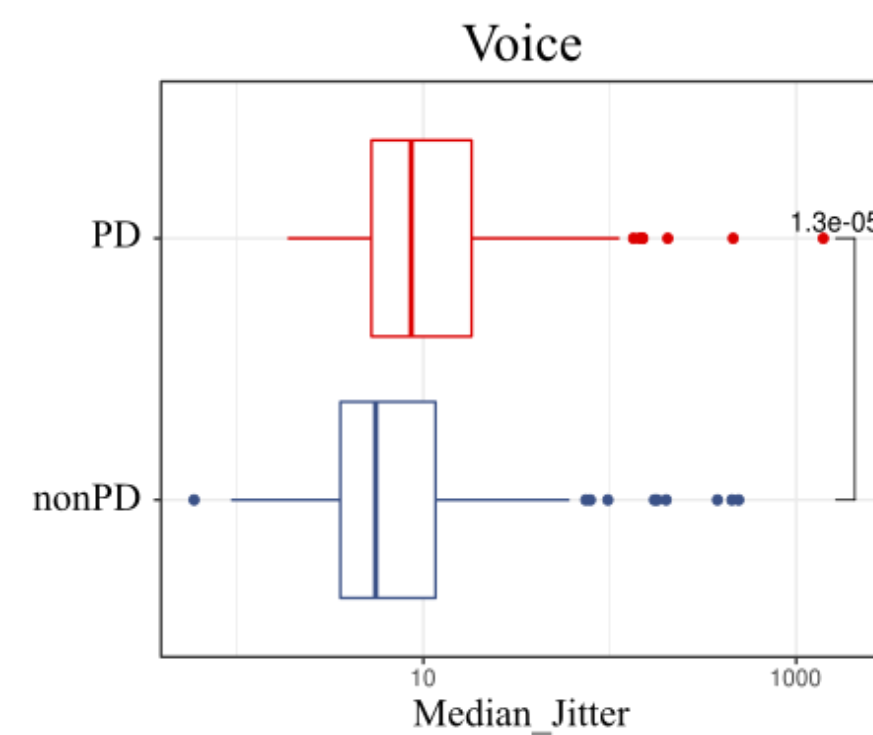
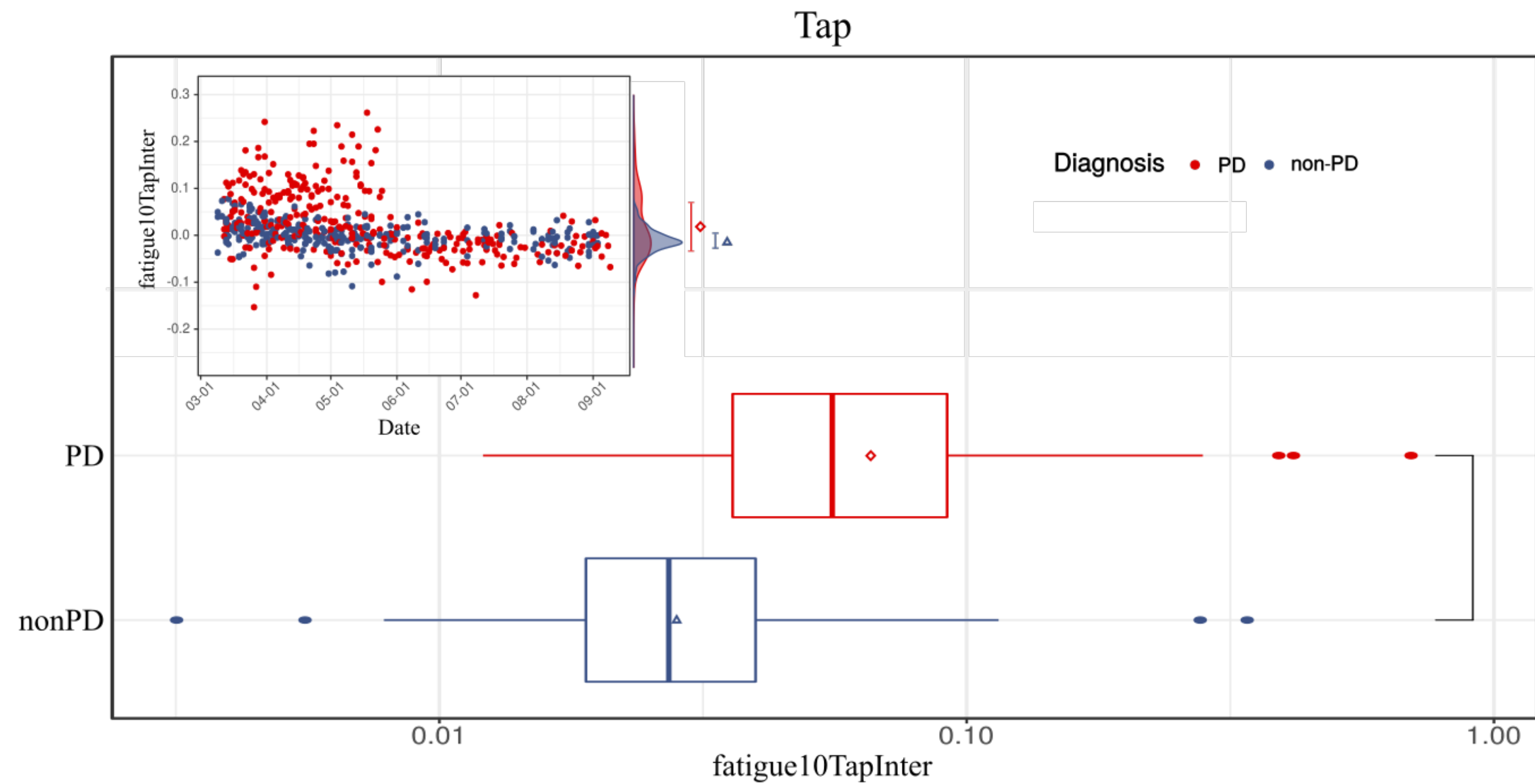


In the wild measurements: **what is happening in life?**





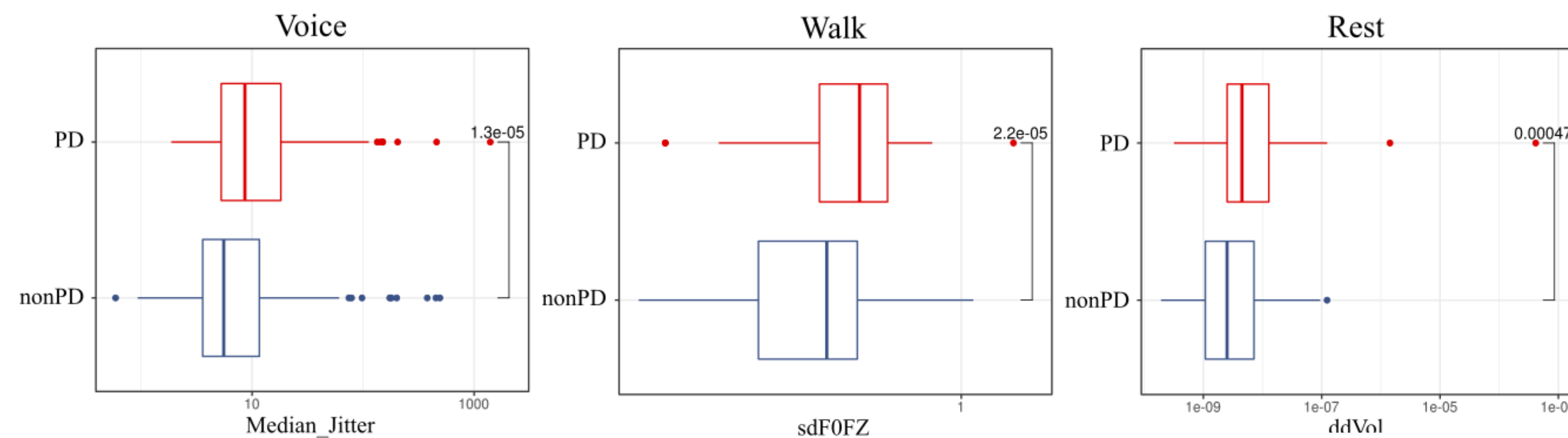
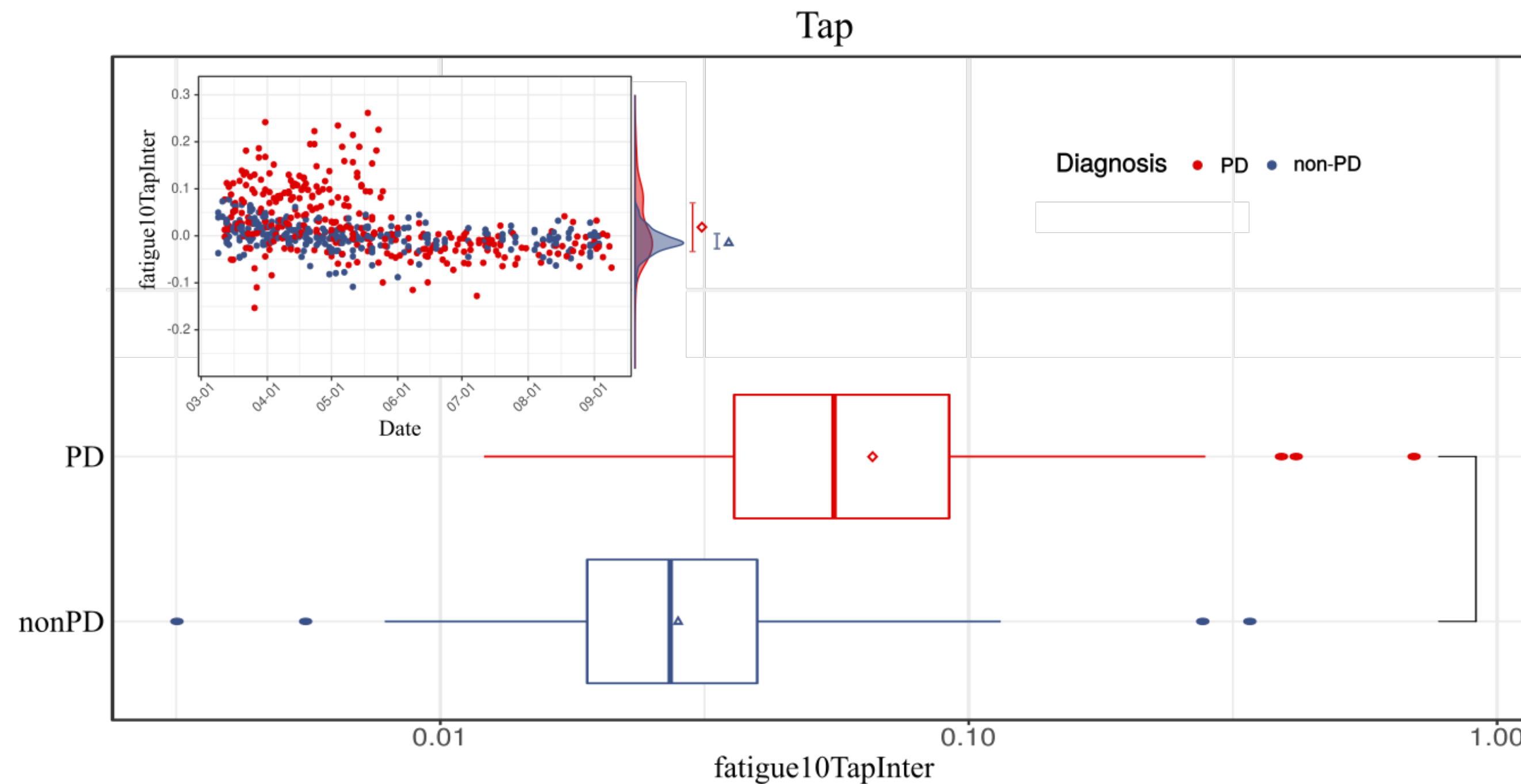
In the wild measurements: Variation is a sign of disease in PD



Omberg, L. *et al.* (2021) Remote smartphone monitoring of Parkinson's disease and individual response to therapy Nature Biotechnology. 1-8.



