

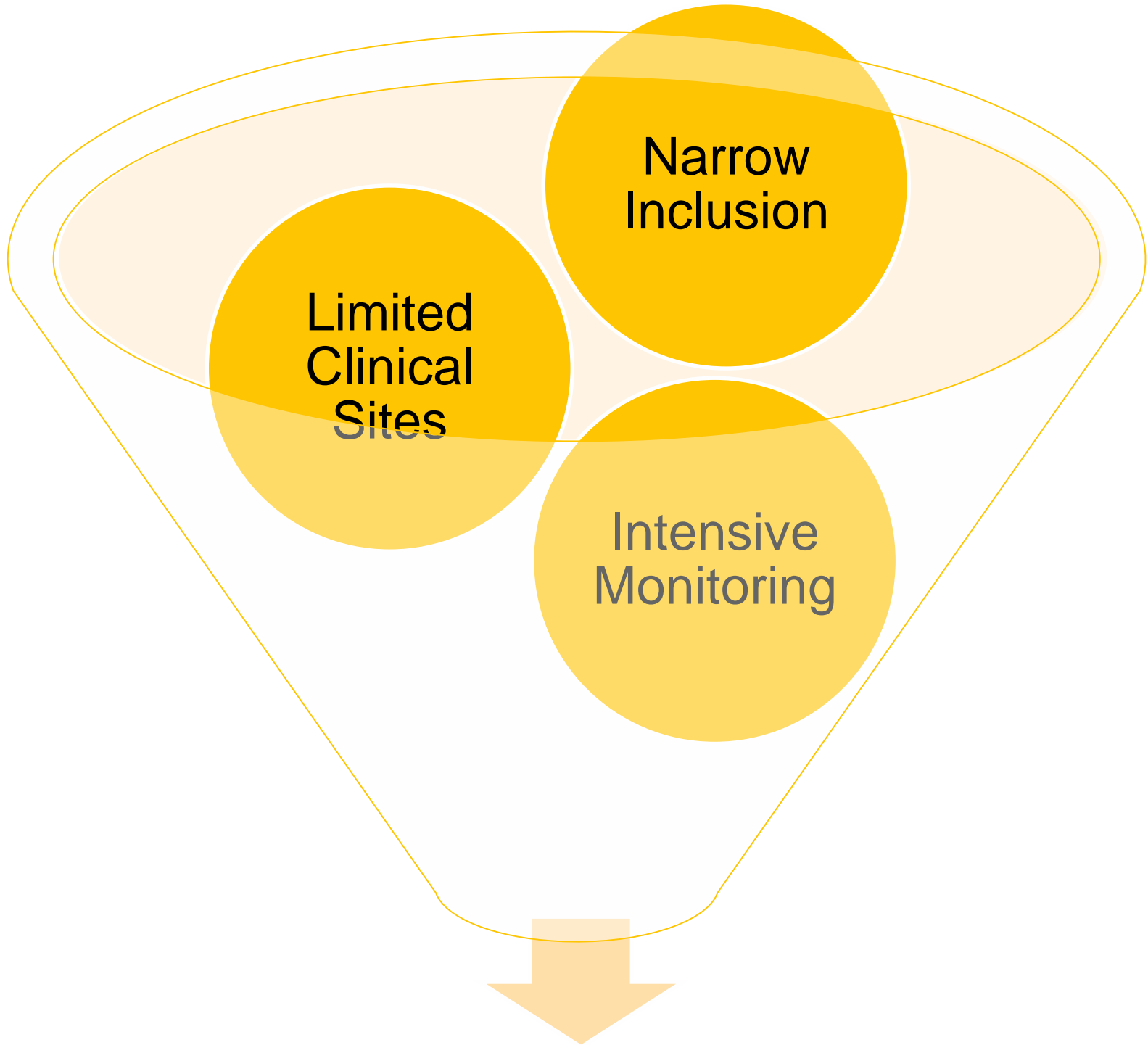
