



evidation

Using Patient- (Participant-) Generated Health Data as Real World Evidence

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Patients and their outcomes have historically been characterized using limited, visible-to-the-system data sets.

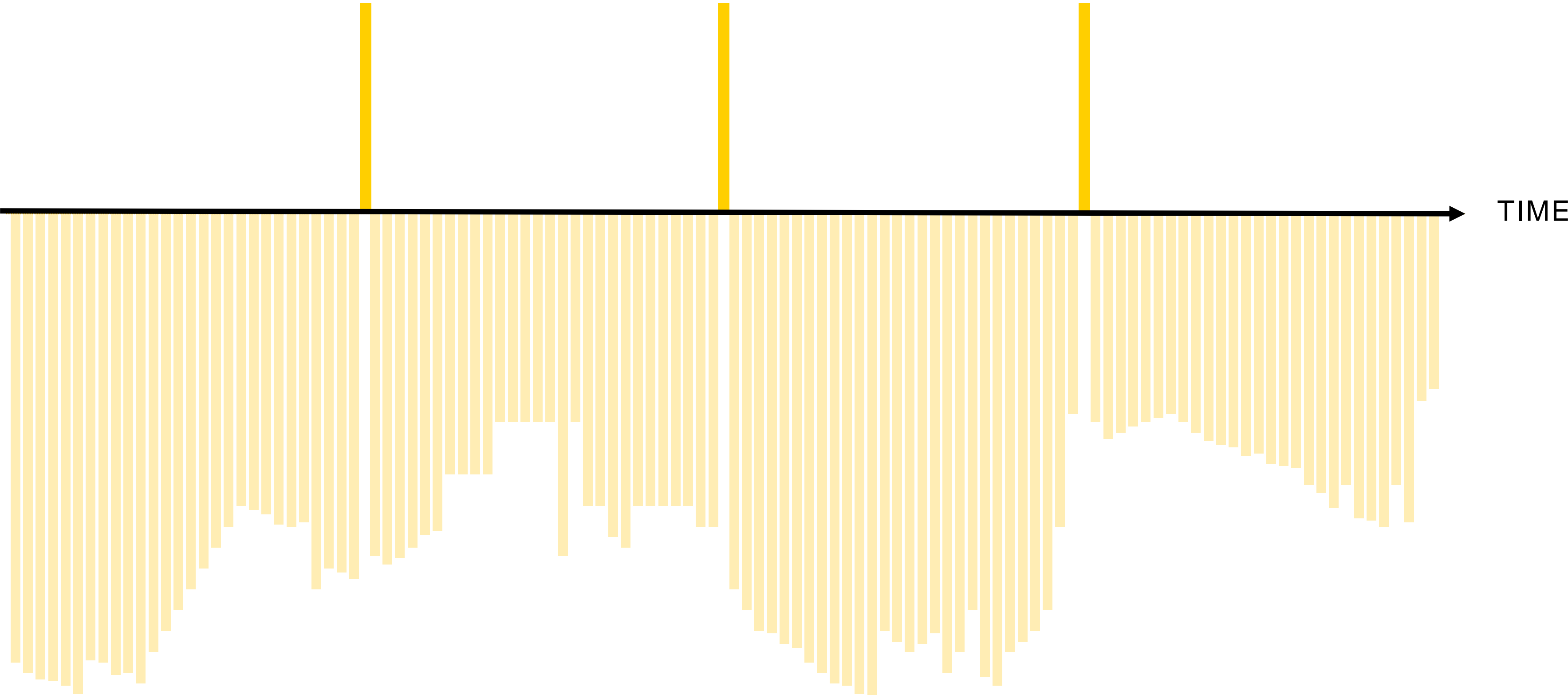
DATA POINTS

Visible

episodic

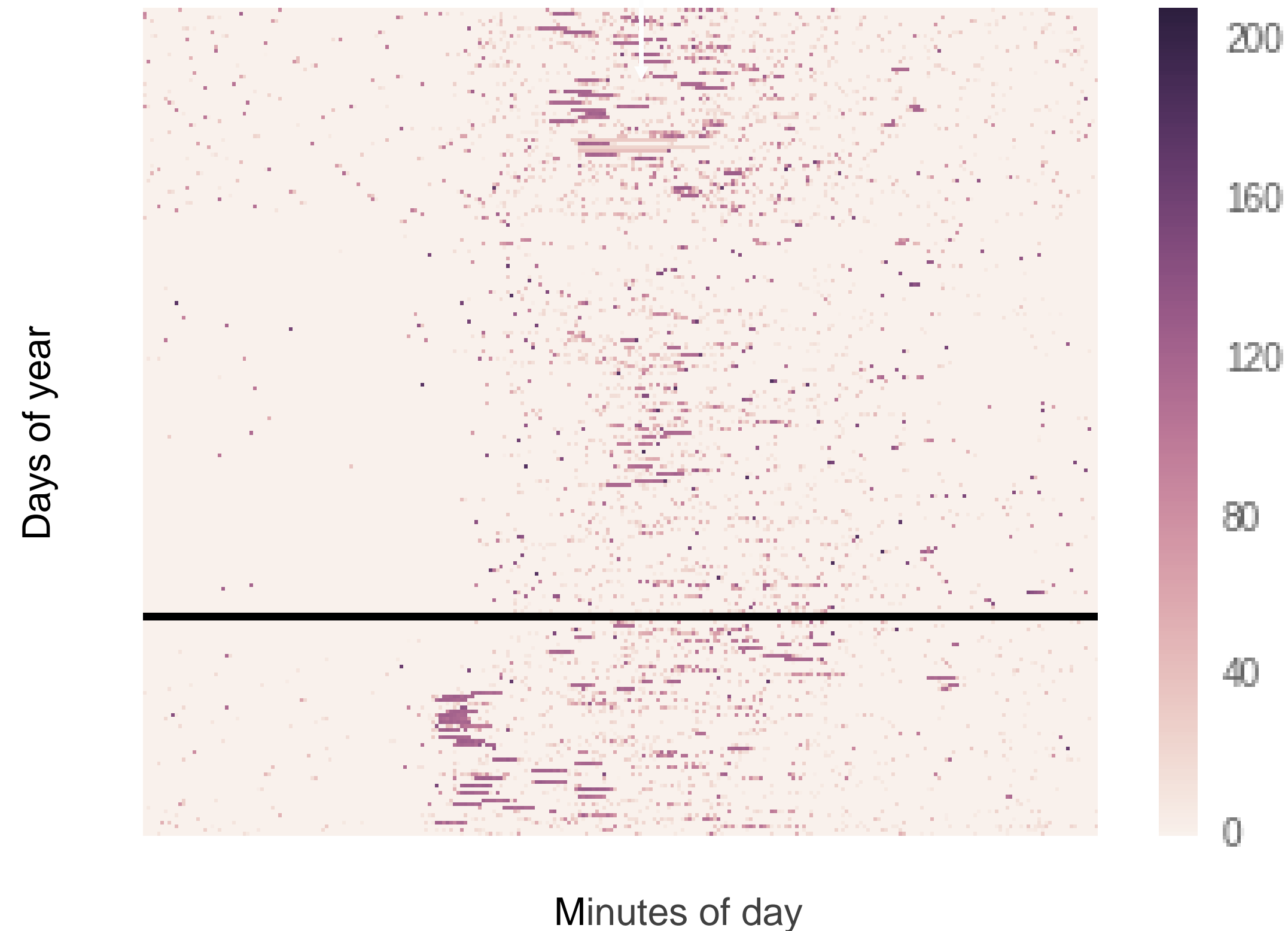
Invisible

continuous,
passive