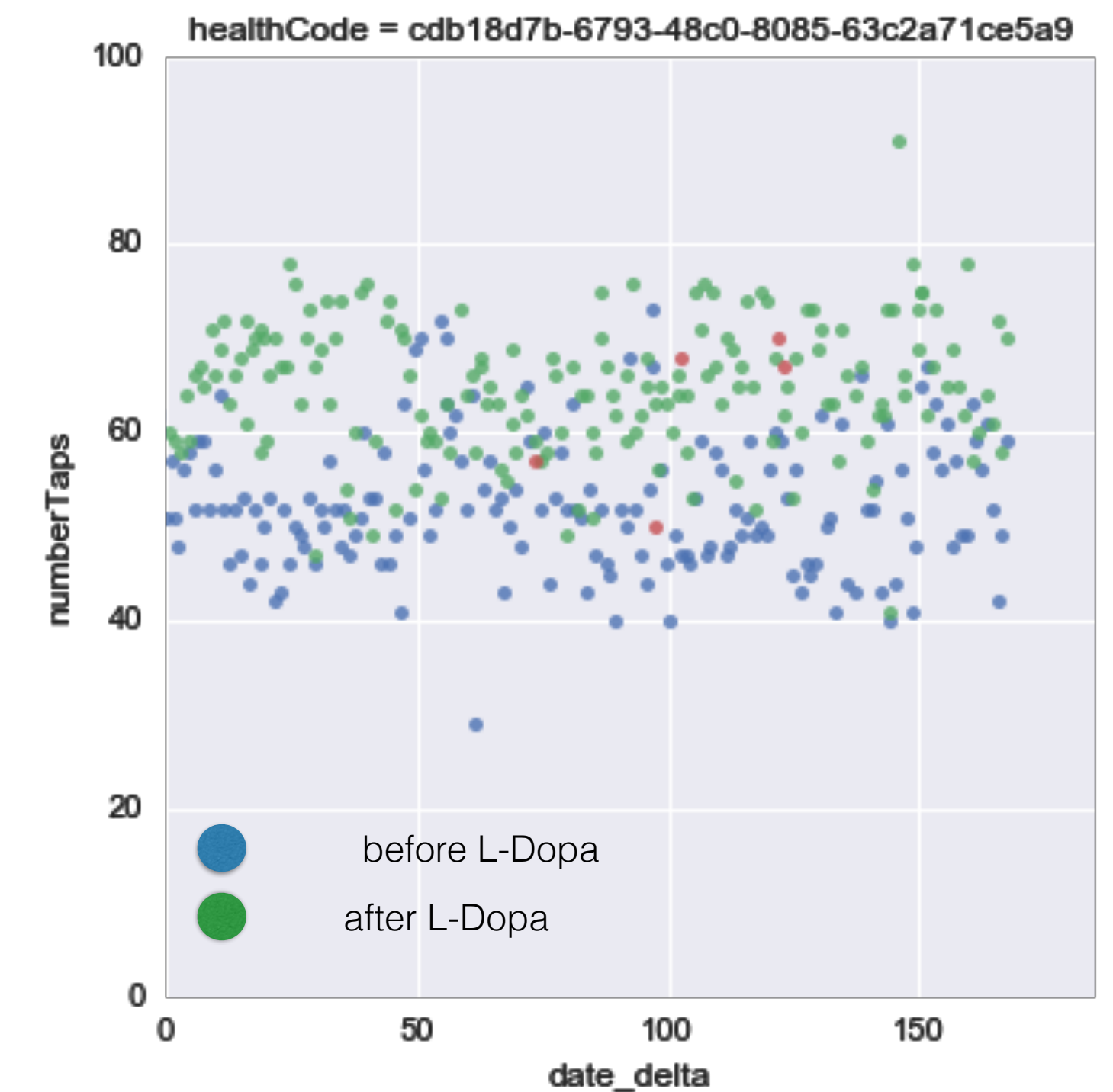
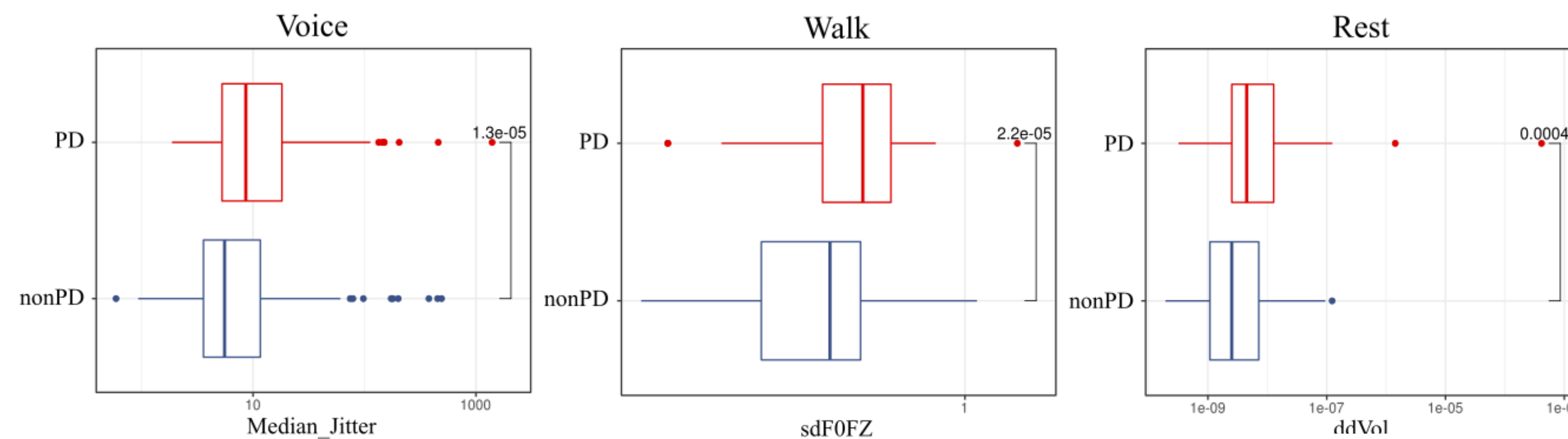
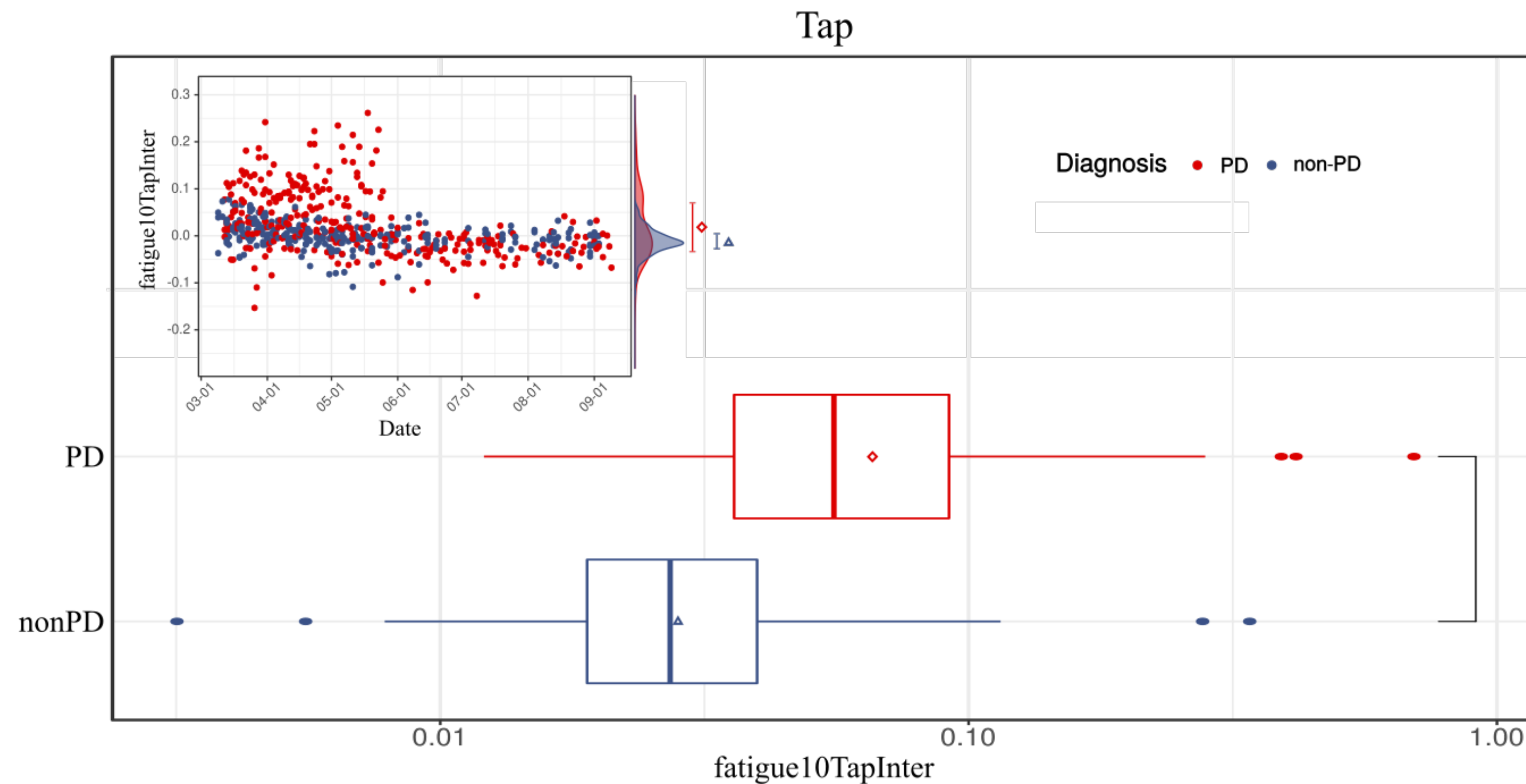
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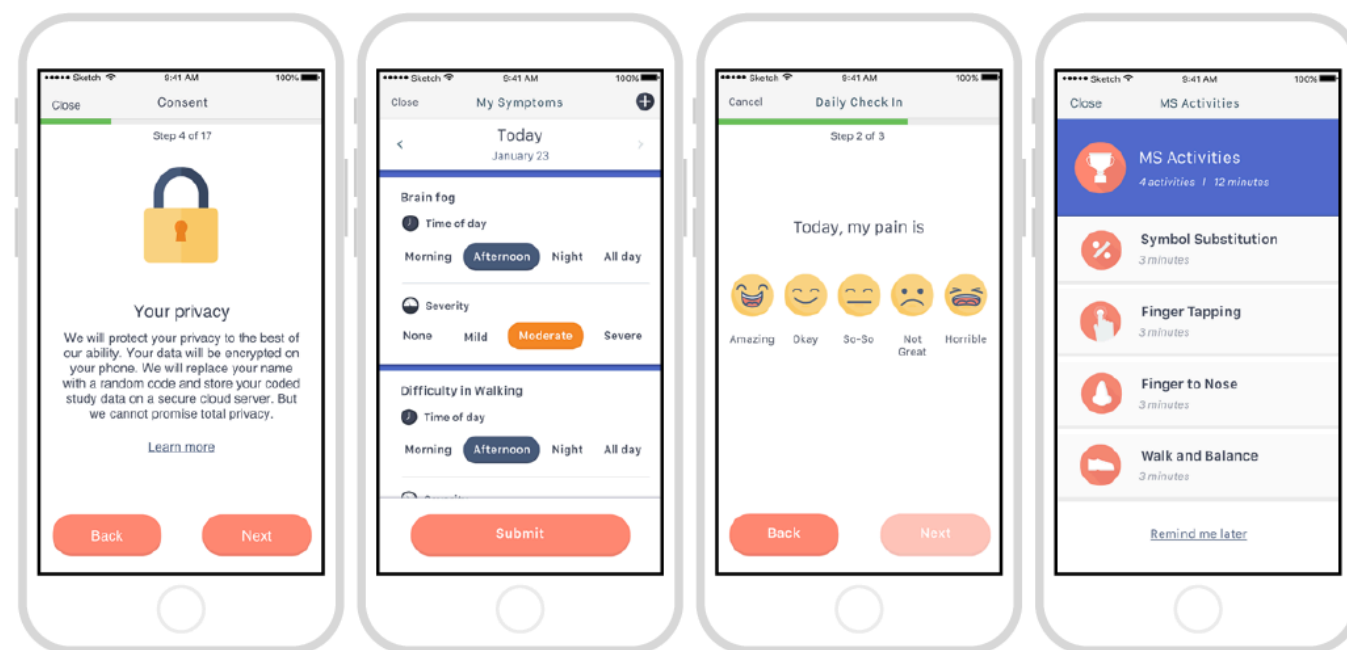
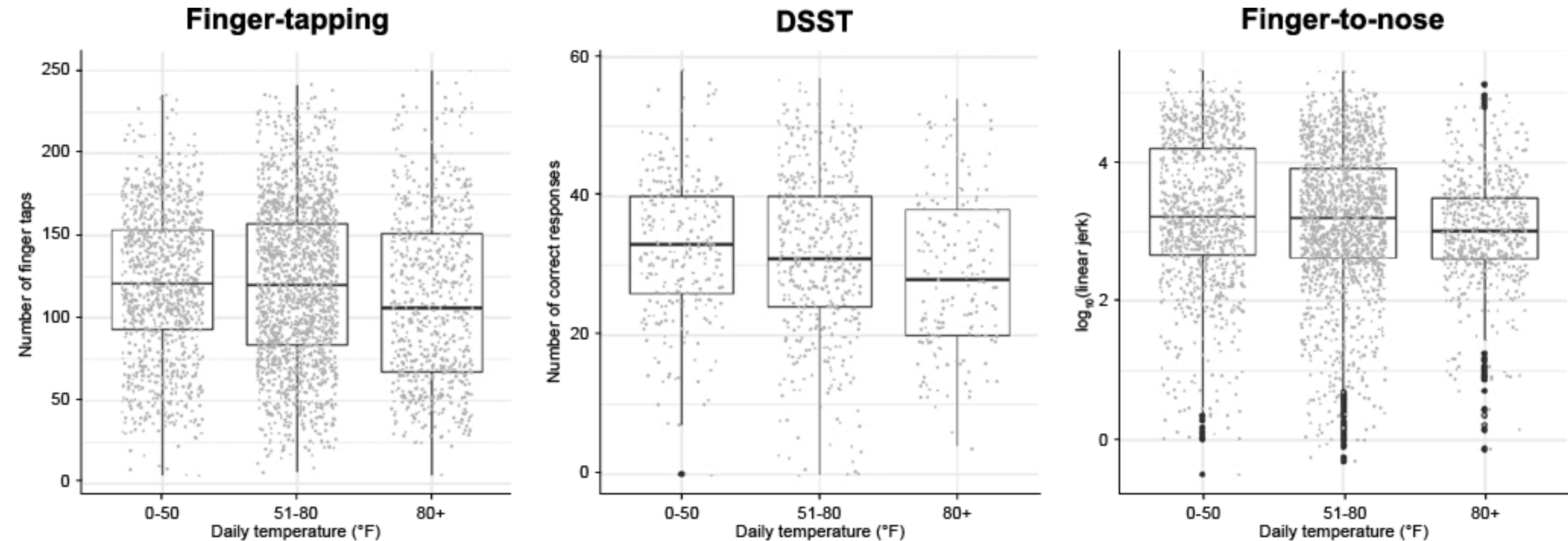


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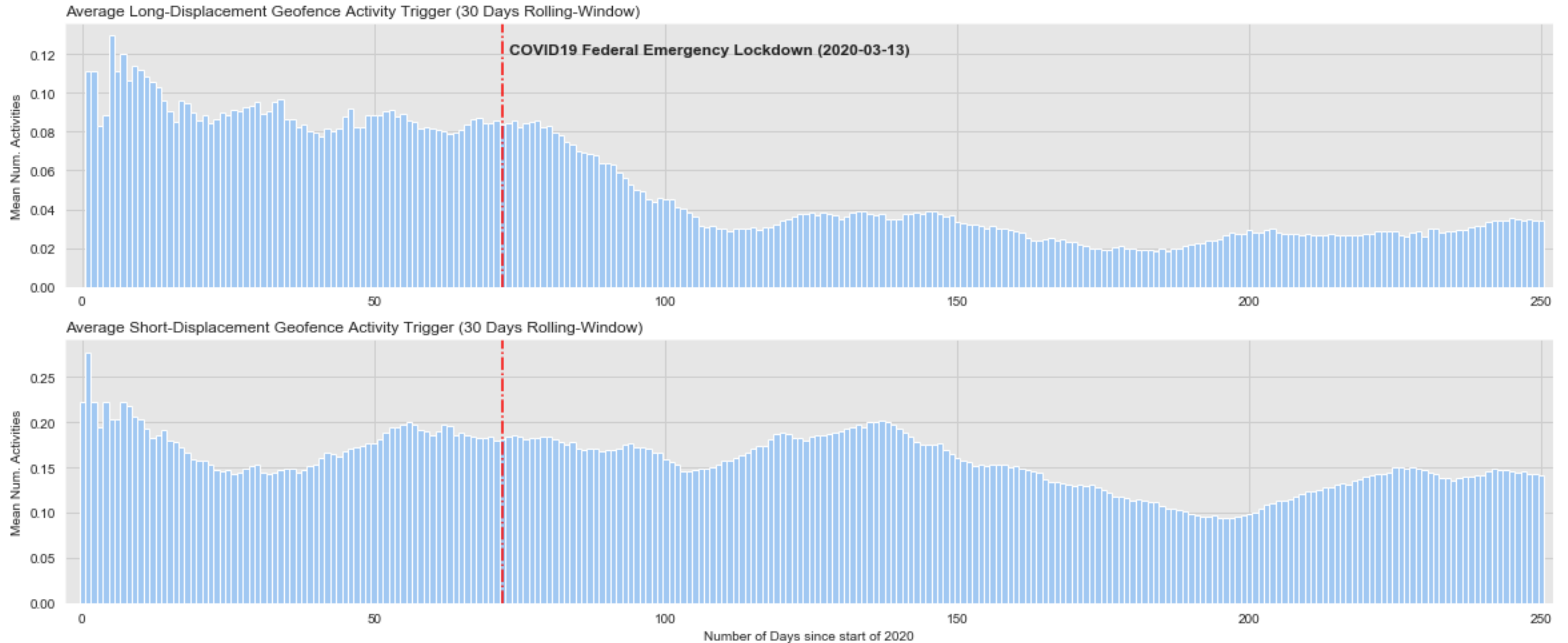
Context Matters: A Disease specific example where the environment is a disease modifier



Pratap, A. *et al.* (2020) Evaluating the Utility of Smartphone-Based Sensor Assessments in Persons With Multiple Sclerosis in the Real-World Using an App (elevateMS): Observational, Prospective Pilot Digital Health Study. *JMIR mHealth*. Vol 8, No 10 (2020): October

