

CONTINUOUS MONITORING THROUGH PASSIVE SENSORS



Study watch

Investigational wrist-worn sensor for continuous recording of physiological and environmental data



App

Mobile interface for self-reported and passive data acquisitions



Sleep sensor

Commercially available, placed under mattress to passively monitor multiple physiologic data parameters



Study hub

Safely sends device data to secure, encrypted Baseline database

Project Baseline

27

27

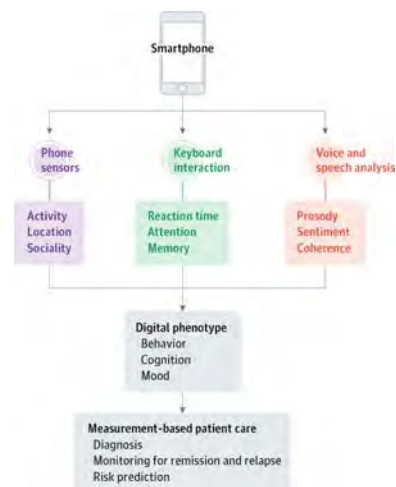


The process of digital phenotyping

Digital phenotyping involves collecting sensor, keyboard, and voice and speech data from smartphones to measure behavior, cognition, and mood.



The JAMA Network



Insel TR. Digital phenotyping technology for a new science of behavior. JAMA. 2017;318:1215-16. doi:10.1001/jama.2017.11295

28

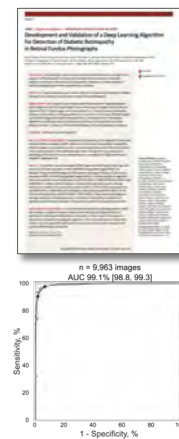
Learning health care systems



www.fda.gov

29

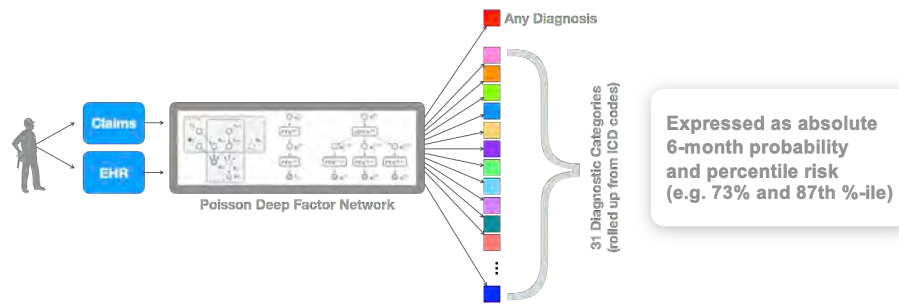
Innovations jointly deployed by Google + Verily