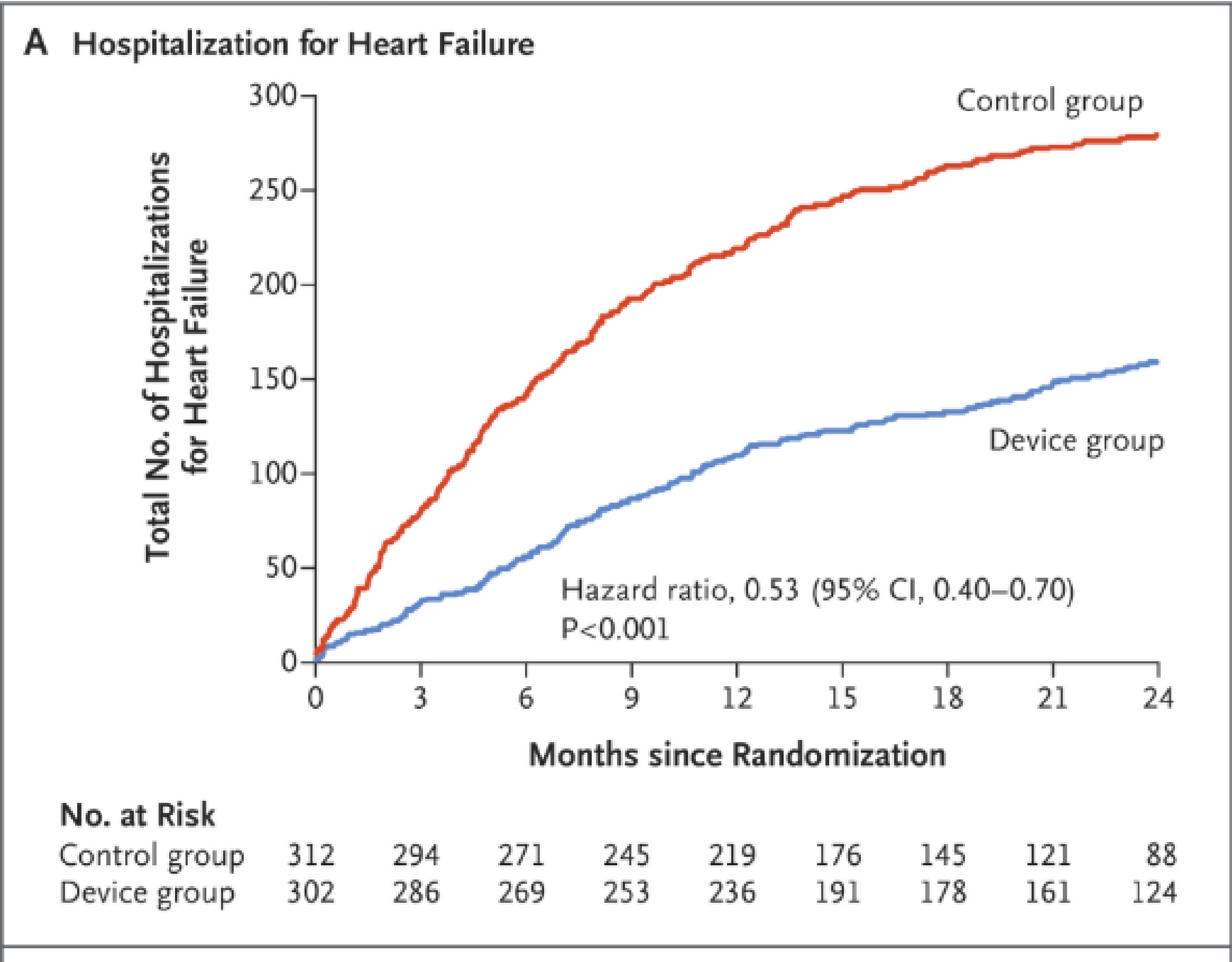