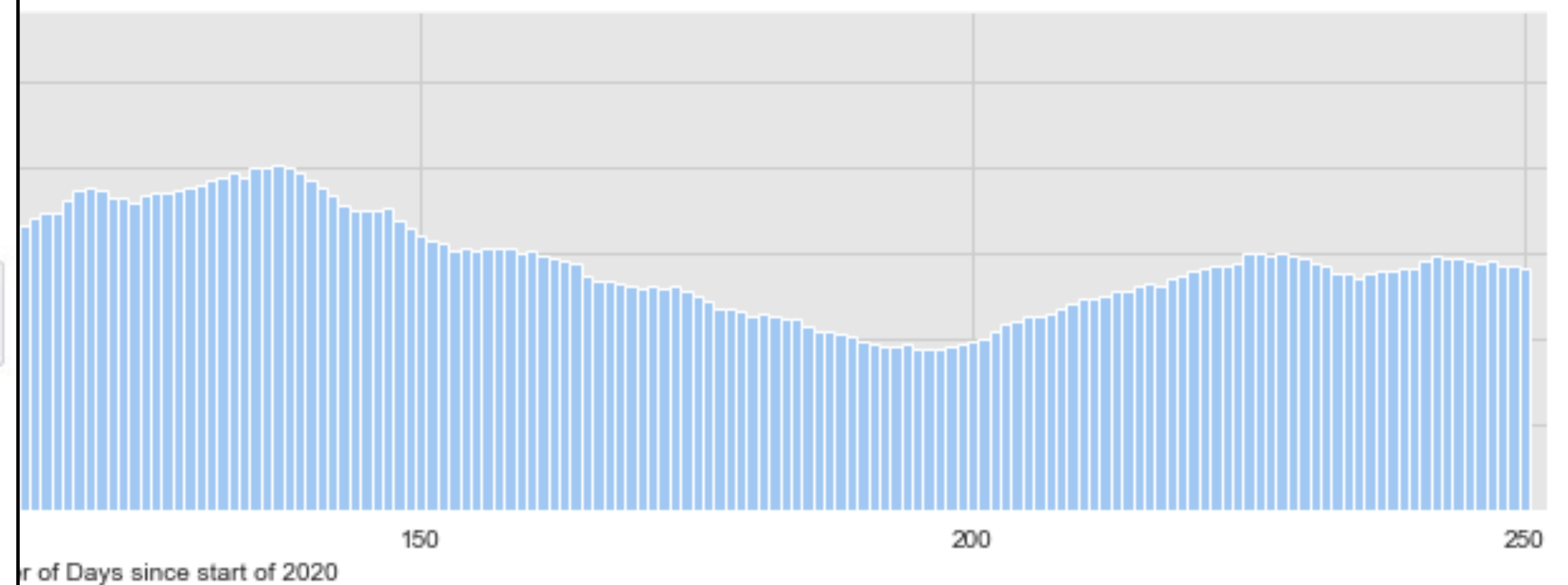
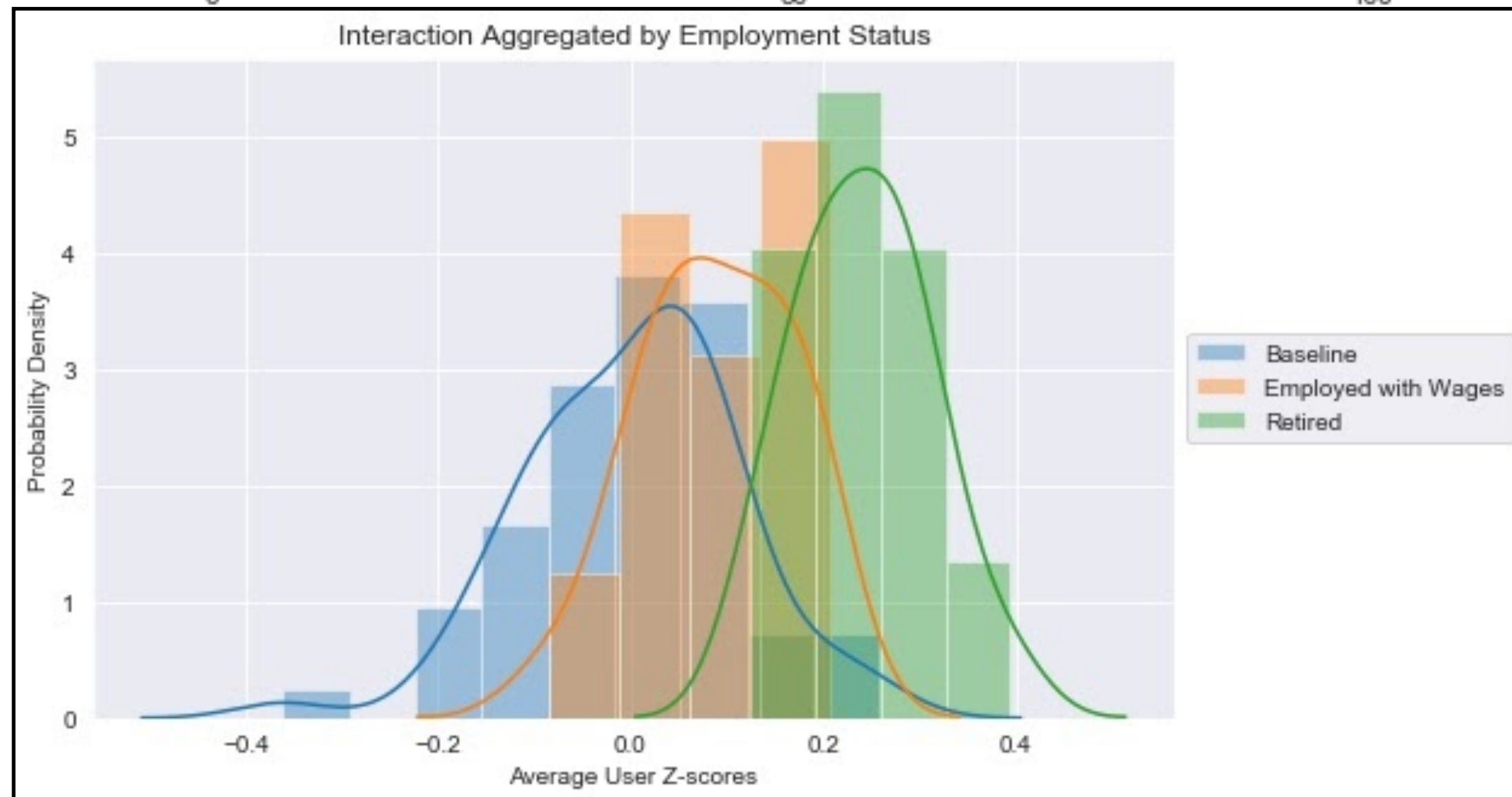
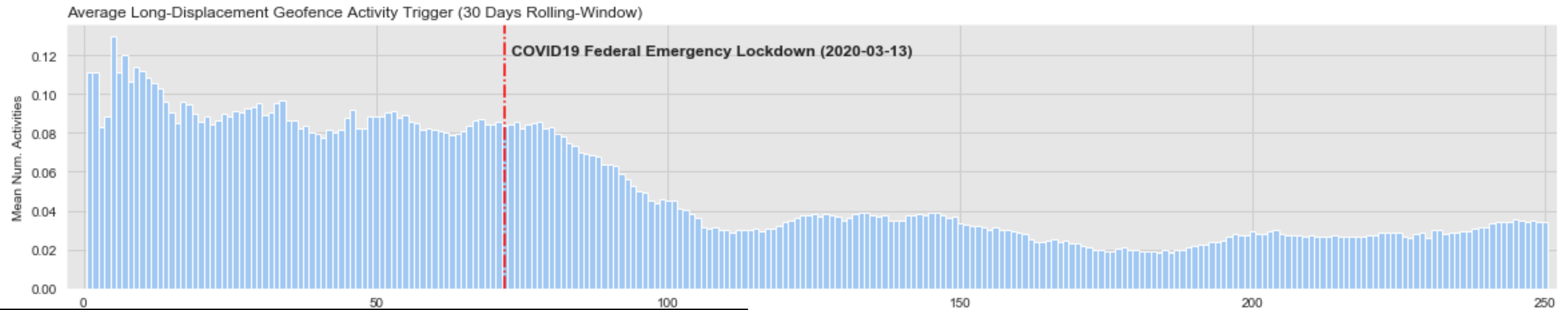
Context Matters: A Recent Example

Effect of COVID-19 on Mobility patterns and Severity



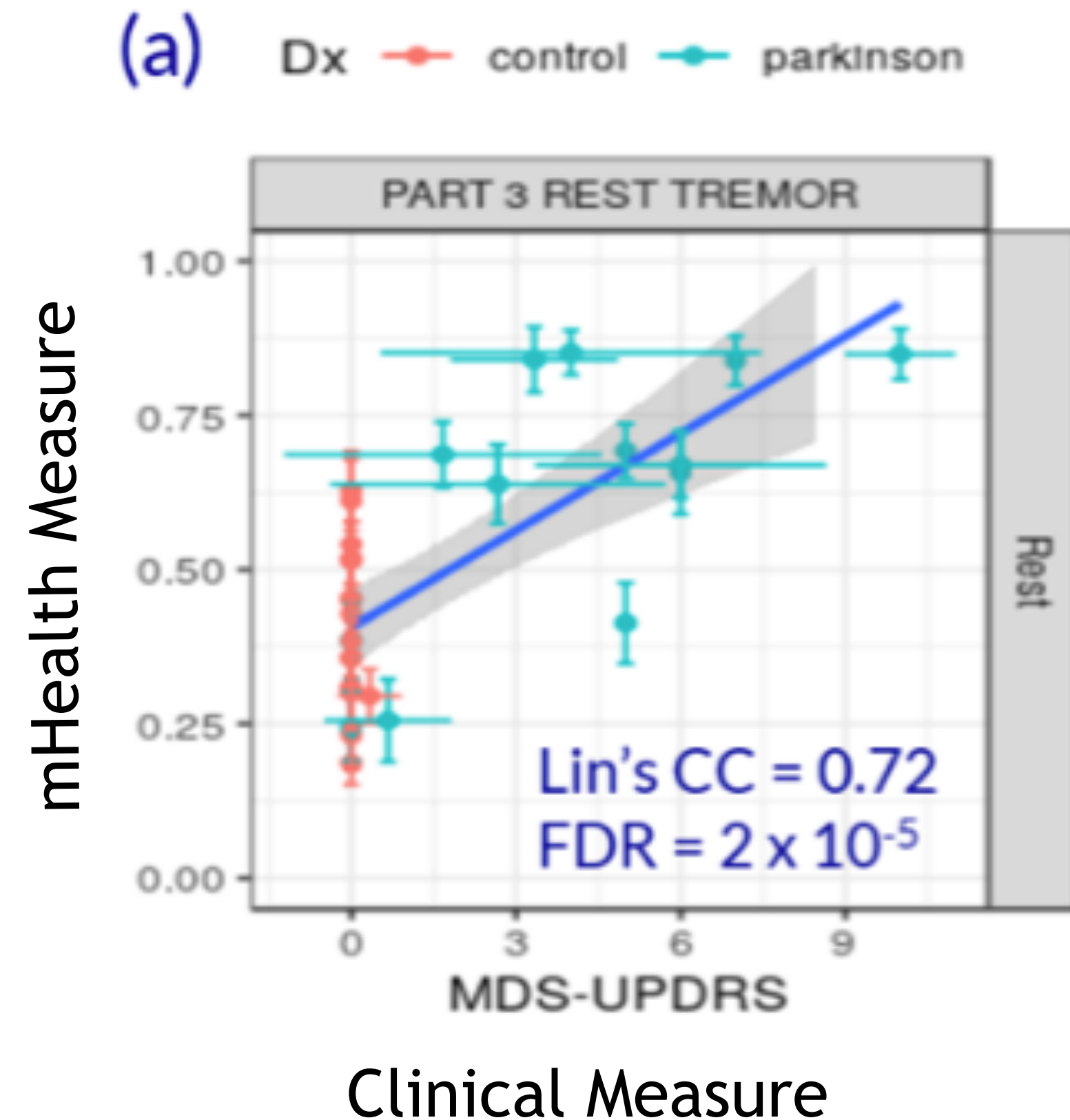
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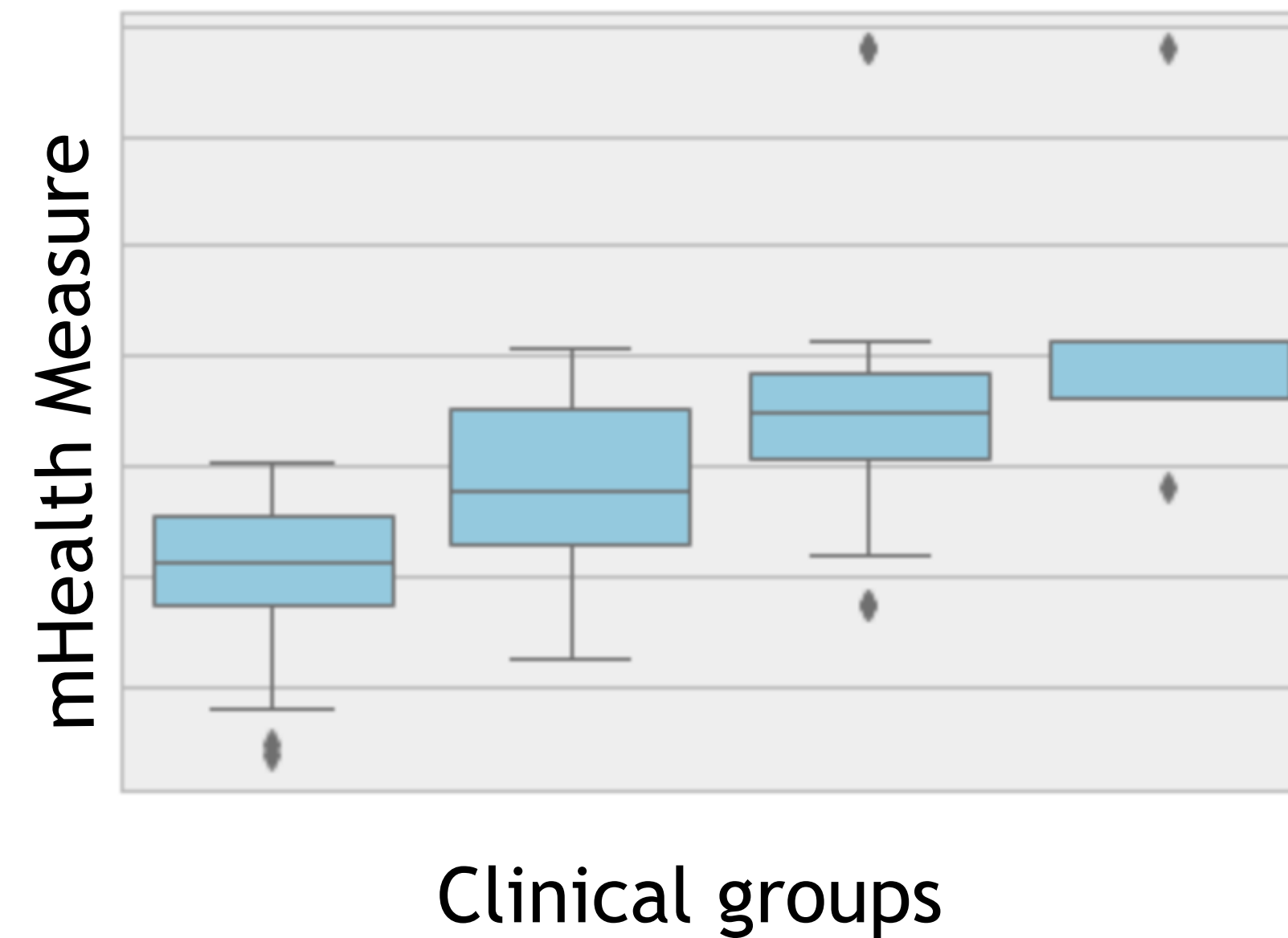