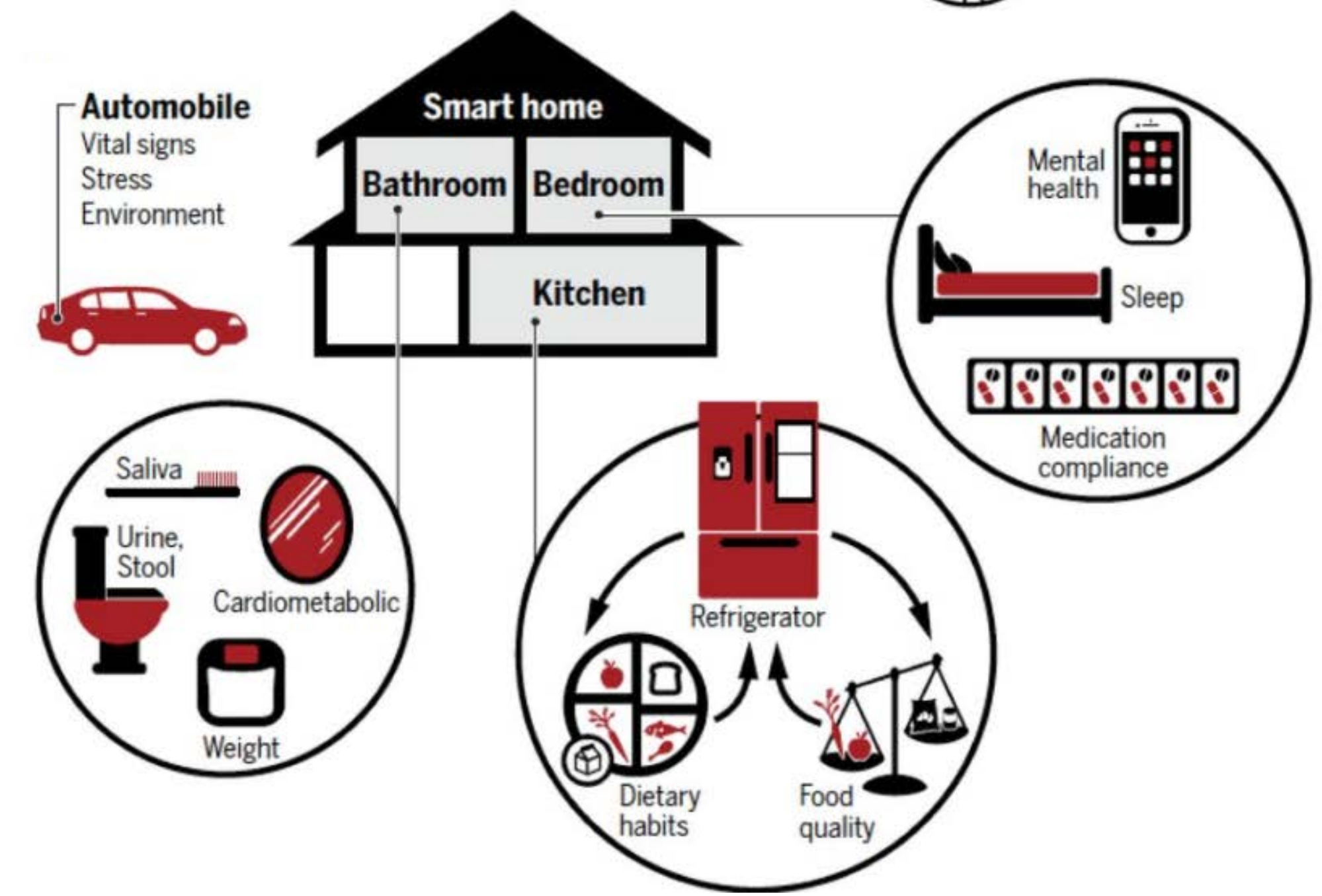
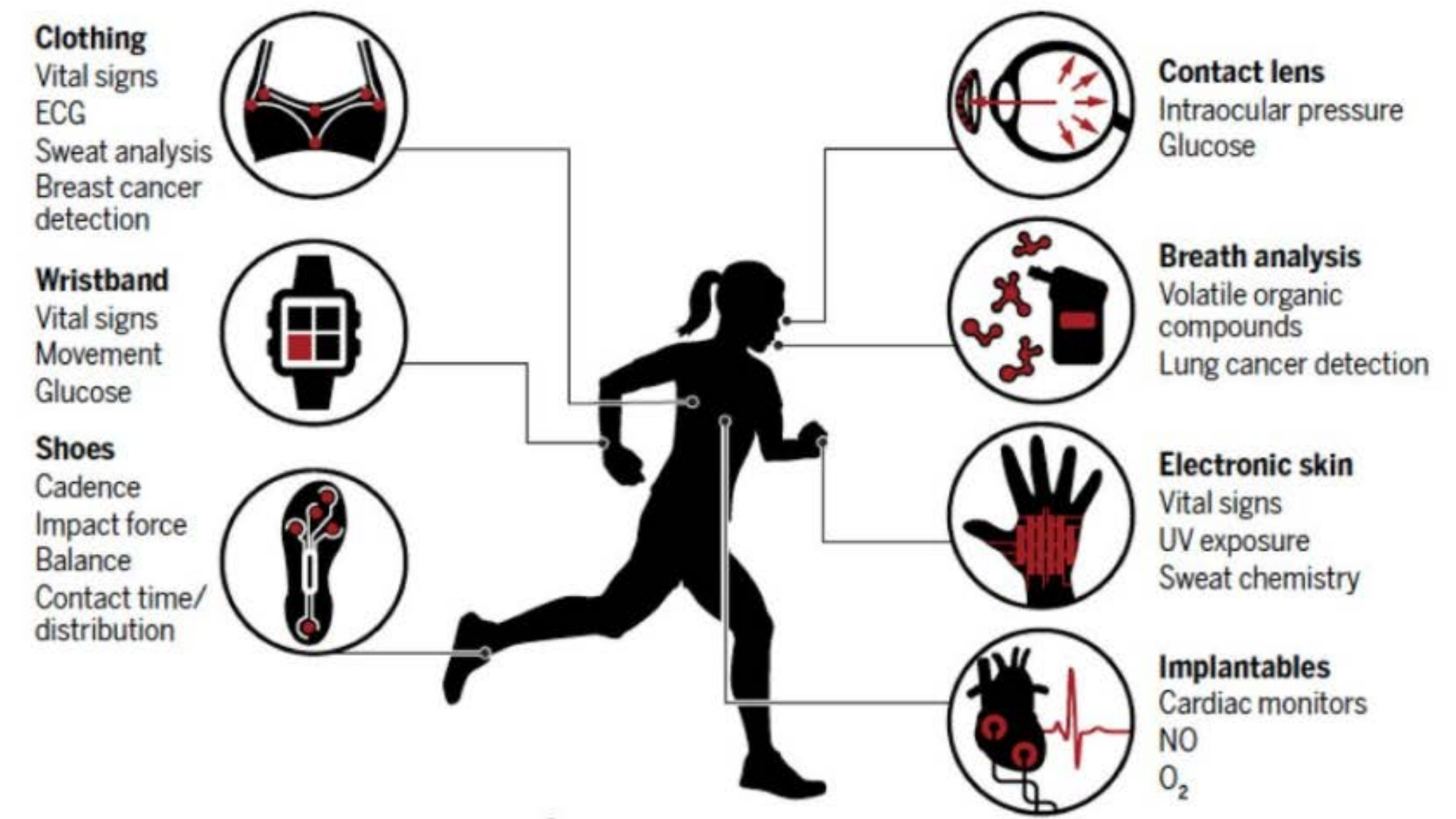
PGHD and Volume: from billions to tens of trillion data points