**EVIDATION HEALTH:
EMPOWERING PATIENTS TO DRIVE HEALTHCARE THROUGH REAL WORLD
DATA**

NOVEMBER 2018

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VP, Clinical & Regulatory
@evidation

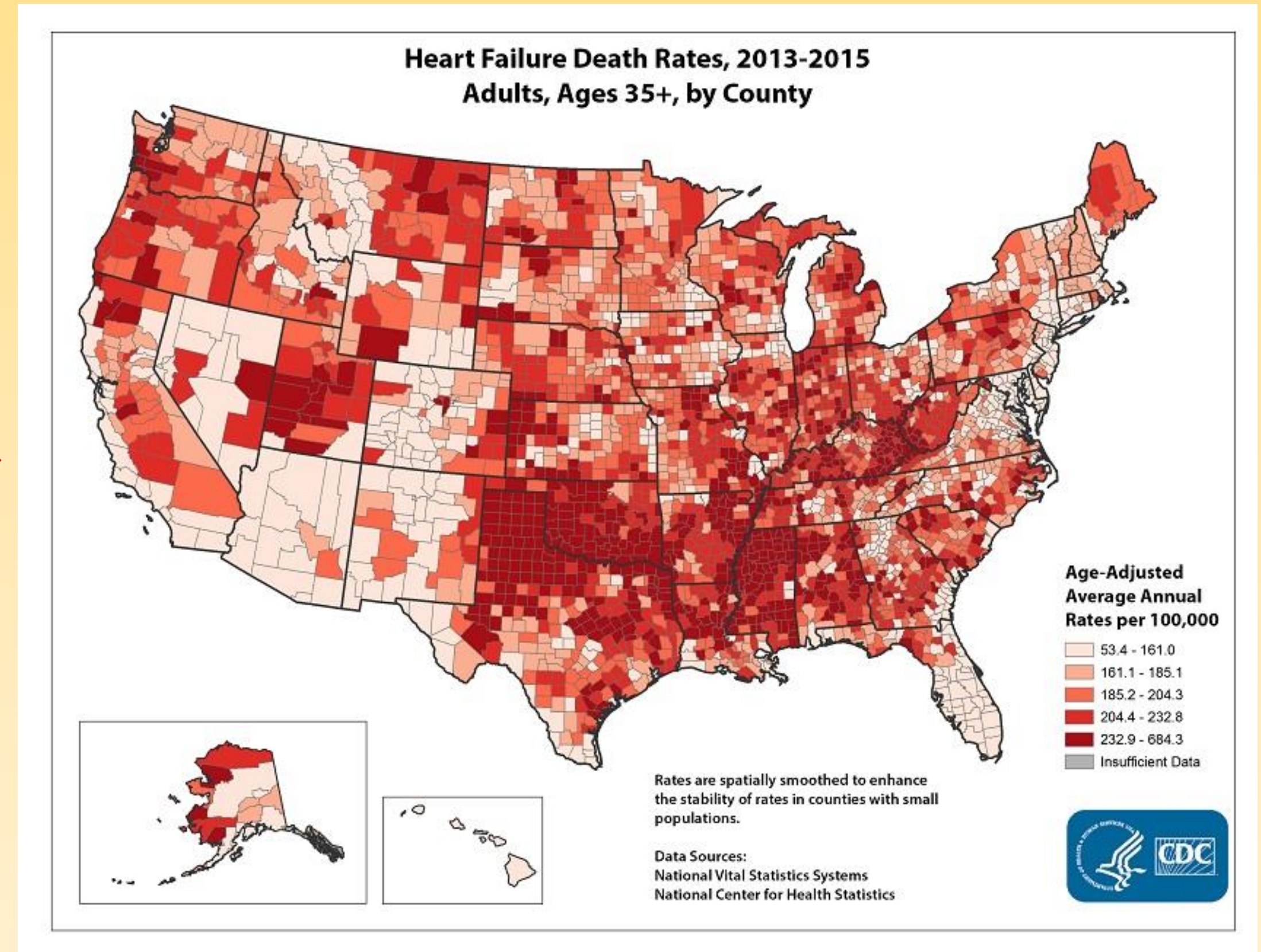
The Gold Standard: *Randomized Clinical Trials for Safety / Efficacy*