We want validated, robust, and trusted measures and biomarkers

validated



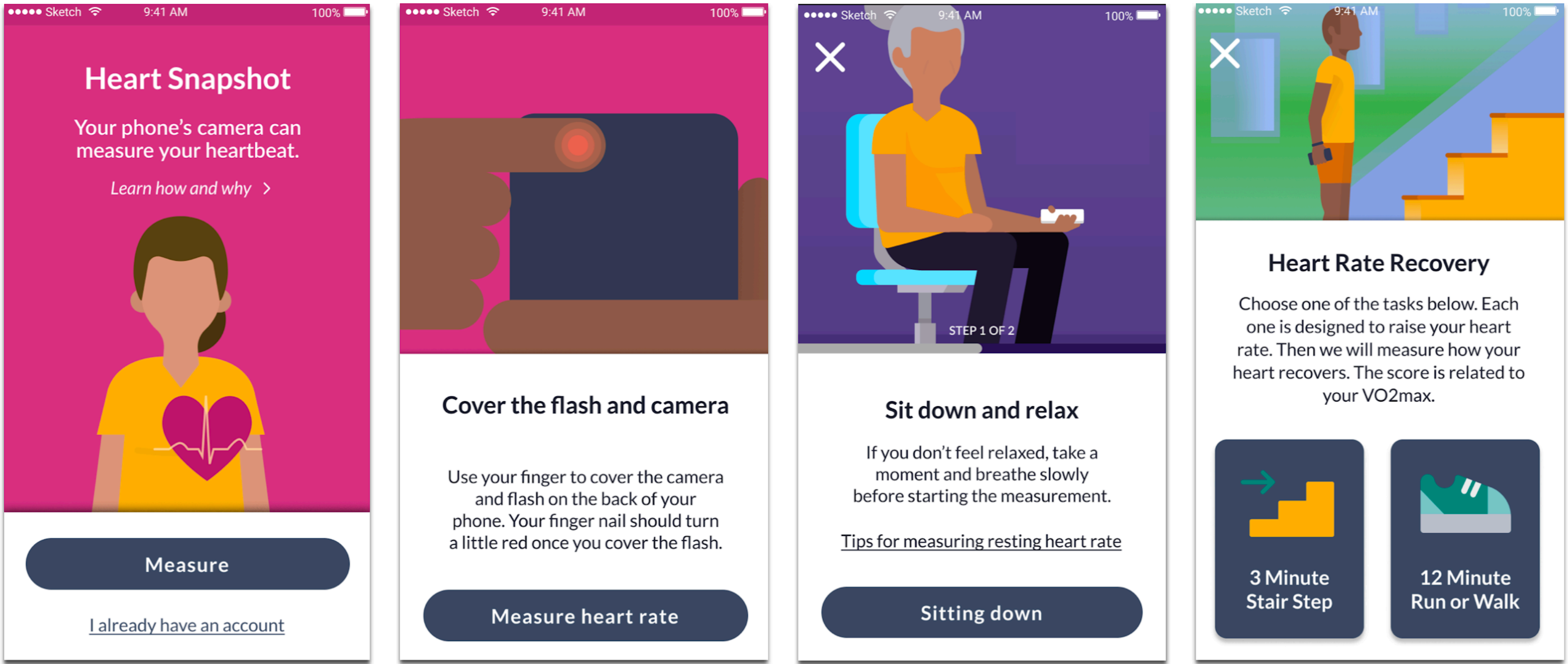
sensitive



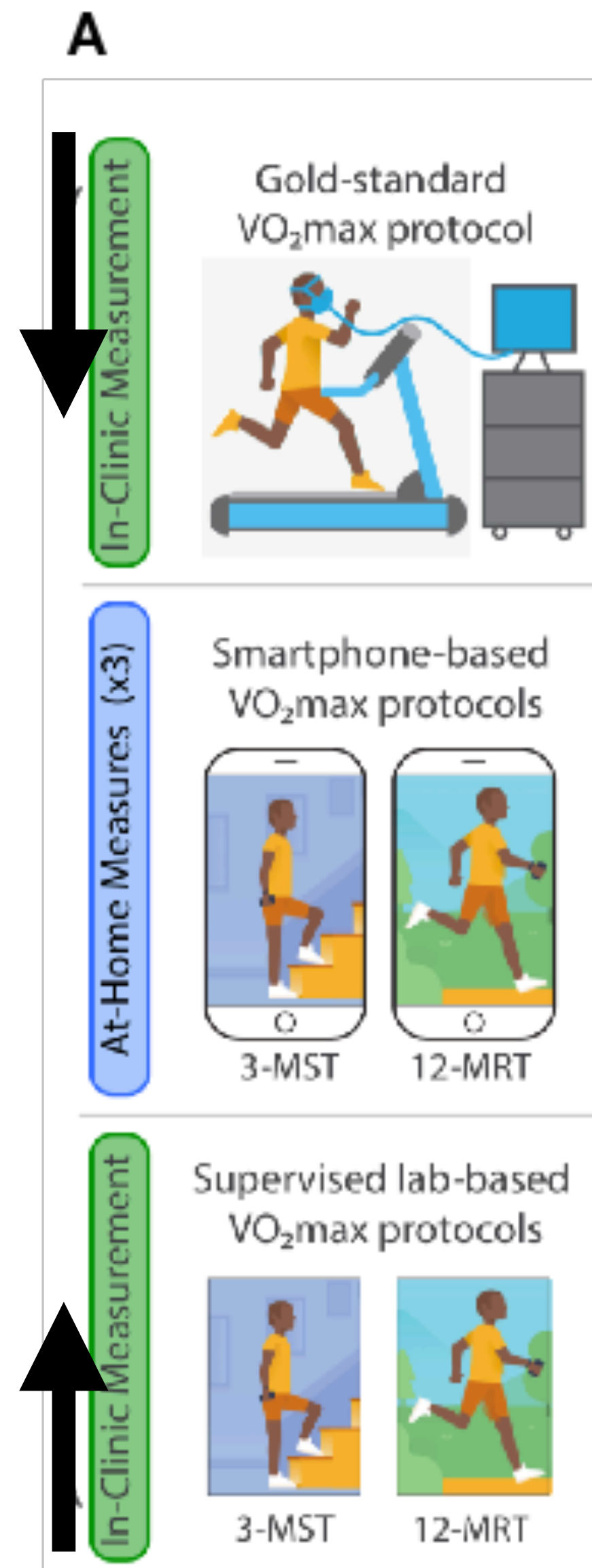
and the study designs that support them

Validation Strategies need to change

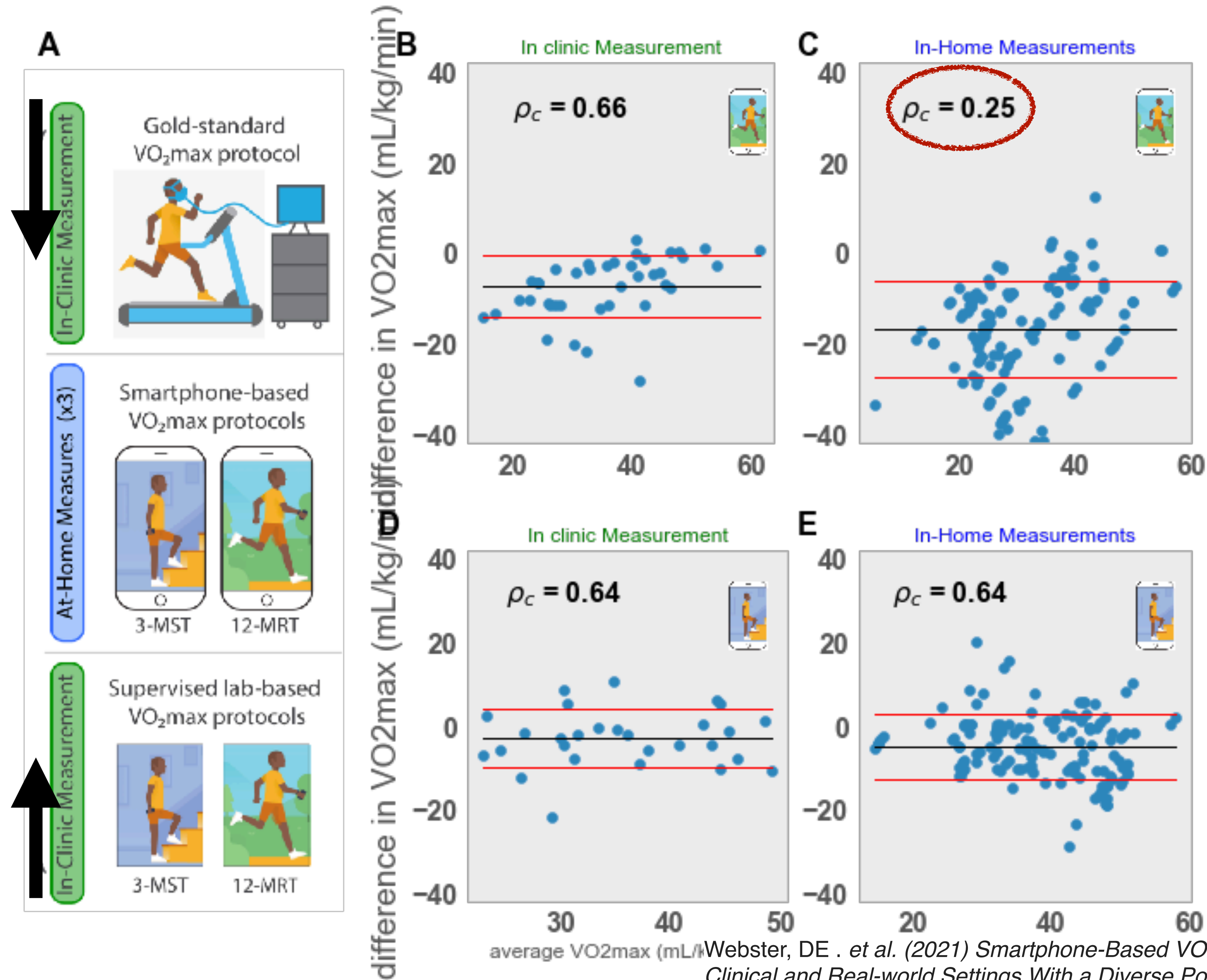
A validation study for Cardiorespiratory fitness



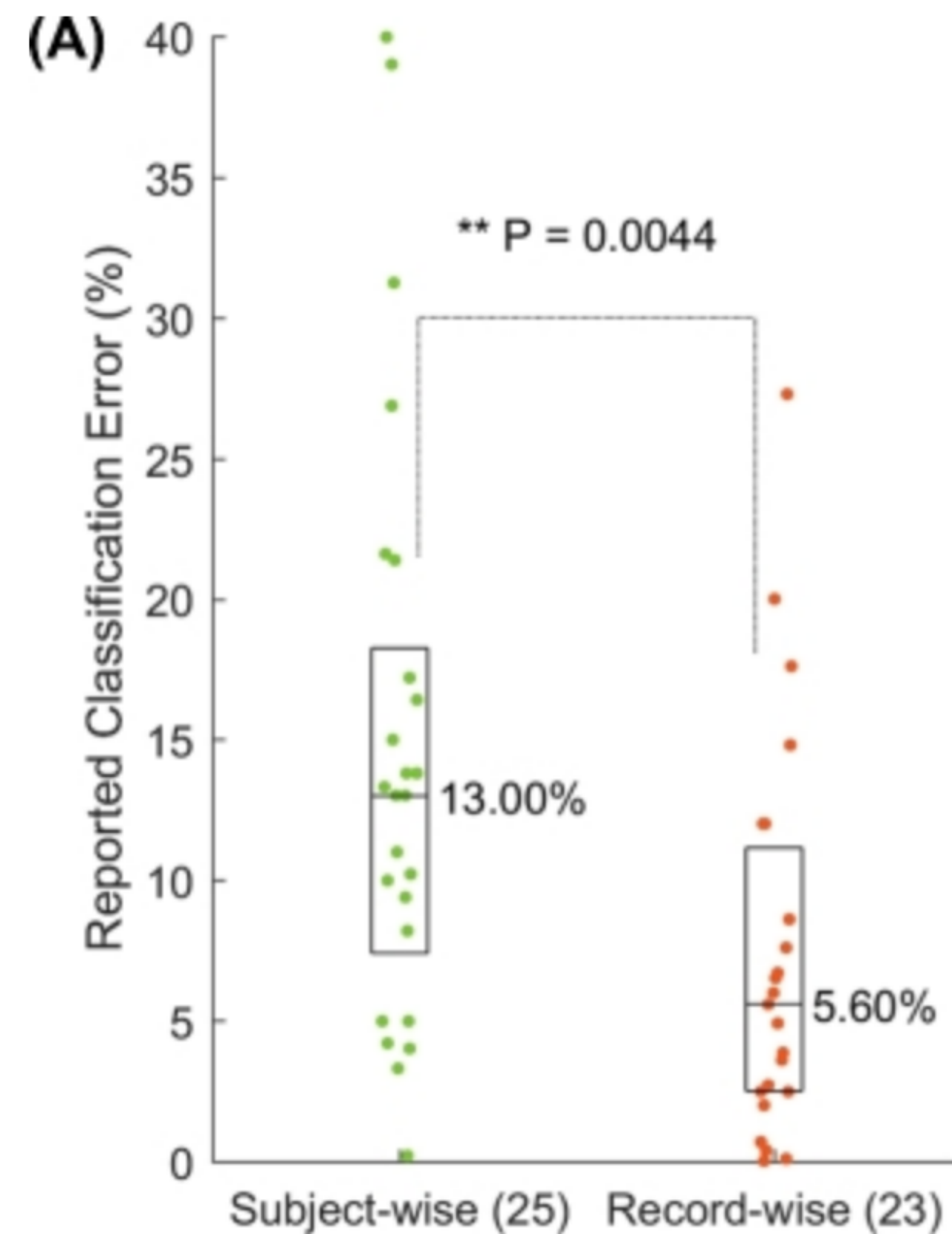
Multiple Avenues of Validation - at home vs clinic or lab



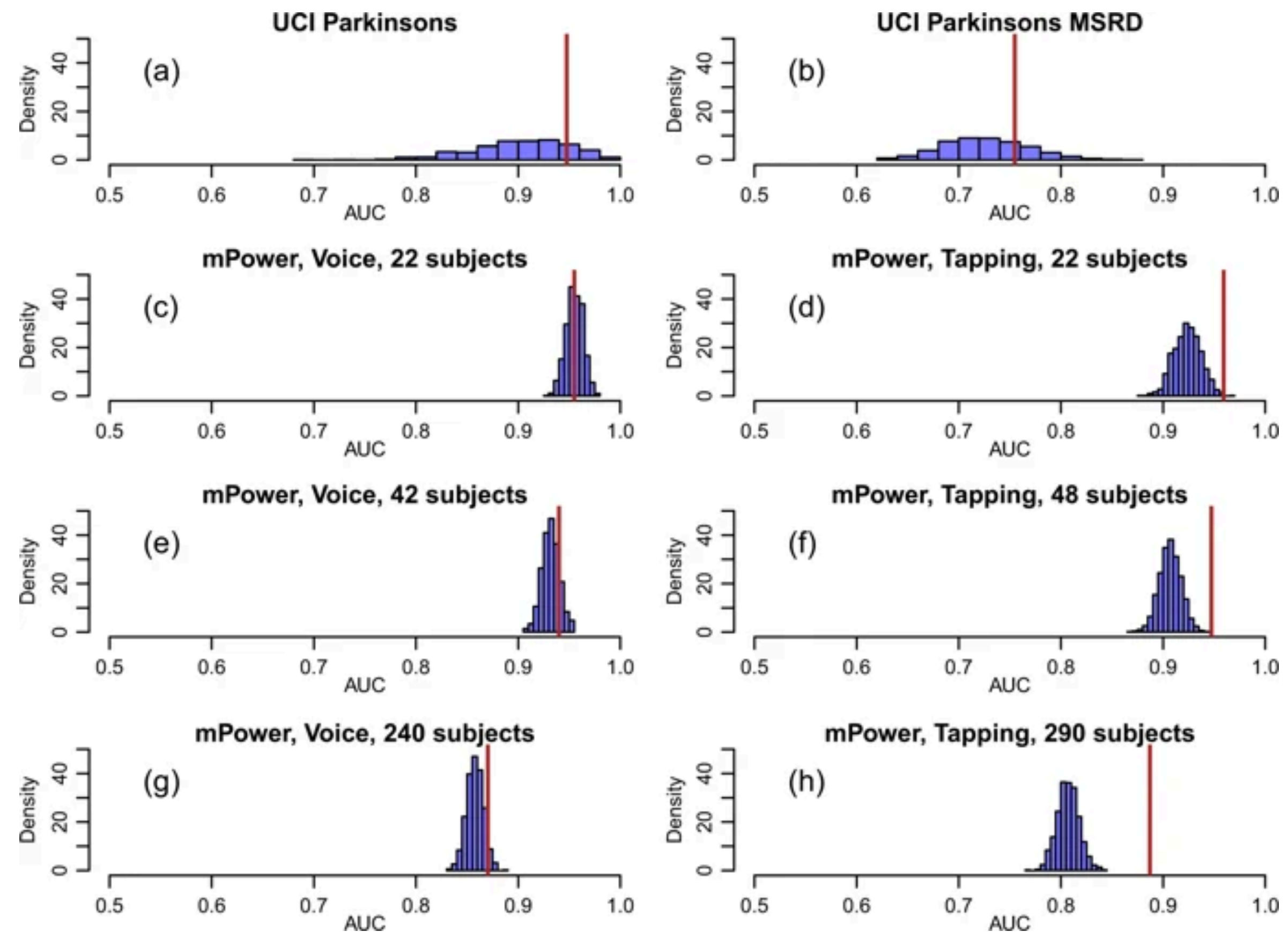
Multiple Avenues of Validation - at home vs clinic or lab



Nearly half of previous studies using proof of principle overestimated the success



Saab, S et al (2017)



Chaibub Neto et al (2019) Detecting the impact of subject characteristics on machine learning-based diagnostic applications, NPJ Digital Medicine **2** (1).

Saab, S. et al (2017) The need to approximate the use-case in clinical machine learning , Giga Science 6 (5).