Provider Name	From Date	Thru Date	Paid Date	Total Charge	Total Paid	CPT Code	CPT Description	Prime ICD9	ICD9Desc
WALGREEN	12/27/09	12/27/2009	12/27/2009	0.00	0.00	RX	TEMODAR 100 MG CAPSU		
WALGREEN	12/27/09	12/27/2009	12/27/2009	0.00	0.00	RX	TEMODAR 20 MG CAPSUL		
WALGREEN	12/27/09	12/27/2009	12/27/2009	0.00	0.00	RX	TEMODAR 5 MG CAPSULE		
WALGREEN	12/22/09	12/22/2009	12/22/2009	1.60	1.60	RX	PROMETHAZINE 25 MG T		
DAVID BRACH MD	11/24/09	11/24/2009	12/10/2009	588.00	449.00	77301	NTSTY MODUL RADTHX P	191.4	MALIGNANT NEO OCCUPI



PGHD and Variety:

All traditional RWD data sources may eventually become PGHD



Adapted from: Gambhir, Sanjiv Sam, et al. "Toward achieving precision health." Science translational medicine 10.430 (2018)

PGHD Value(1): Measure novel outcomes at population level

ACTIVITY TRACKERS ONLY	MS Trackers	Matched Control Trackers
N	498	1,400
% Days with Tracked Steps**	73%	77%
Mean Daily Stepcount**	6,379	7,188
Mean Nightly Sleep Duration (hours)	6.3	6.5
Max Time to Fall Asleep (minutes)**	18.58	13.91

*p < 0.05; **p < 0.001 corrected for FDR

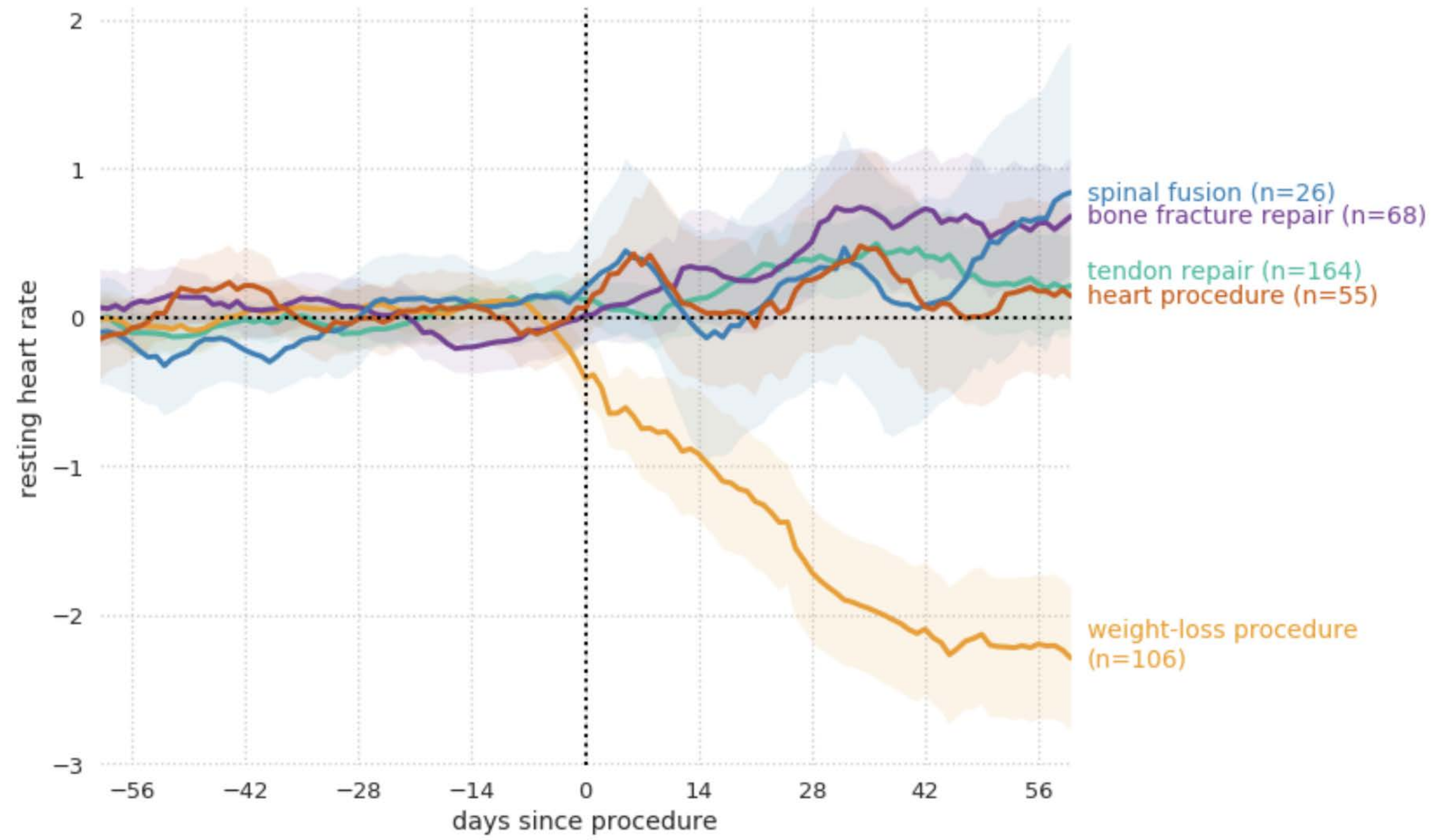
	T2DM	Controls
Number of trackers	4,459	10,321
% Days with tracked steps	78.7%**	80.7%
Mean nightly sleep duration (hours)	6.48**	6.69
Resting heart rate (bpm)	71.2**	66.0
Mean Daily Stepcount	6,256**	7,374
Average daily cardio exercise sessions	0.20**	0.41