FDA Approval & Treatment Guidelines

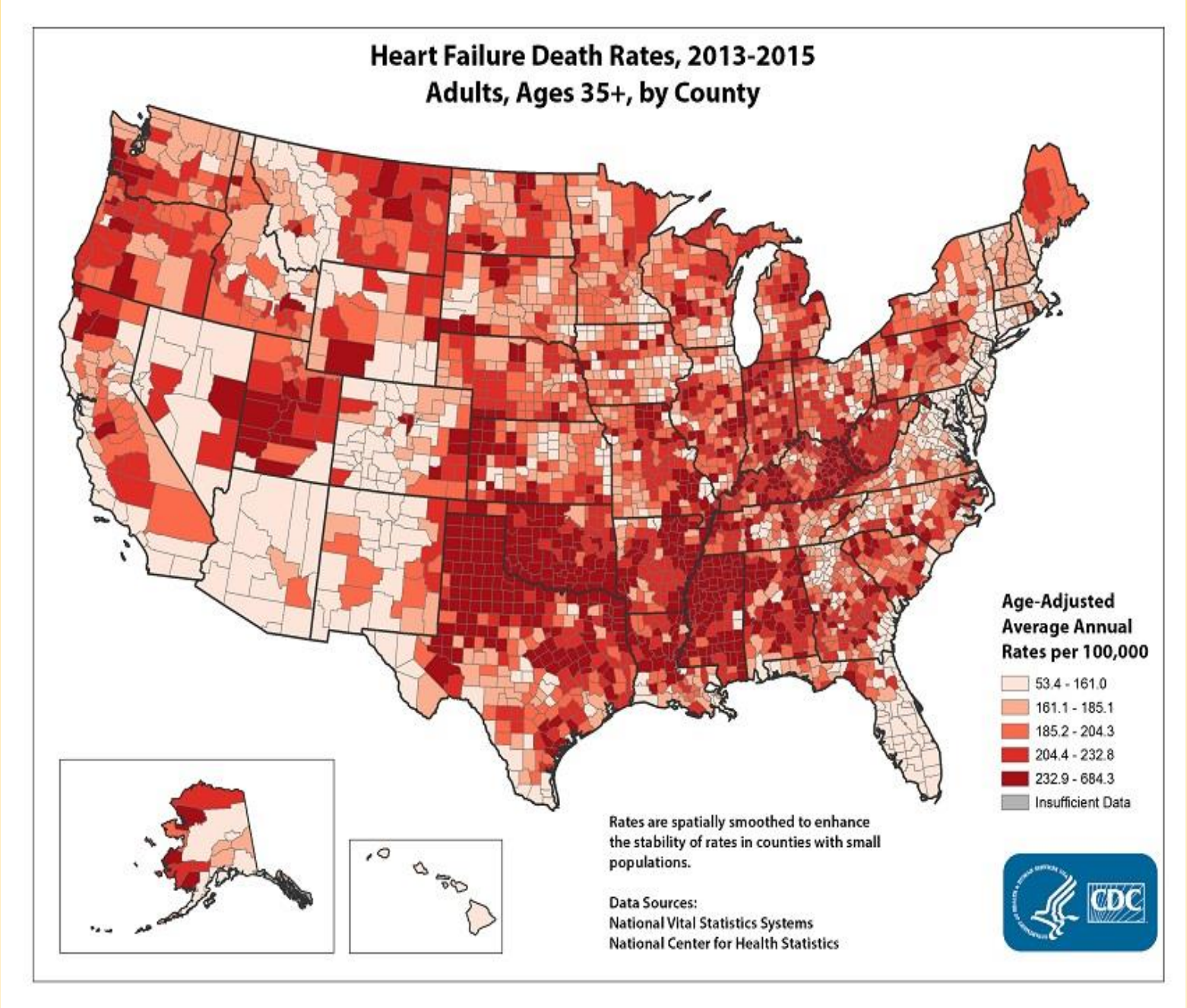
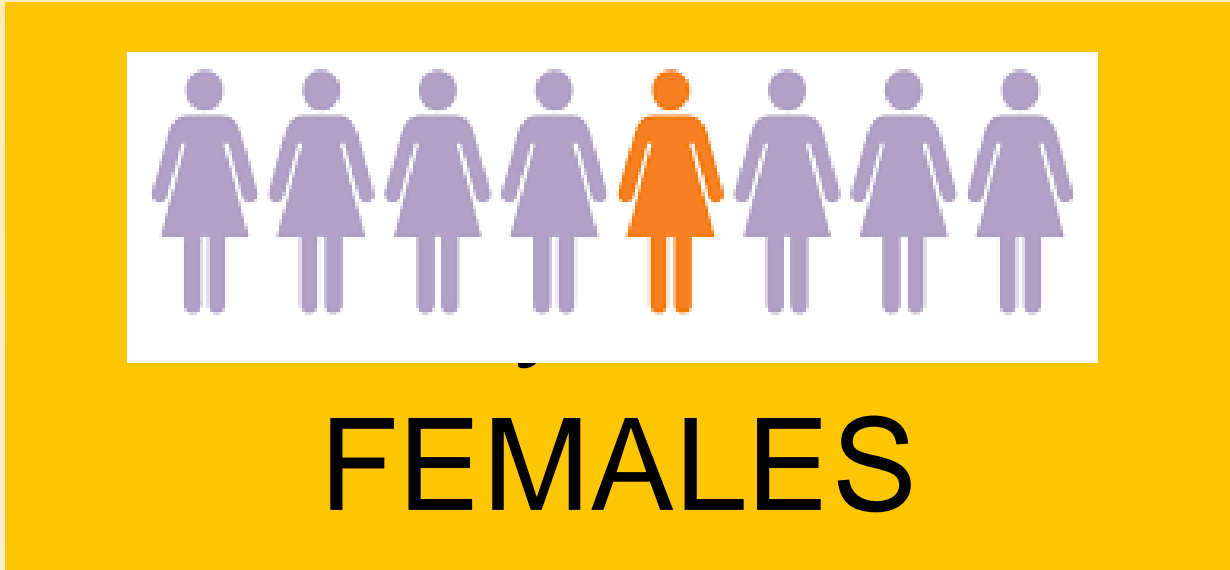