There are actually a very large number analytical of issues:

Issue 1: patient acceptance

Issue 2: Noisy data

Issue 3: outcome provide utility to disease

Issue 4: there can be strong confounders

Issue 5: Interactions between confounders

Issue 6: strong autocorrelation due to frequent sampling

Issue 7: Identity Confounding

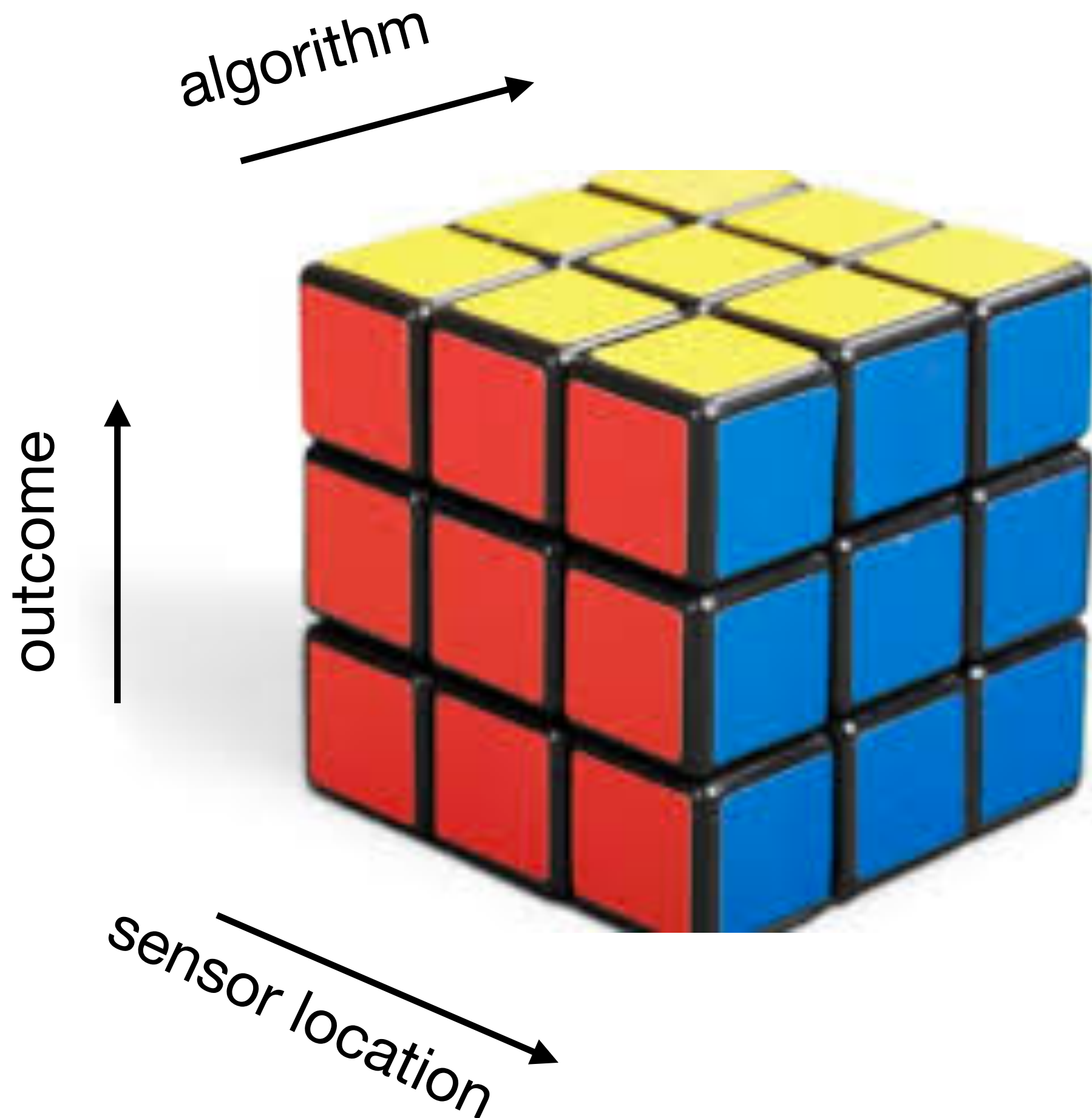
Issue 8: in wild recruitment can lead imbalanced population

Issue 9: dimensional reduction is hard

Omberg et al Clinical Pharmacology (2020)
Dorsey et al Journal of Parkinson's Disease (2020)
Pratap et al Nature Digital Medicine (2020)
Sieberts et al BioArxiv (2020)
Neto et al arXiv:1911.05139 (2020)
Neto et al Nature Digital Medicine (2019)
Neto et al SIGKDD (2019)

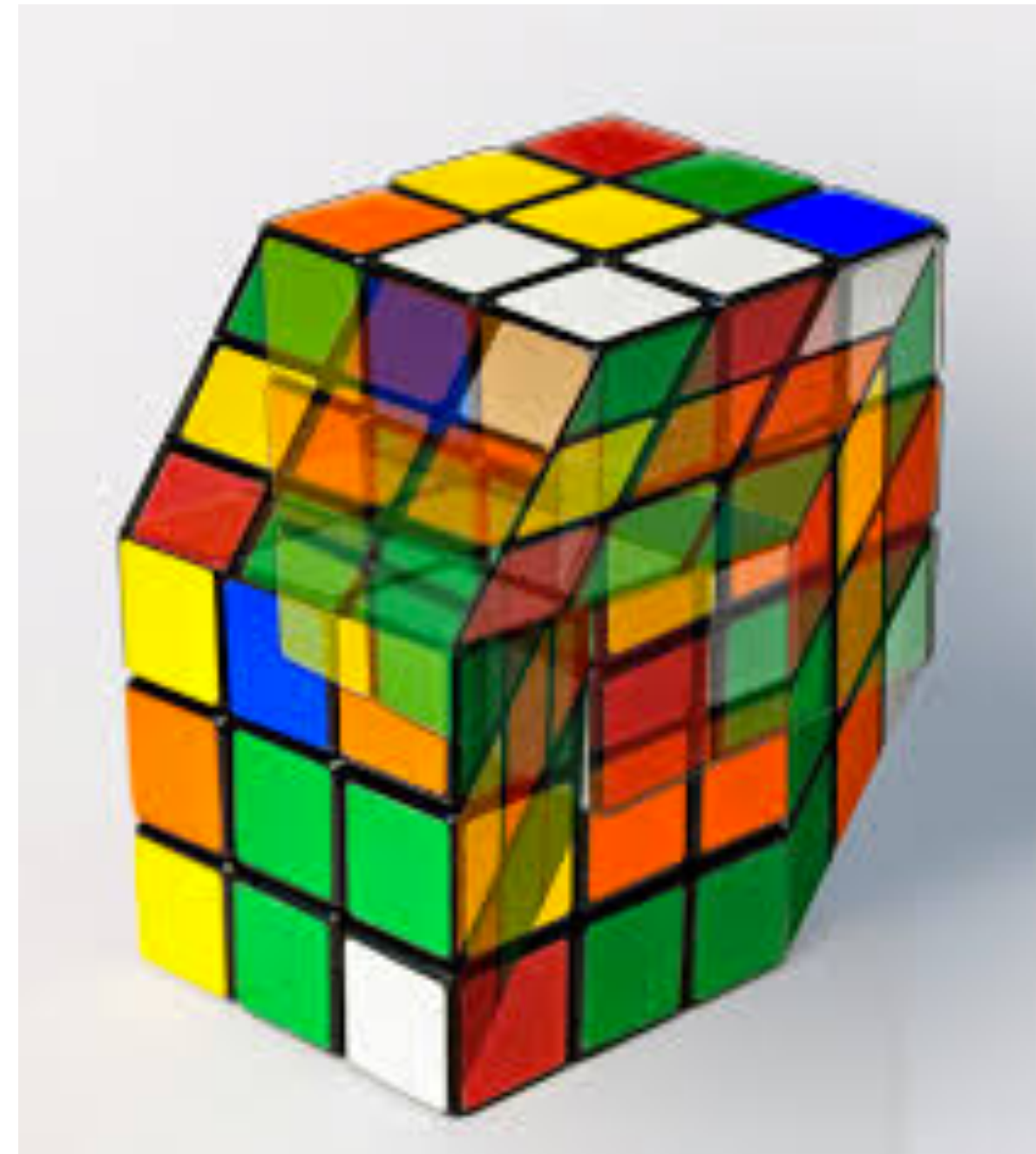
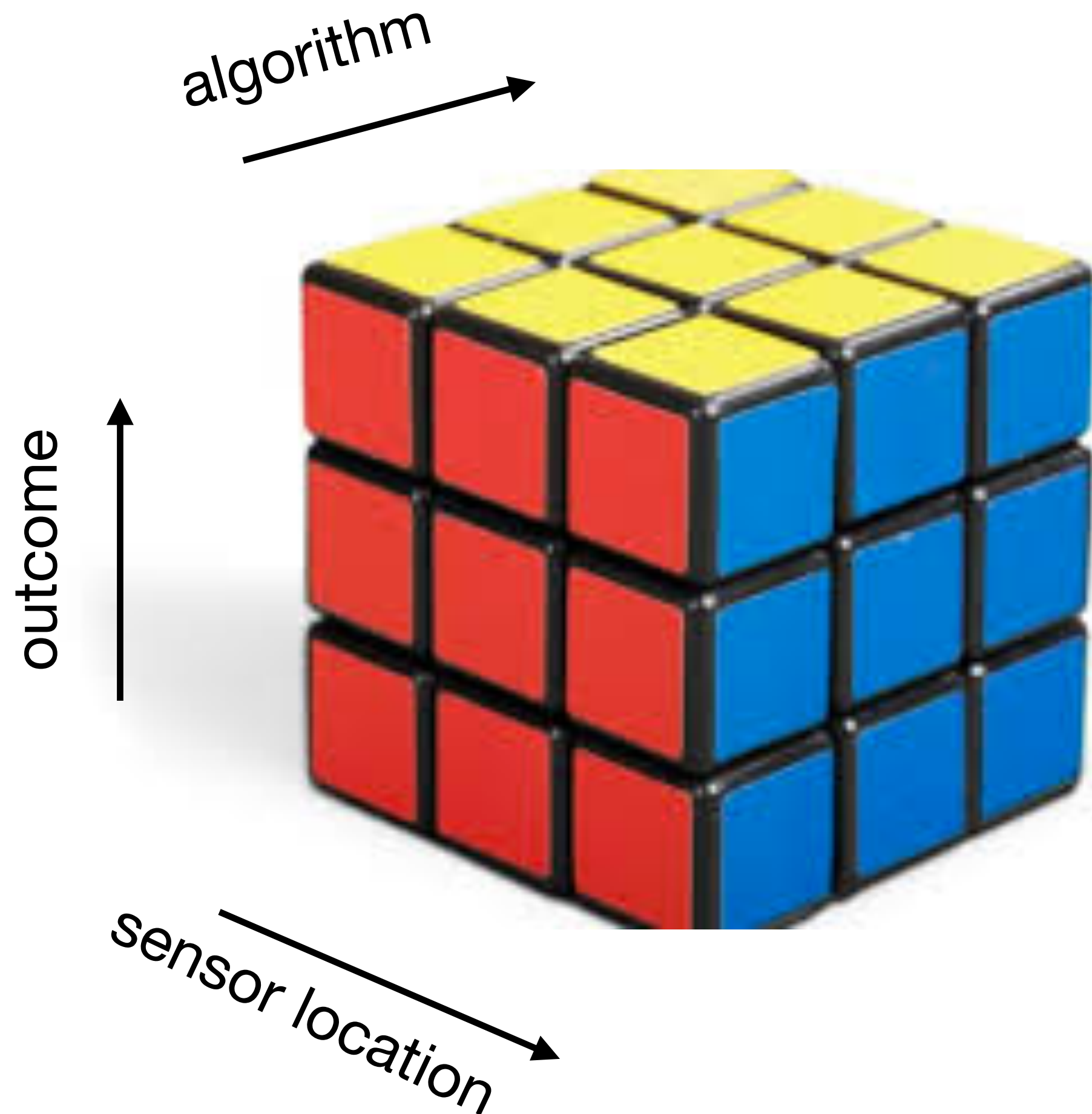
Validation and Benchmarking strategies

Goals: What works when, where and under what circumstances, for what diseases, with what sensor placement