*p < 0.05, **p < 0.001

Evidation & Novartis: "Real-World Use of Wearable Devices in a Large Multiple Sclerosis Cohort". Presented at the American Academy of Neurology (AAN) Annual Meeting 2018

Evidation & Sanofi: "Using Claims And Wearable Devices Data To Quantify Influenza Outcomes Among Type 2 Diabetes Patients - A Population Study". Presented at the American Diabetes Association (ADA) Scientific Sessions 2018

PGHD Value (2): Quantify individual change over time

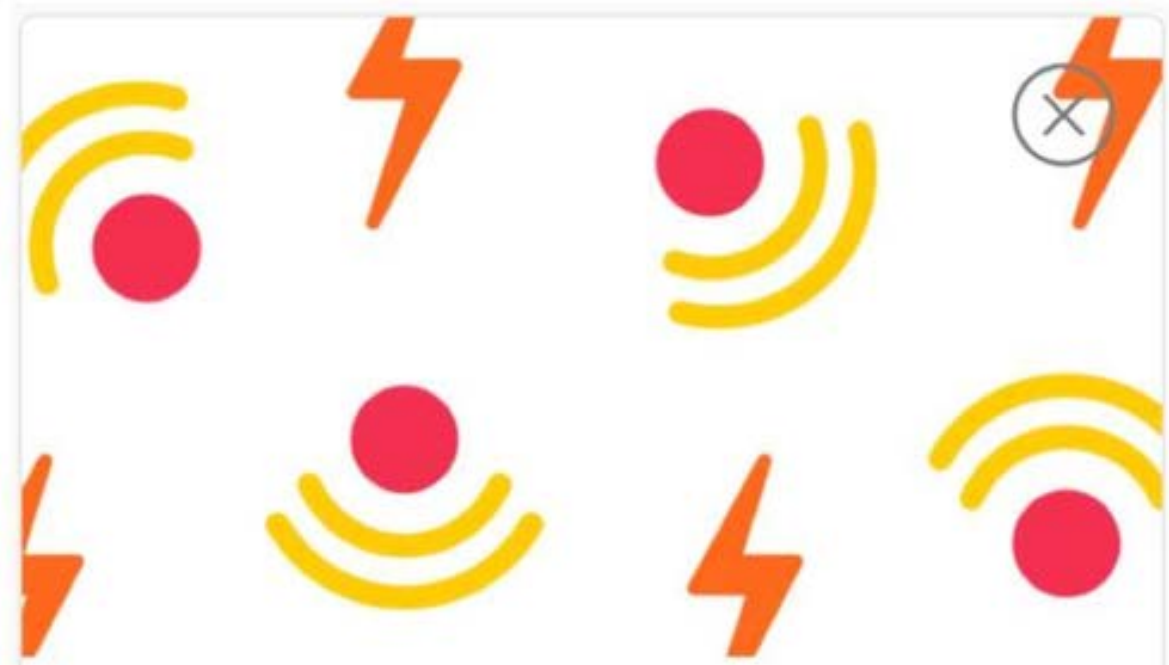


Based on 116K survey responders who responded yes to: "Have you had any type of medical procedure or surgery since June 2016?"