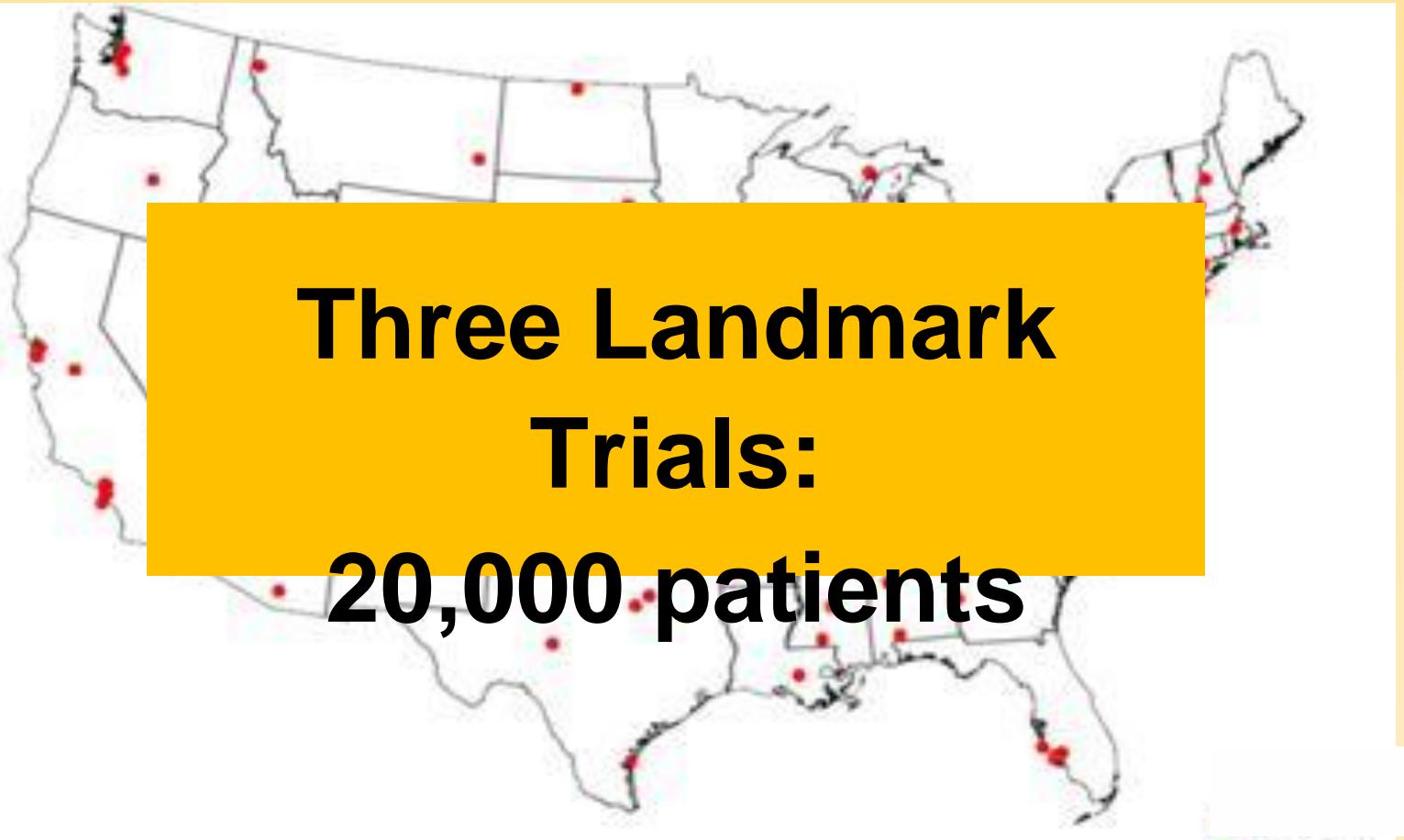
Stone et al, Transcatheter Mitral-Valve Repair in Patients with Heart Failure. NEJM, 2018.