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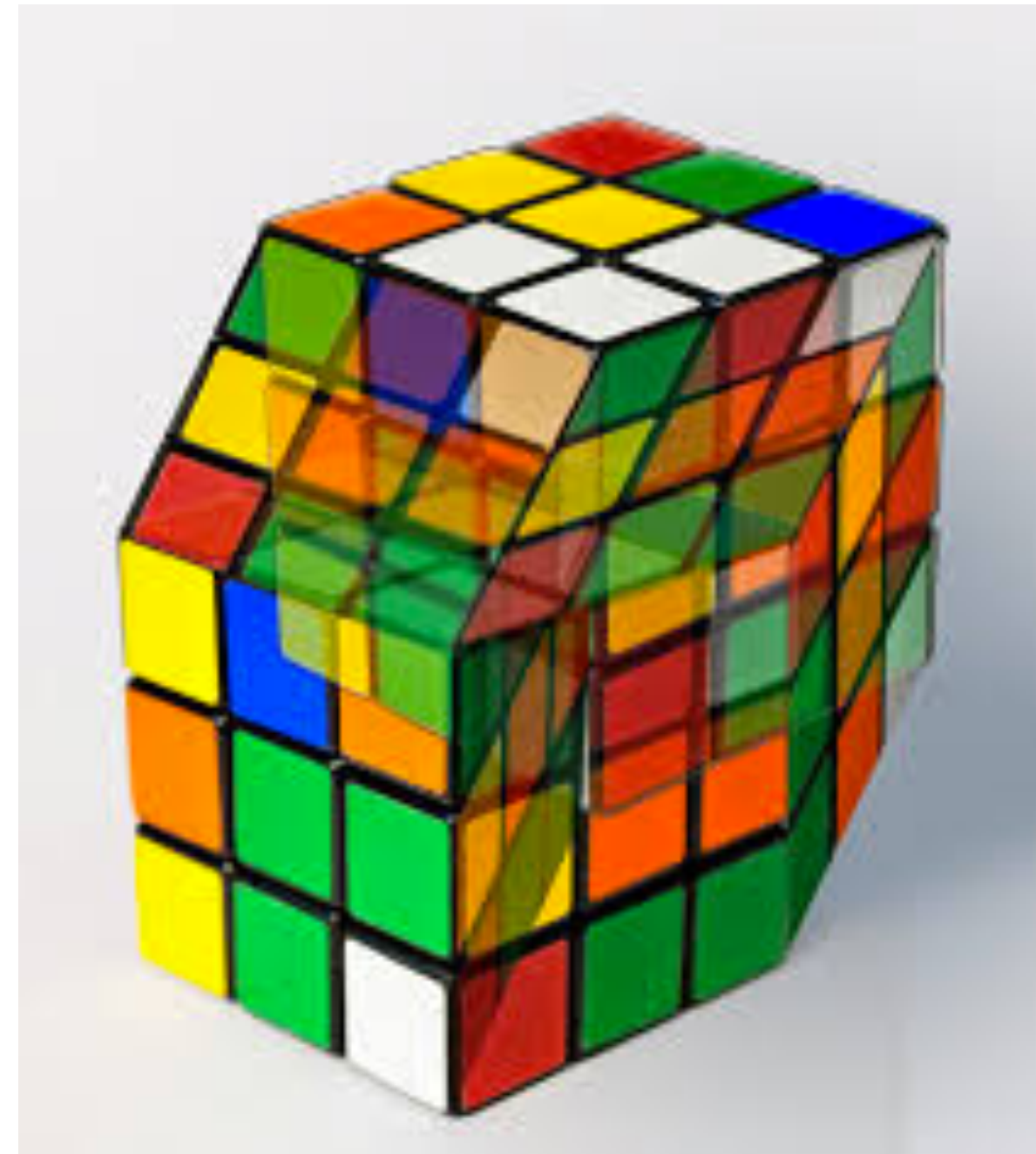
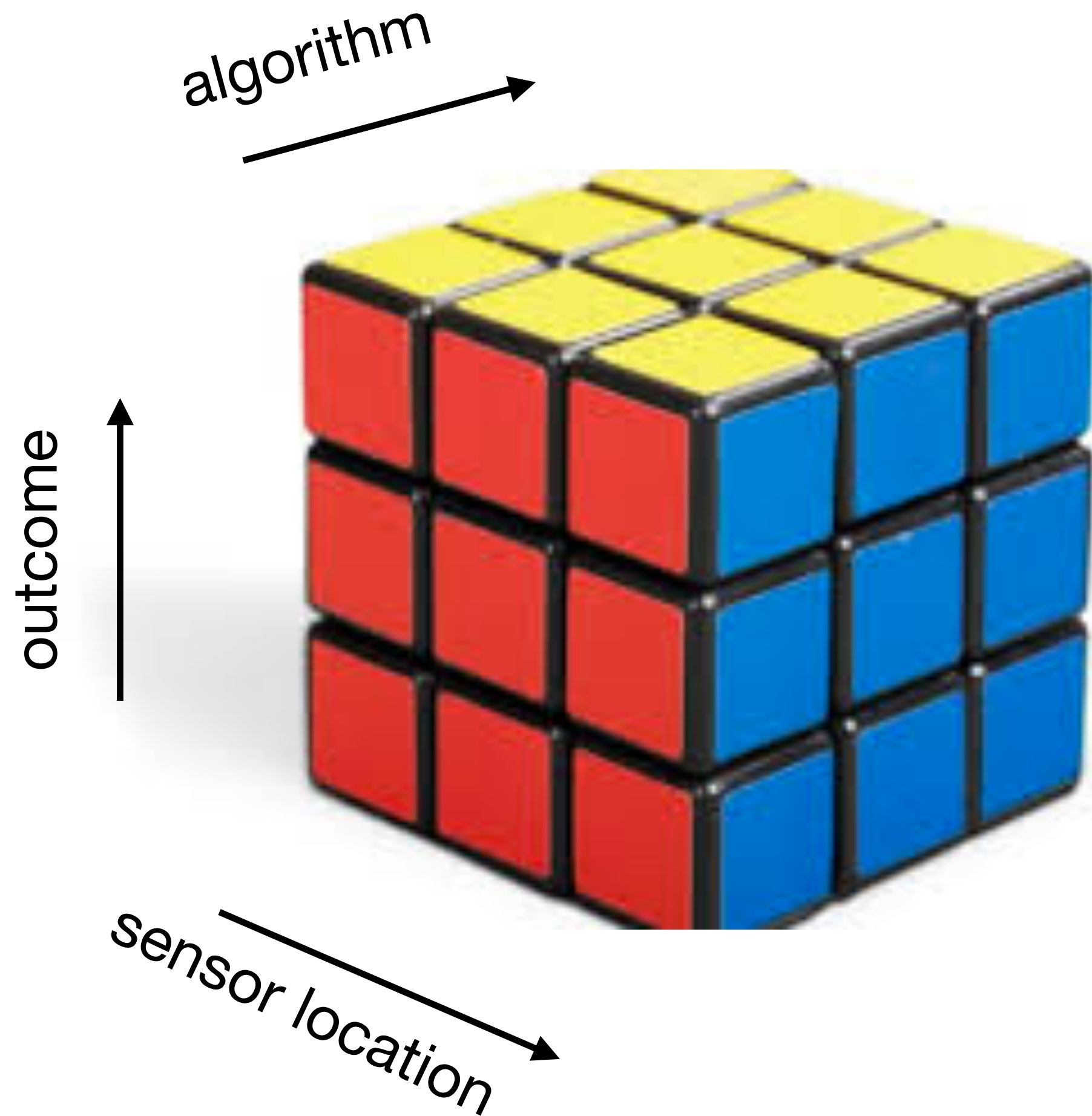
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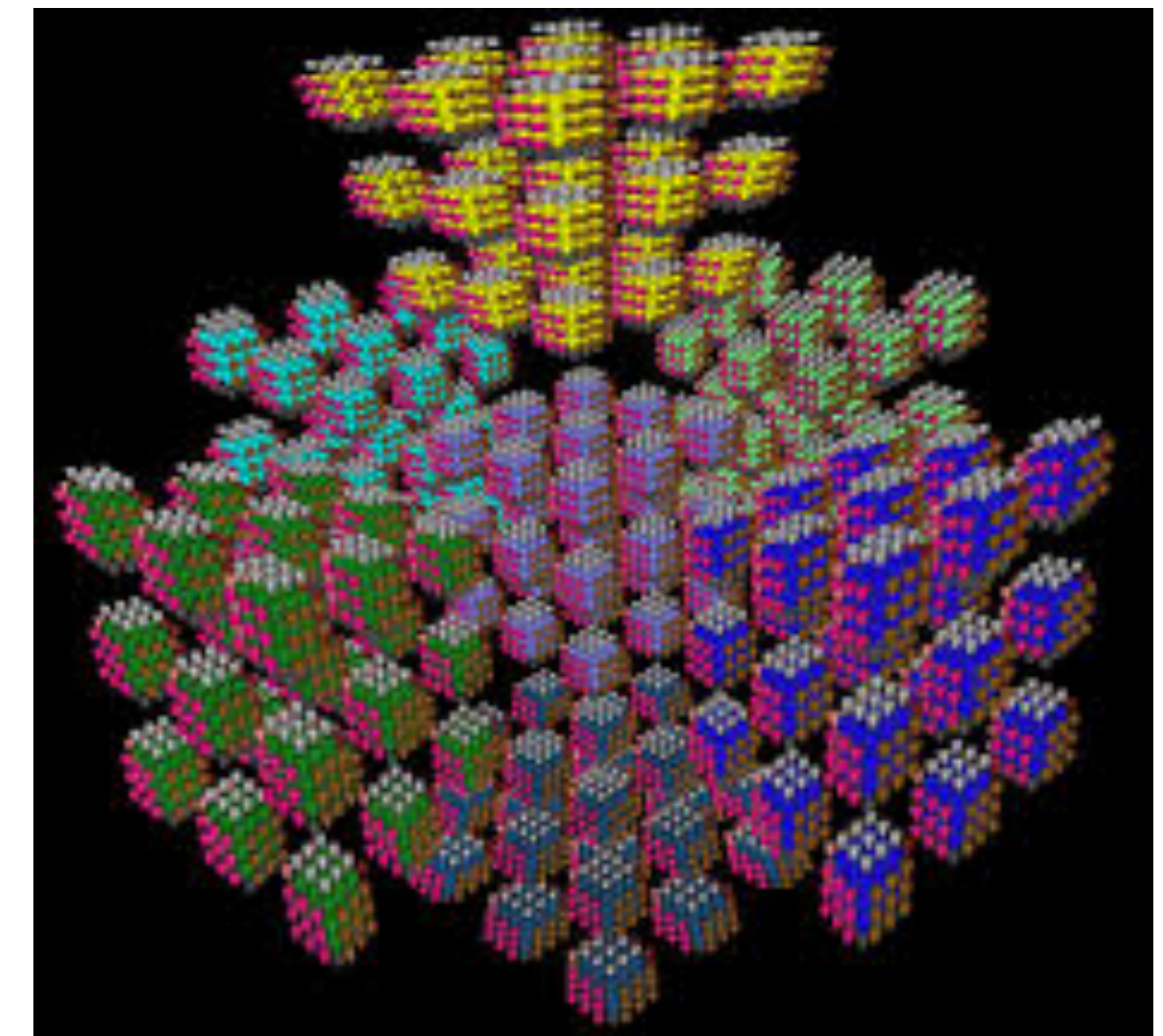
4D

Validation and Benchmarking strategies

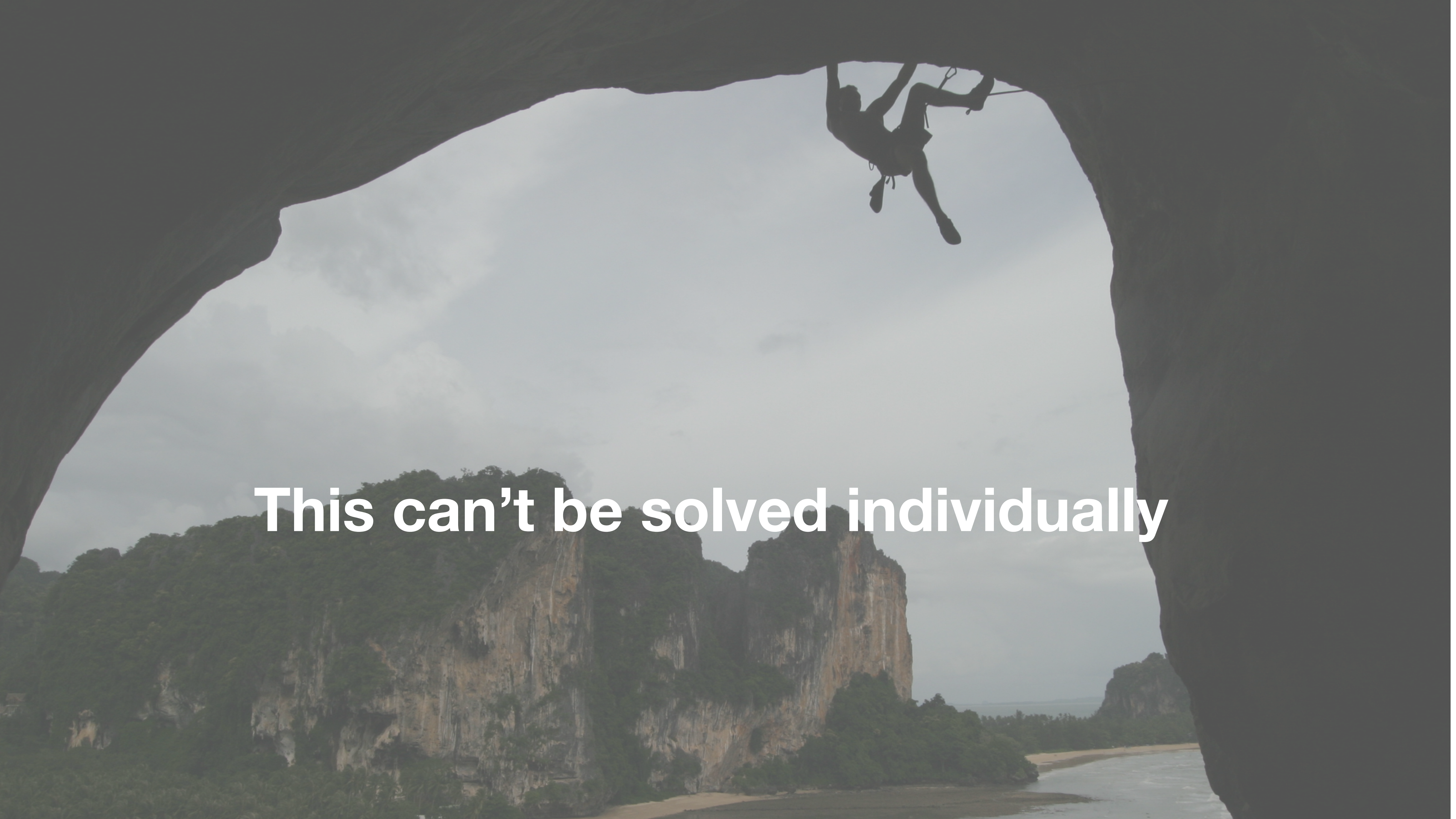
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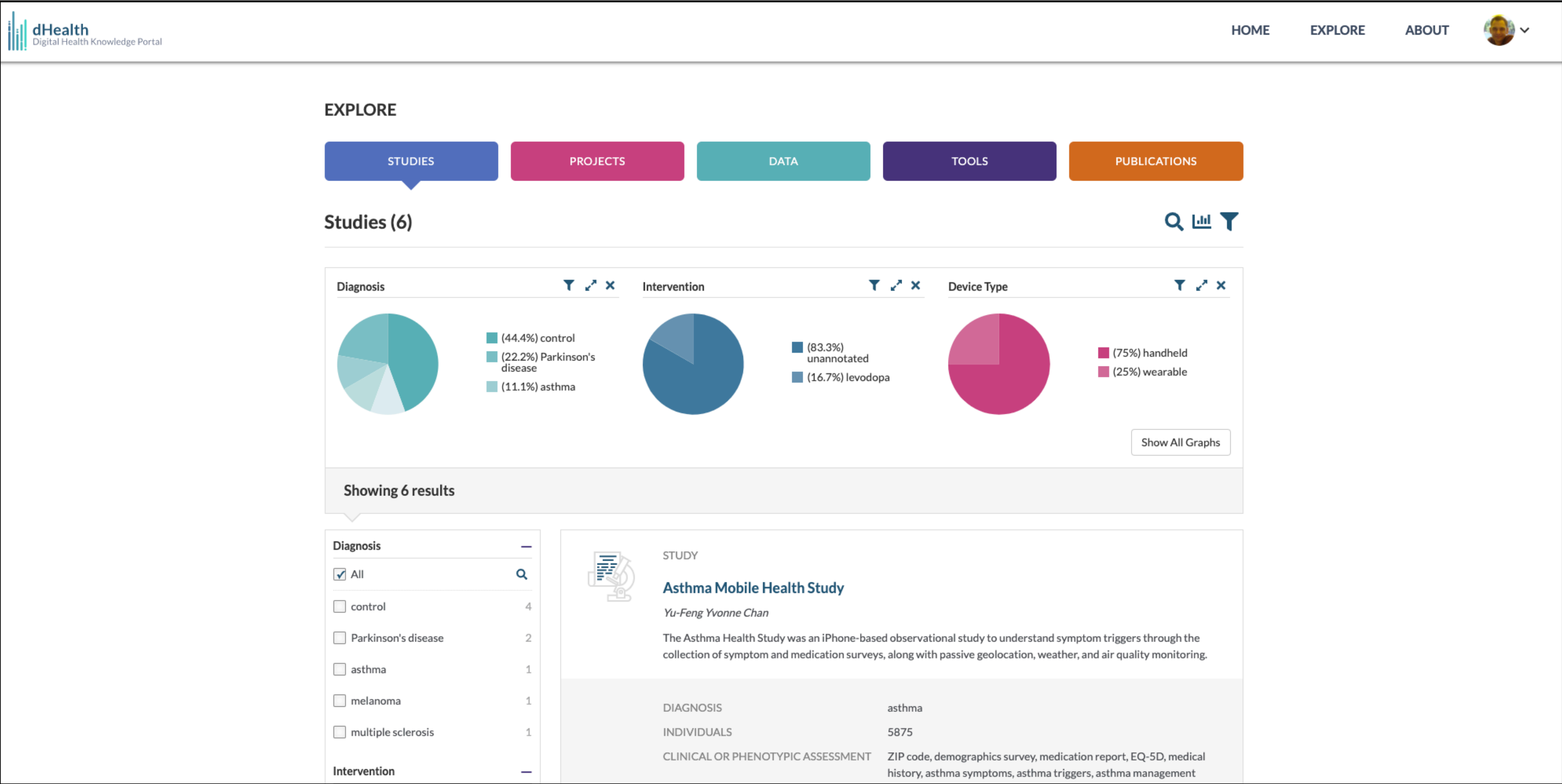


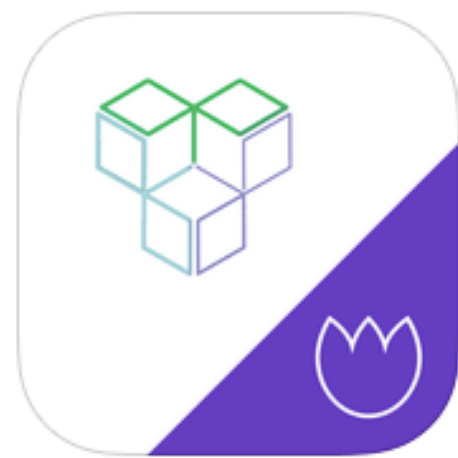
7D

A person is seen rappelling down a rope from the edge of a large, dark cave opening. The person is silhouetted against a bright, cloudy sky. Below the cave, a rugged coastline is visible, featuring steep, rocky cliffs covered in lush green vegetation. A sandy beach and the ocean are visible in the distance. The overall scene conveys a sense of adventure and individual effort.