PGHD blurs the line between RWE and CT



DiSCover Project
Digital Signals in Chronic Pain



CHRONIC PAIN STUDY - EARN UP TO \$40 IN POINTS

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MOBILE TECHNOLOGY SELECTION



DATA COLLECTION, ANALYSIS, & INTERPRETATION



FDA SUBMISSION & INSPECTION



DATA MANAGEMENT

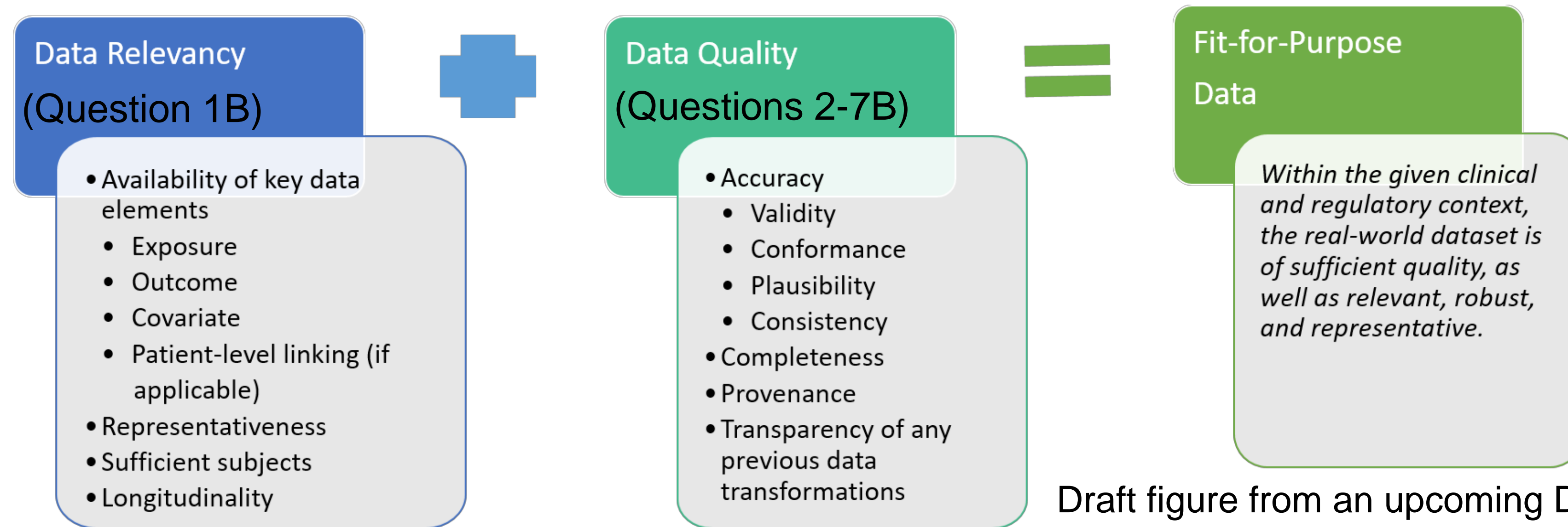


PROTOCOL DESIGN & EXECUTION



CTTI: Executive Summary: Advancing the Use of Mobile Technologies for Data Capture & Improved Clinical Trials

Conclusion: What's the same and what's different?



Draft figure from an upcoming Duke-Margolis white paper, permission to share

What traits are unique to PGHD but common across clinical research?

- Veracity: Data quality, missing data, attribution (Questions 3B)
- Variability in measurements & the importance of UX (Question 4B)
- Velocity: repeated measurement enable change detection and monitoring

What traits are both unique to PGHD and unique to RWE?

- New sources of bias & confounders unusual see in observational studies (Question 2B)
- New models of data use agreement that keep participants in the loop. (Question 7B +)