But how does this translate to medical practice in the Real World?



Real World Example:

Congestive Heart Failure: 5.7 Million Patients in the US



Masoudi et al, Most hospitalized older persons do not meet the enrollment criteria for clinical trials in heart failure. Am Heart J, 2003 Aug;146(2)250-7.

DIET

SOCIAL

LOCATION

GLUCOSE

STRESS

SLEEP

At Evidation, we see patients like this in the digital era of medicine.

EXERCISE

ROUTINES

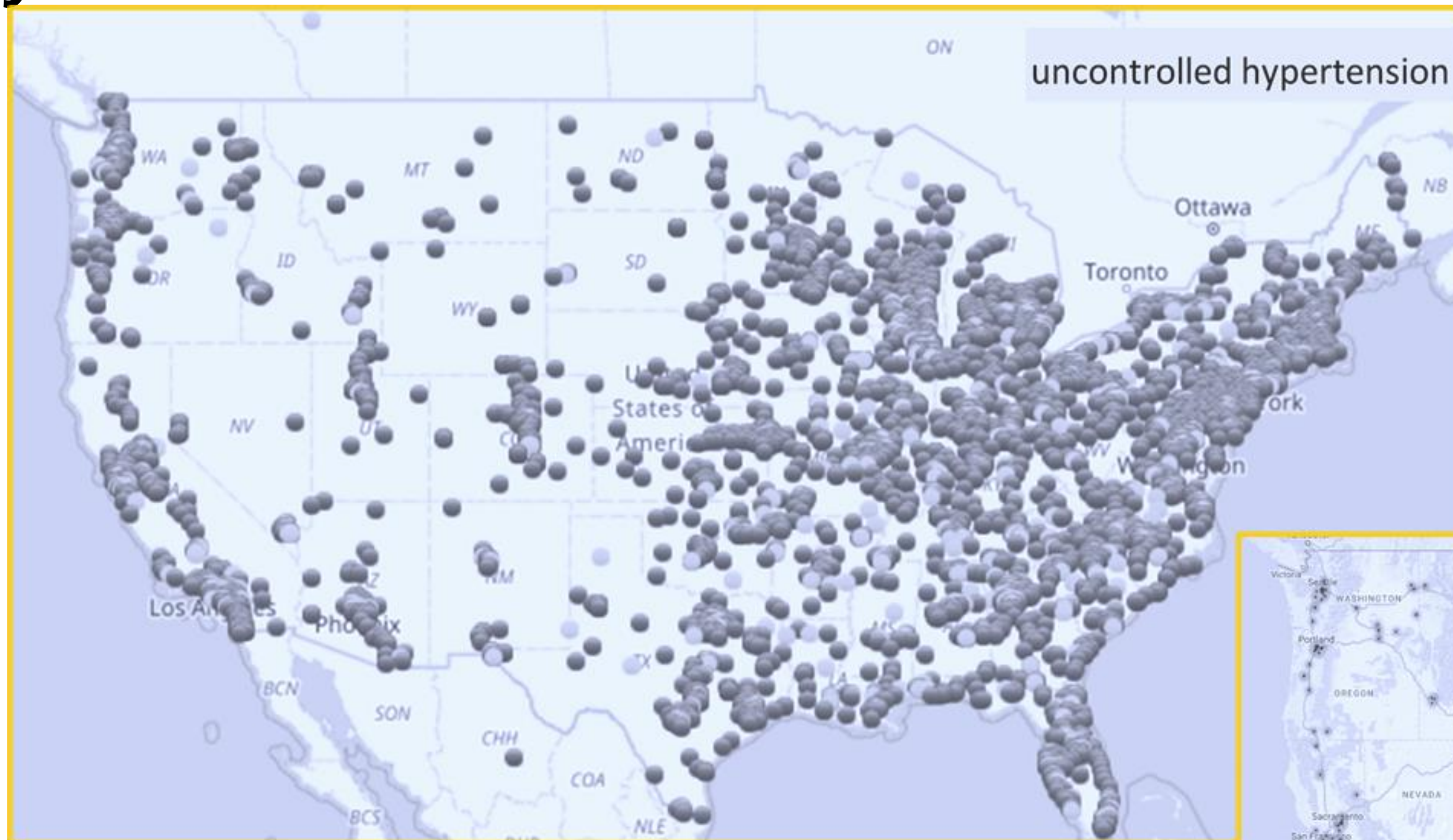
SPEECH AND VOICE

MOVEMENT

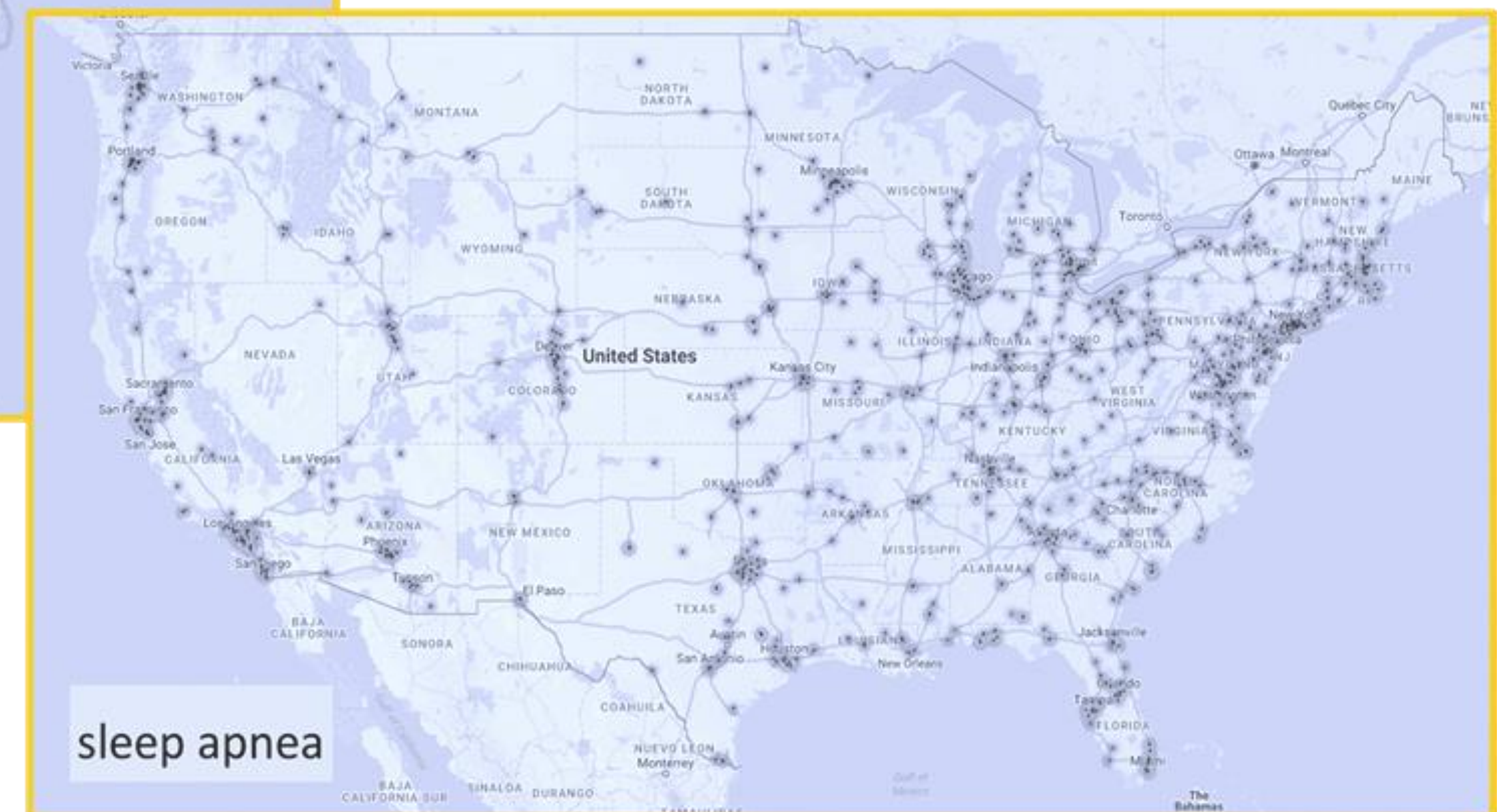
HEART RATE

APP INTERACTIONS