This can't be solved individually

Make data and algorithms available





mPower - Researcher Community

 mPower Public Researcher Portal 



Larsson Omberg (larssono)



Help



Synapse ID: syn4993293

DOI: doi:10.7303/syn4993293

Storage Location: Synapse Storage 

 Share

 Annotations

 Tools 

Wiki 

Files 

Tables 

Discussion 

mPower Public Researcher Portal 

1 - Accessing the mPower data

2 - Data description 

3 - mPower research community

4 - Publications

5 - FAQs

6 - Contact us



mPower: Mobile Parkinson Disease Study

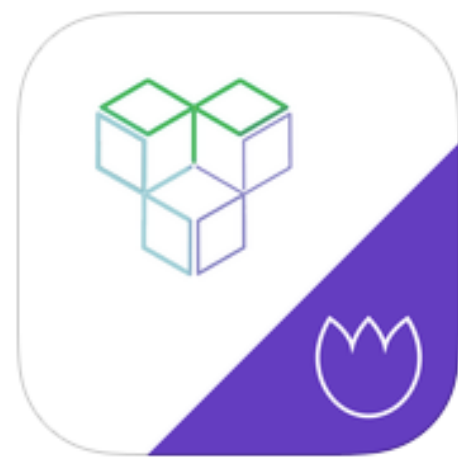
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Accessing the data

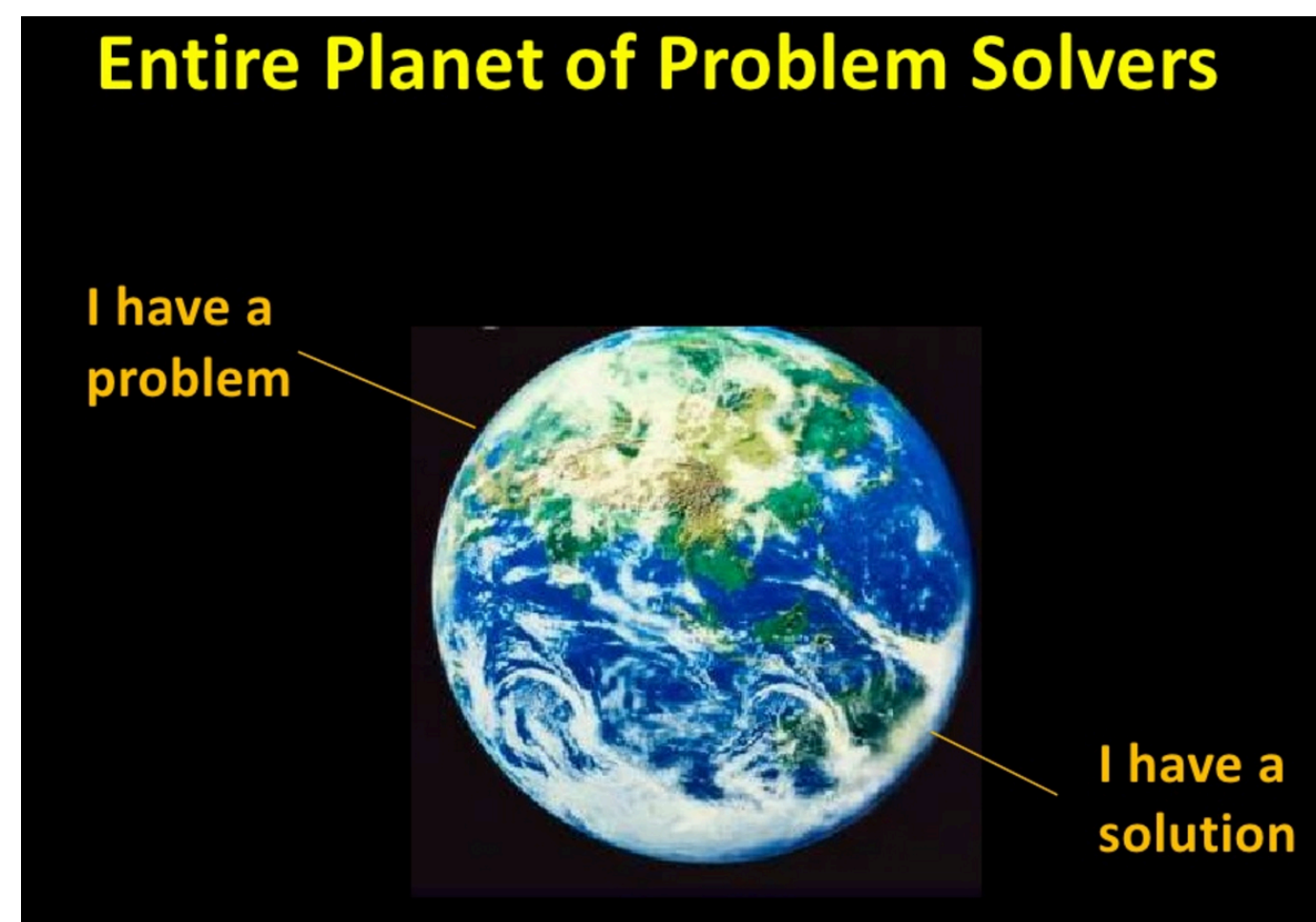
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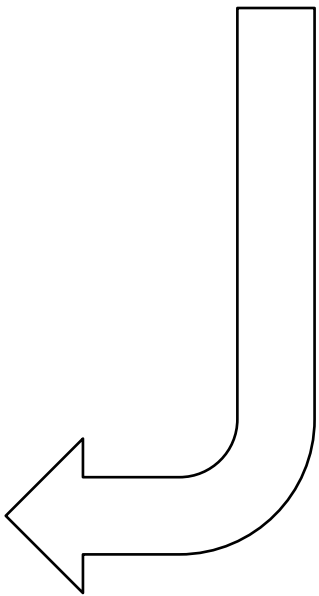
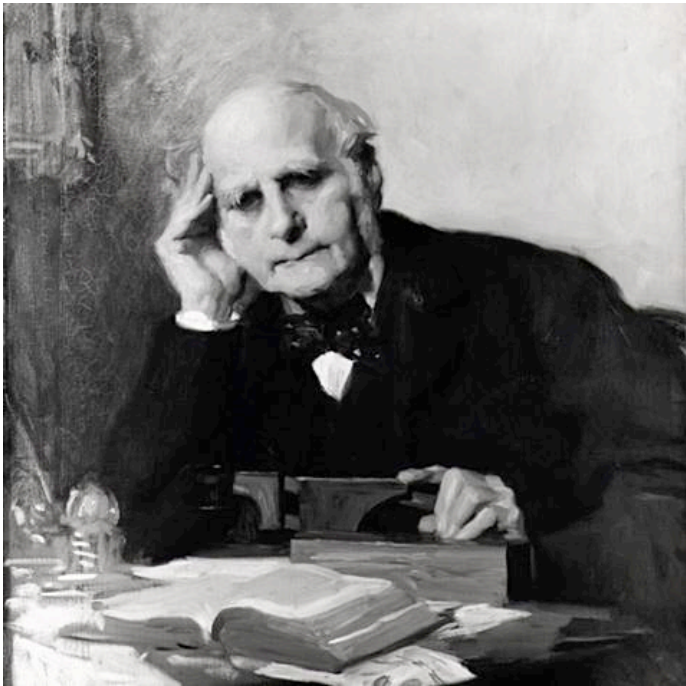
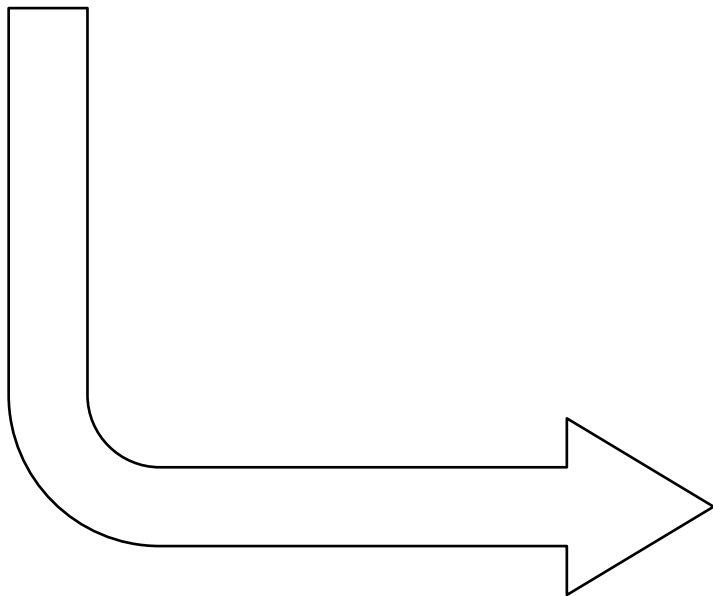
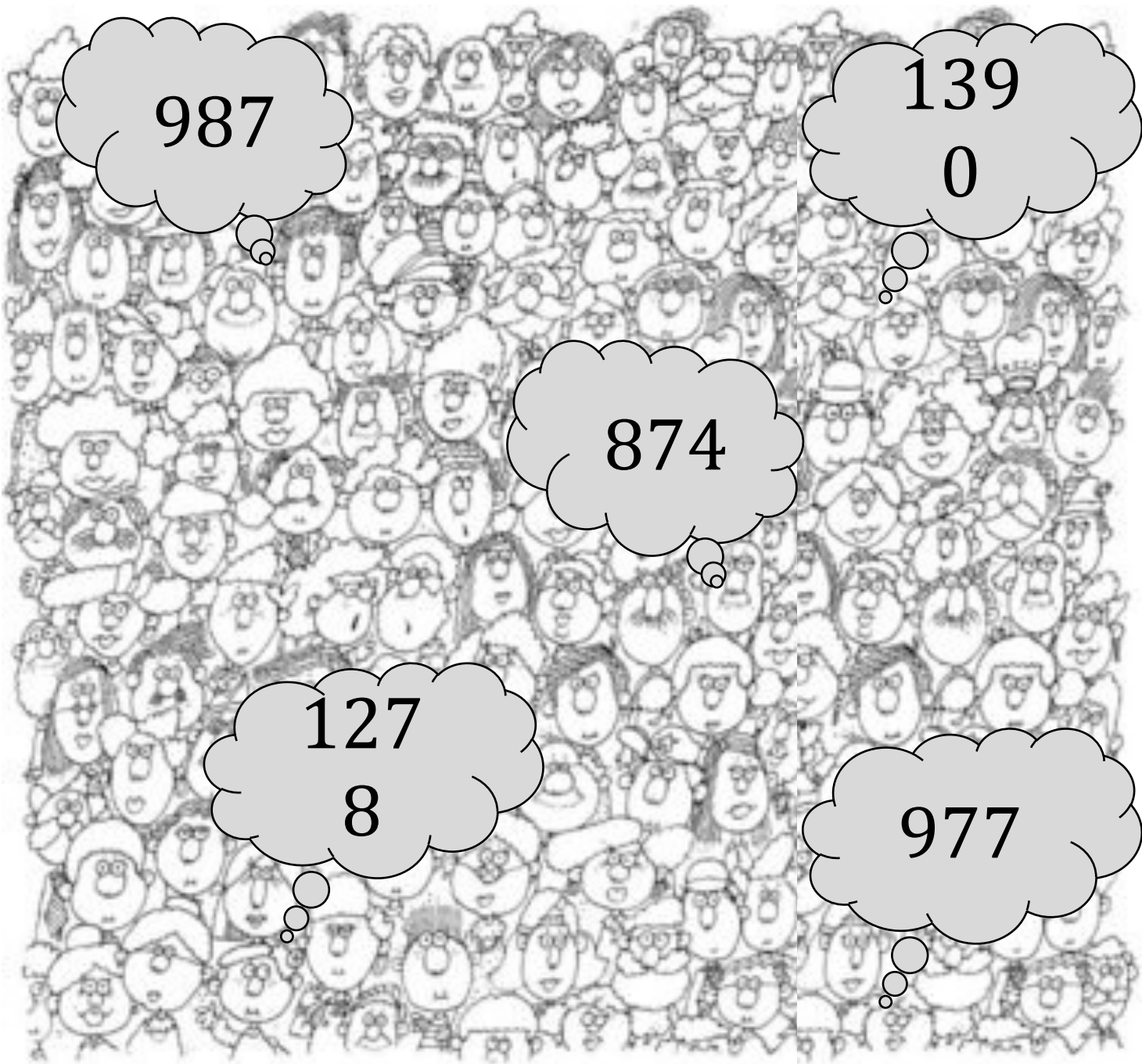
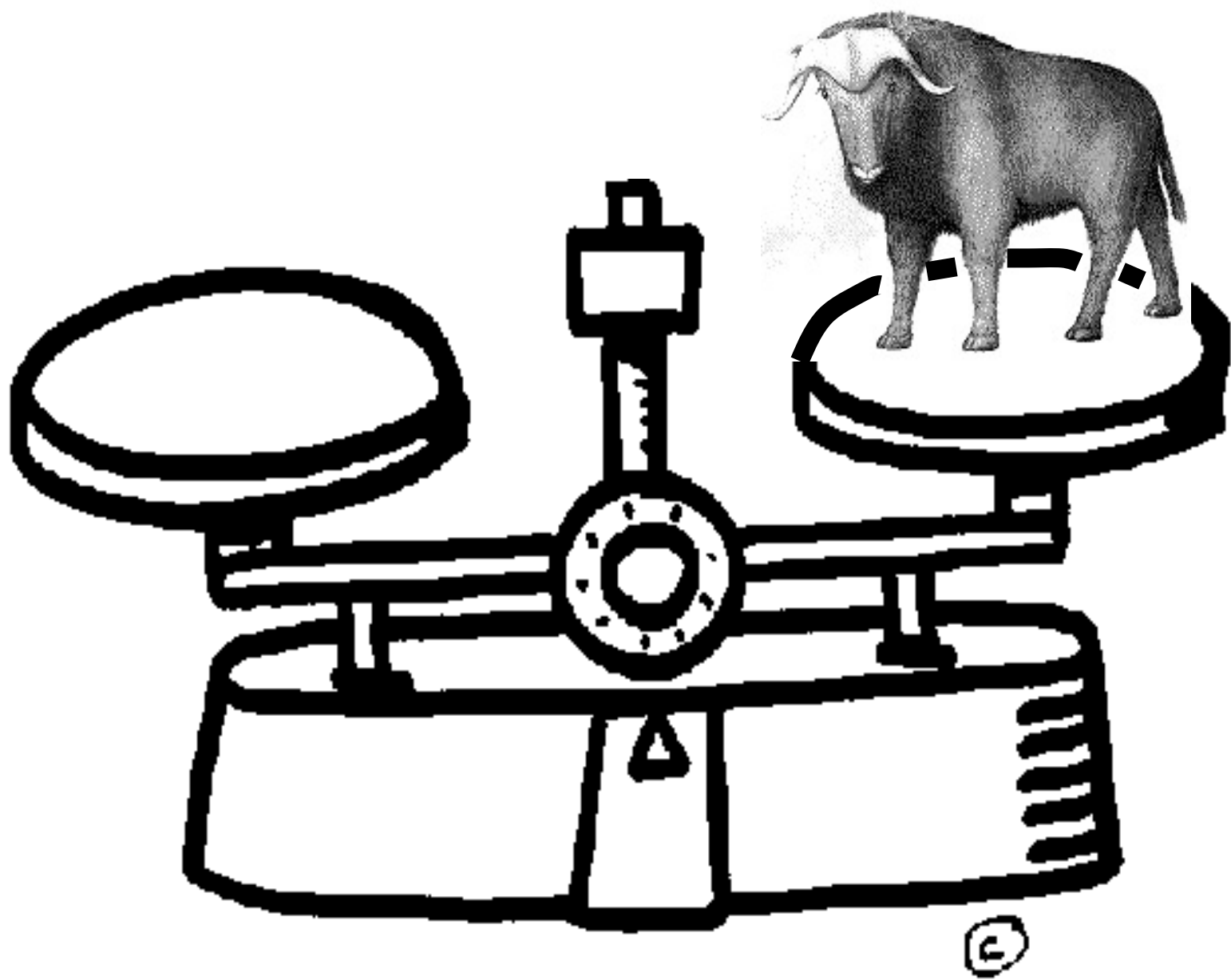
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Community Challenges and Public Benchmarking

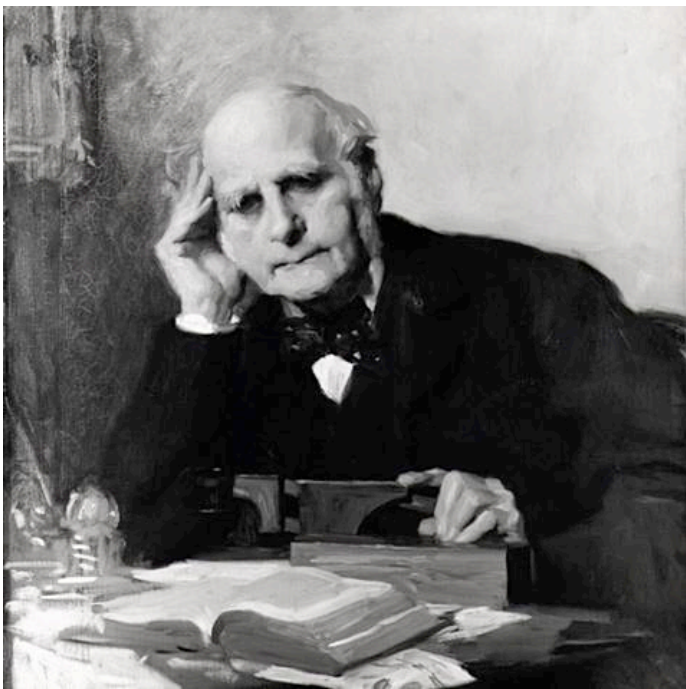
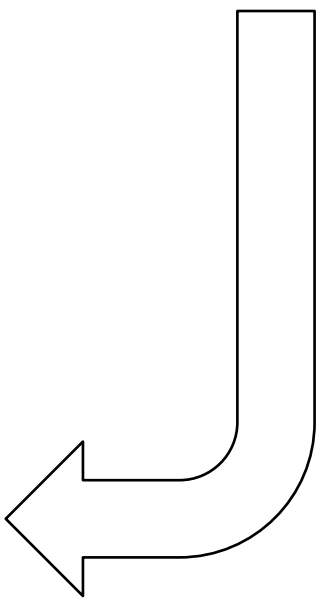
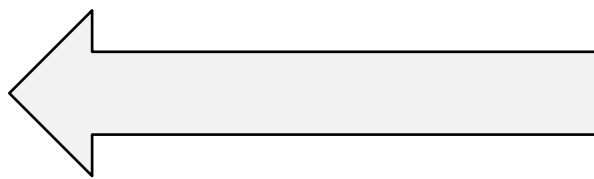
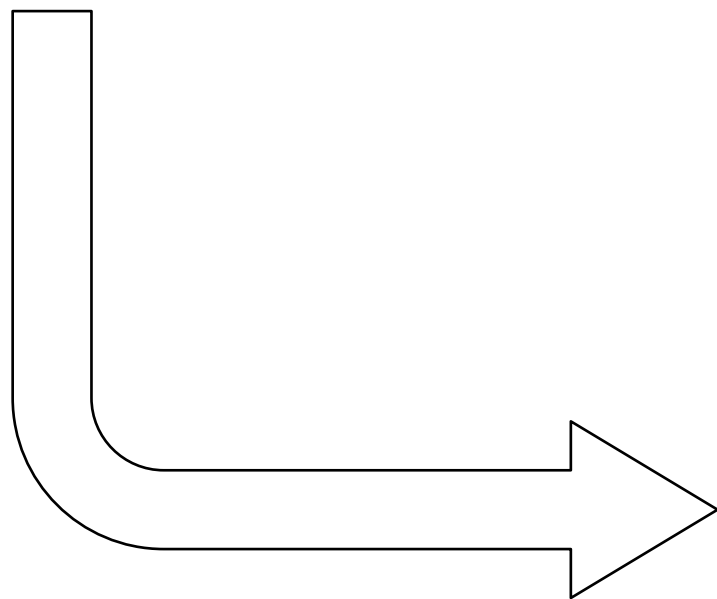
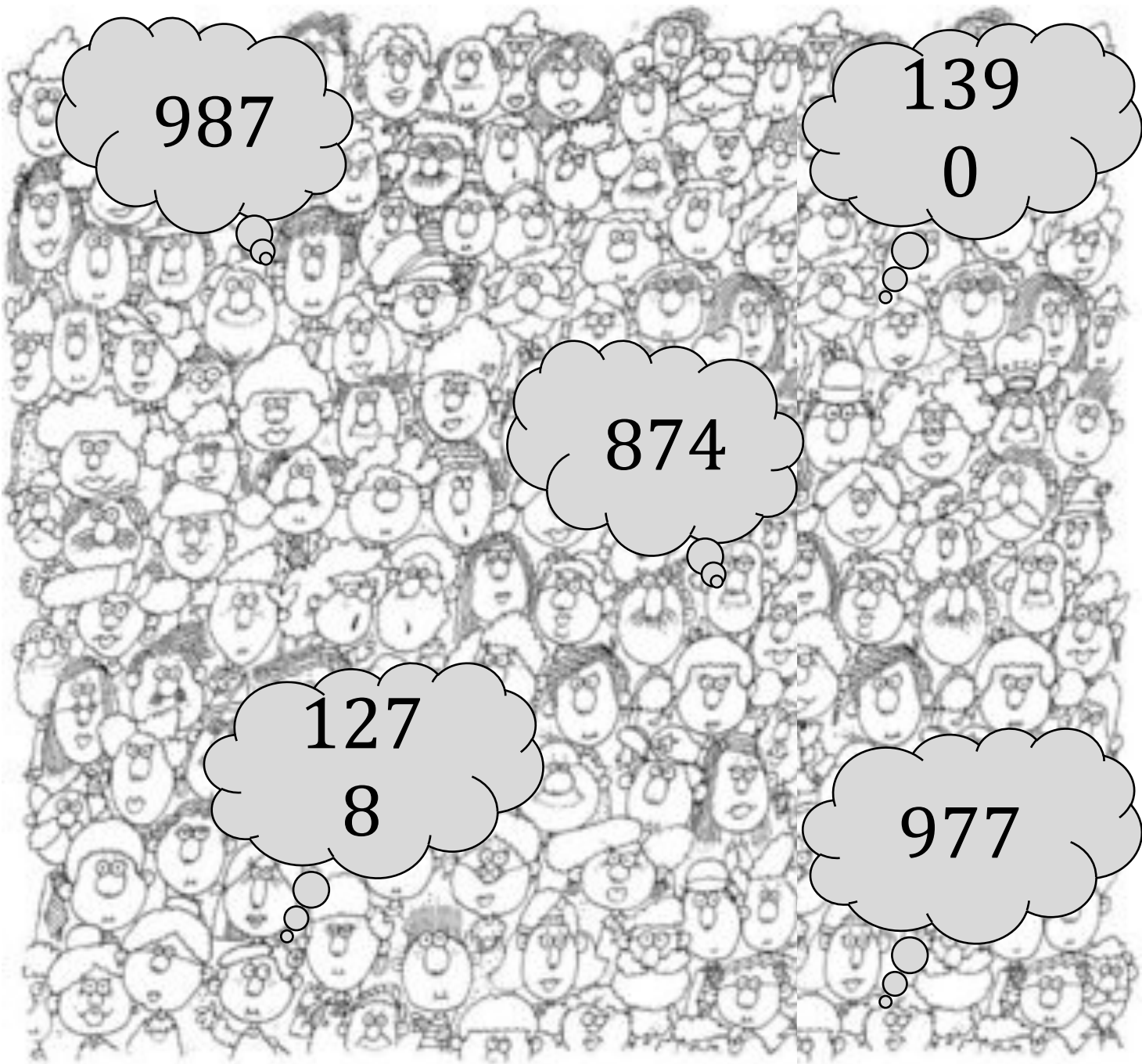
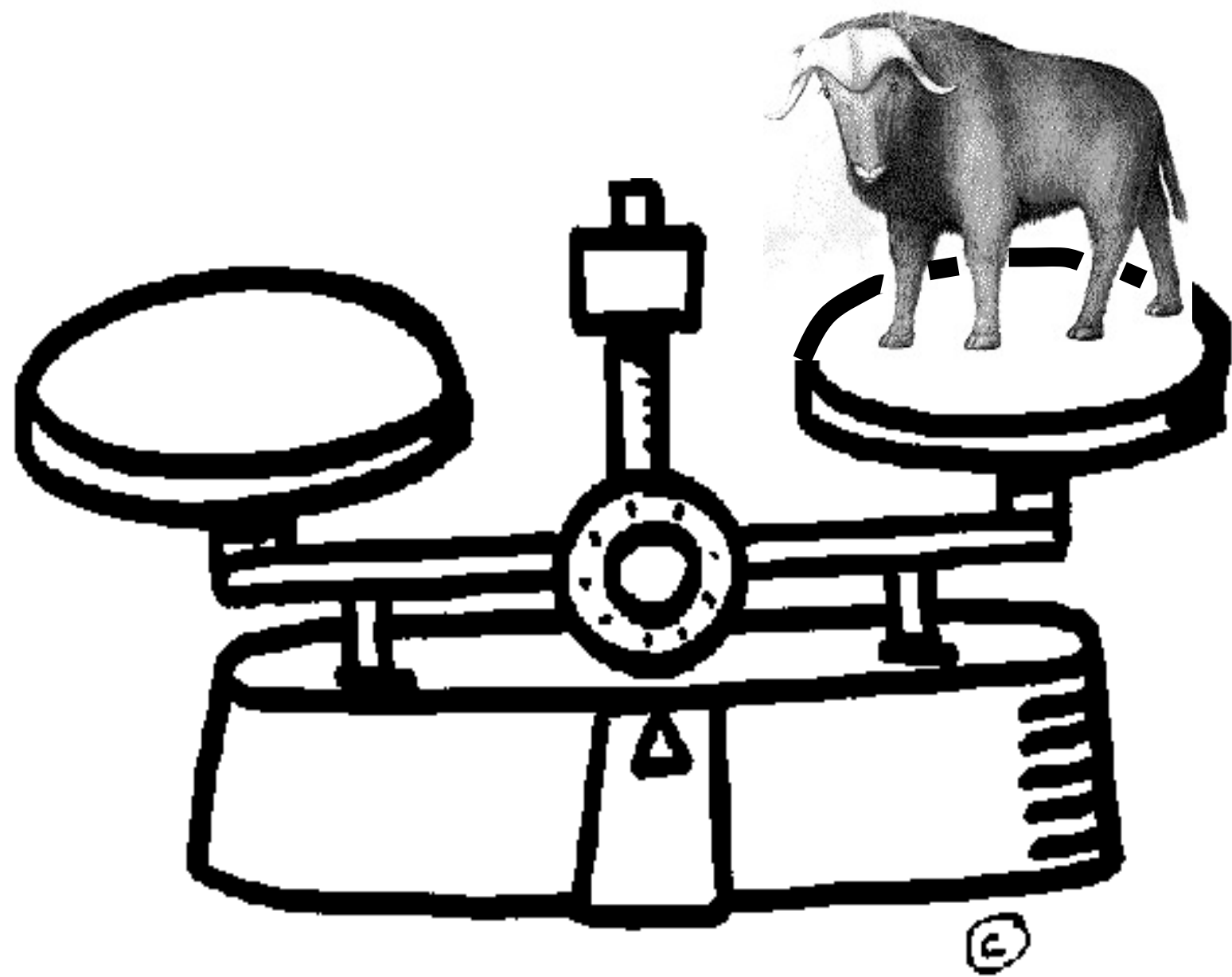
- “Self-assessment” has impeded the translation and dissemination of biomedical tools and methods.
- New incentives are required to convene research communities to develop domain standards and benchmarks.
- Quickly explore a large space of solutions



The Wisdom of Crowds



The Wisdom of Crowds



2017



**Parkinson's Disease Digital Biomarker
DREAM Challenge**

ENABLED BY

 **HARVARD**
UNIVERSITY

 **THE MICHAEL J. FOX FOUNDATION**
FOR PARKINSON'S RESEARCH

 Robert Wood Johnson
Foundation

 **Sage**
BIONETWORKS

 **verily**

 **UNIVERSITY OF**
ROCHESTER

EARLY SIGNAL

2020



BEAT-PD DREAM Challenge
Biomarker & Endpoint Assessment to Track Parkinson's Disease

 **BRAINCOMMONS**

 **evidation**

 **THE MICHAEL J. FOX FOUNDATION**
FOR PARKINSON'S RESEARCH

 **Radboudumc**
university medical center

 **Shirley Ryan**
Abilitylab.

 **Sage**Bionetworks

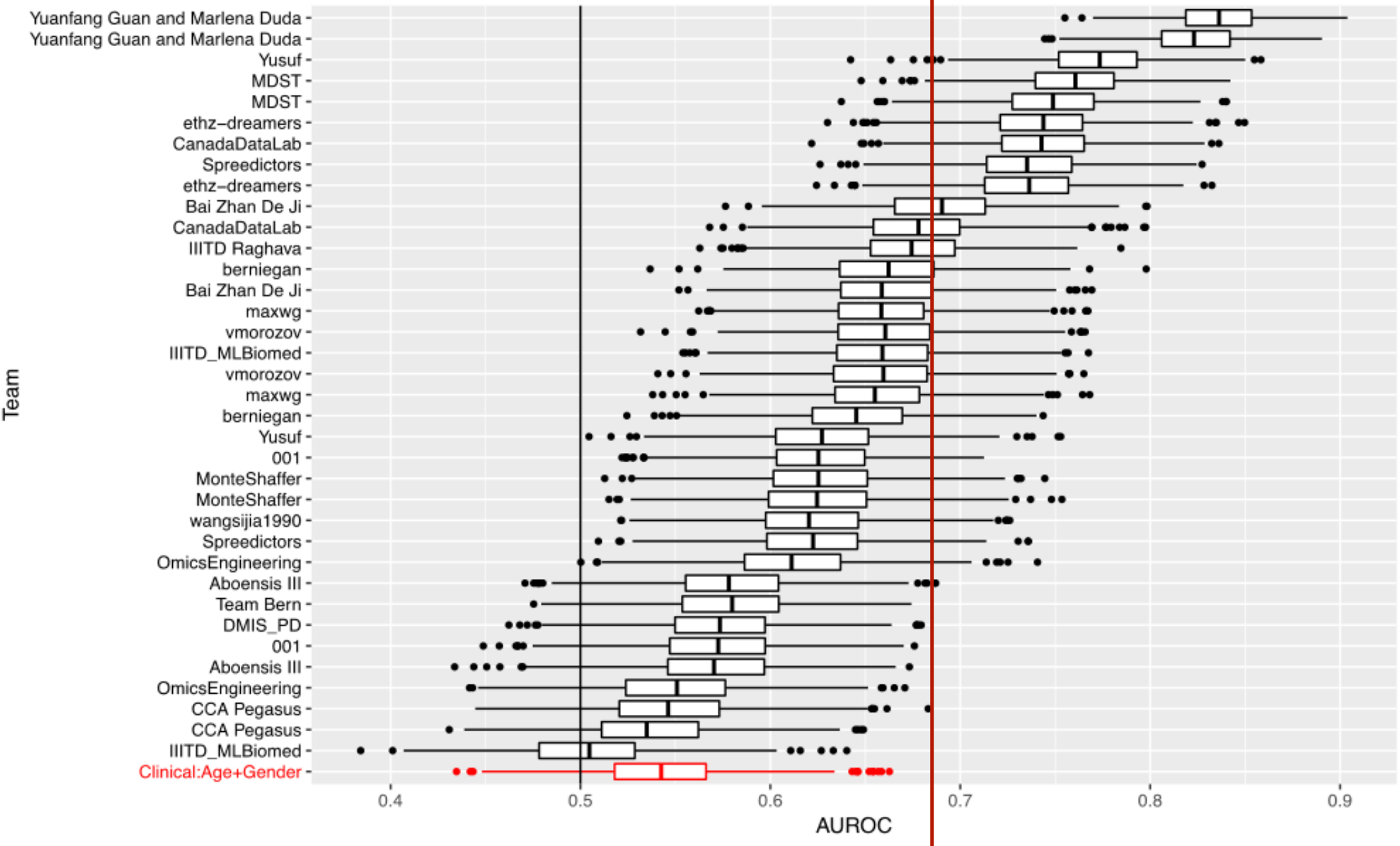
Crowdsourced solution was 38% better than experts



Crowdsourced solution was 38% better than experts



More than 400 registrants



Thank You



Larsson.omberg@sagebionetworks.org