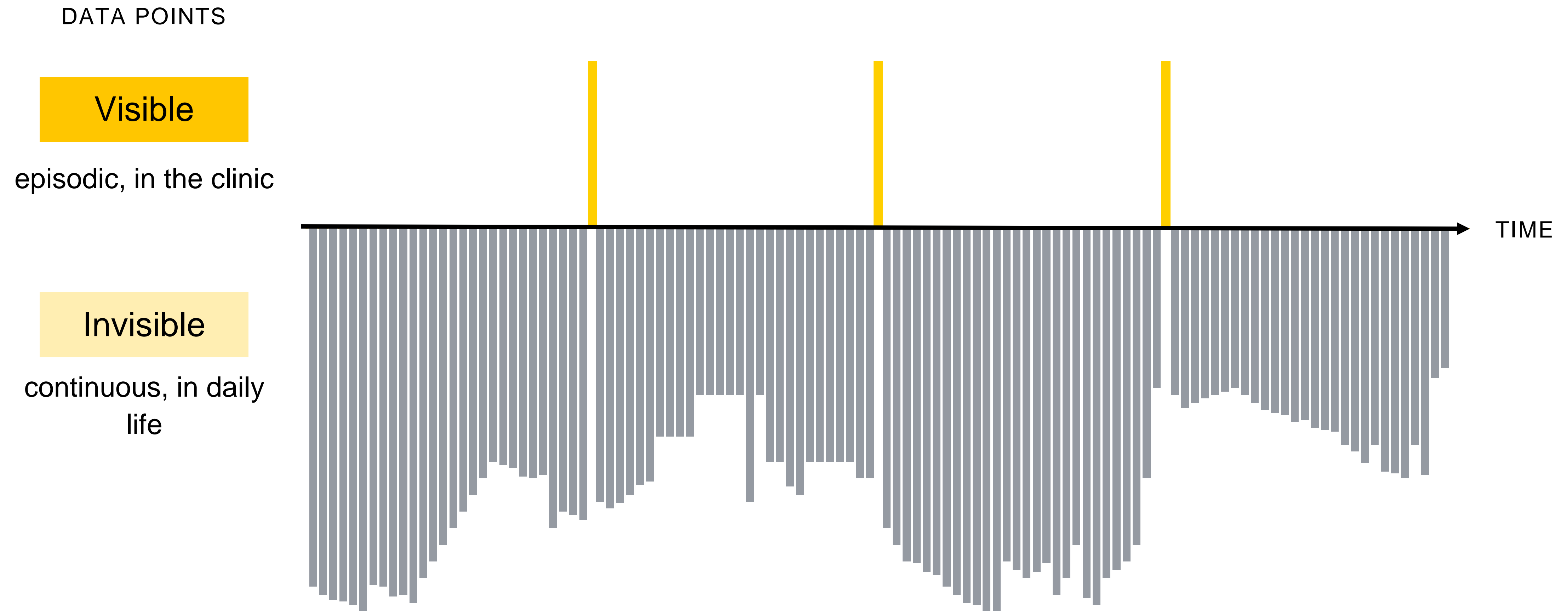
Digital “virtual” studies allow patients to participate—*anywhere, anytime.*



**ENROLLMENT
FOOTPRINTS IN RECENT
PROSPECTIVE STUDIES**

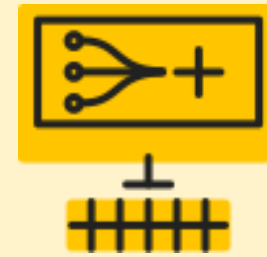


Patient outcomes have been historically measured using limited data from within the system—*not from daily life*.

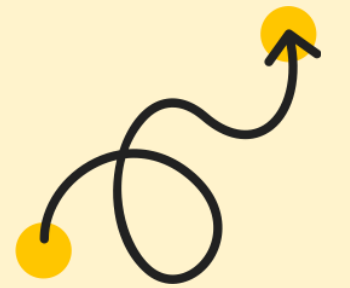


Harnessing this new data source allows us to ask and answer different questions about human health ***in the real world...***

Can quantifying everyday life better stratify chronic pain patients?



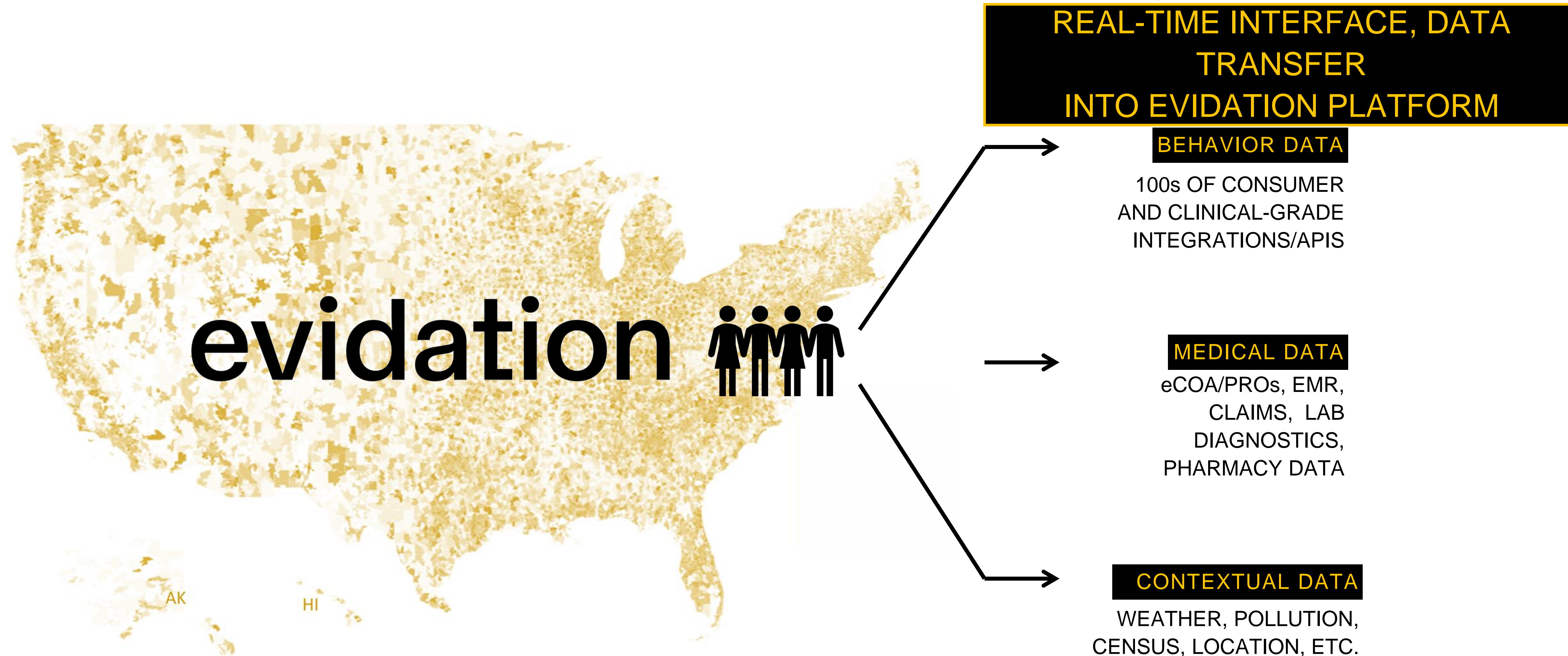
Is a patient's daily movement pattern a better measure of surgical recovery?



How can we measure impact of digital interventions entirely outside clinic walls, *at any scale?*



Today we have >2M connected individuals permissioning their data for use in a whole new approach to measuring outcomes.



Real World Clinical Data – *outside the clinic walls.*

The Medication adherence Improvement Support App For Engagement—Blood Pressure

(MedISAFE-BP) trial

- First prospective trial to rigorously evaluate an mhealth application's effect on blood pressure and medication adherence in the U.S.
- Table 1 illustrates diversity that is straightforward to obtain in virtual, site-less clinical research
 - 57% female
 - 29% African American or Hispanic
 - 47% without a college degree
 - The above were not a requirement of study design



BRIGHAM AND
WOMEN'S HOSPITAL

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Table 1. Baseline Characteristics by Treatment Group

Characteristic	Intervention (n = 209)	Control (n = 202)	P Value
Age, mean (SD), y	51.7 (10.5)	52.4 (10.1)	.51
Female, No. (%)	120 (57.4)	127 (62.9)	.26
Race/ethnicity n (%)			.03
Black	43 (20.6)	60 (29.7)	
White	149 (71.3)	119 (58.9)	
Other	17 (8.1)	23 (11.4)	
BMI, mean (SD)	35.38 (7.9)	35.59 (8.6)	.79
Physical activity, No. (%)			.49
≤2 h/wk	127 (60.8)	116 (57.4)	
>2 h/wk	82 (39.2)	86 (42.6)	
Education, No. (%)			.49
Did not finish high school	3 (1.4)	5 (2.5)	
High school graduate	31 (14.8)	20 (9.9)	
Some college	46 (22.0)	56 (27.7)	
College graduate	73 (34.9)	68 (33.7)	
Vocational degree	19 (9.1)	22 (10.9)	
Graduate degree	37 (17.7)	31 (15.4)	

Morawski et al, Rationale and design of the Medication adherence Improvement Support App For Engagement—Blood Pressure (MedISAFE-BP) Trial. Am Heart J;186:40-47, 2017.

Morawski et al, The accuracy of self-reported blood pressure in the MedISAFE-BP Trial. AHA QCOR Scientific Sessions, Quality Care and Outcomes Research, 2017.

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