verily Confidential & Proprietary

30

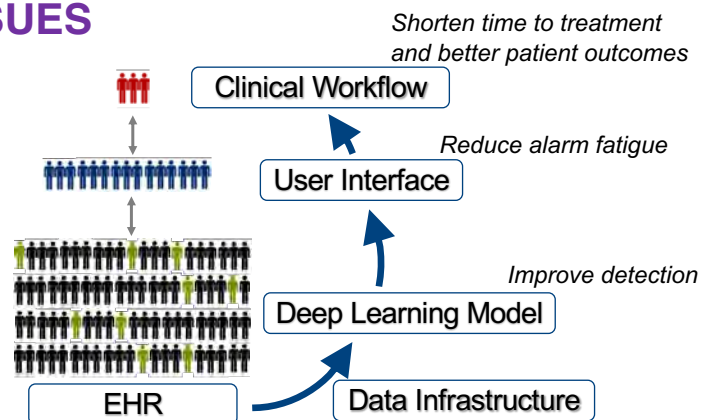
Admission Risk Prediction Model



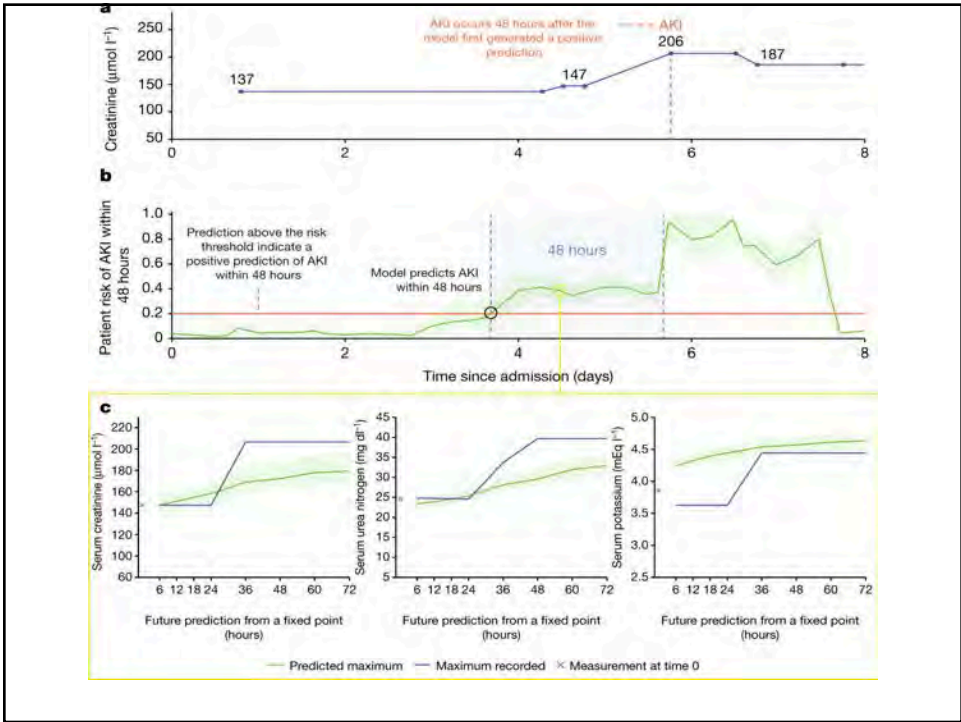
31

31

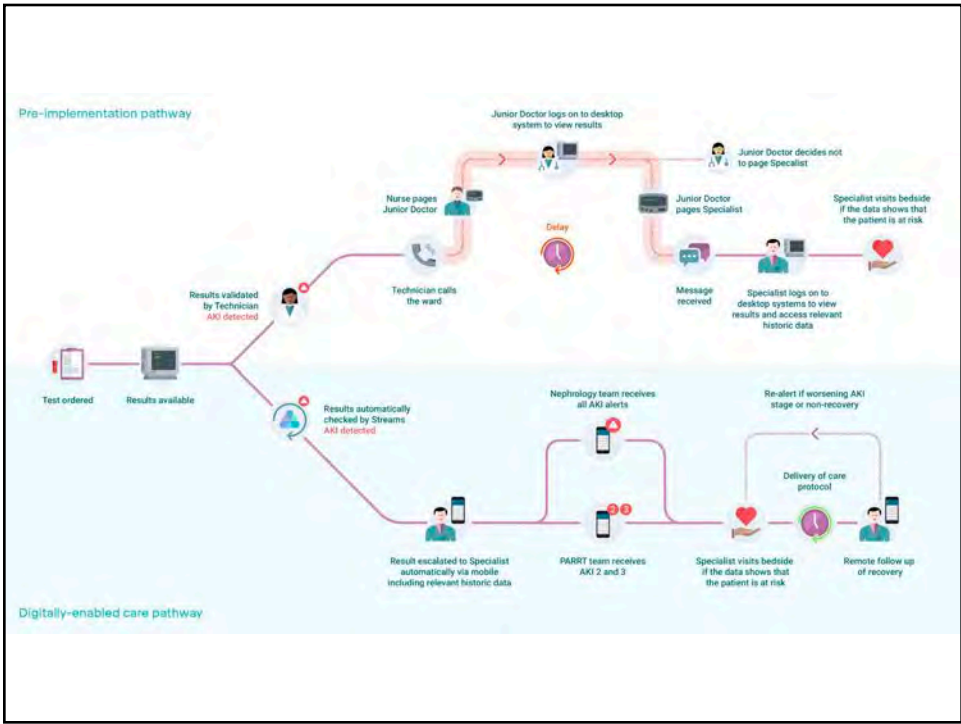
FLAGGING ACUTE INPATIENT ISSUES

3
2

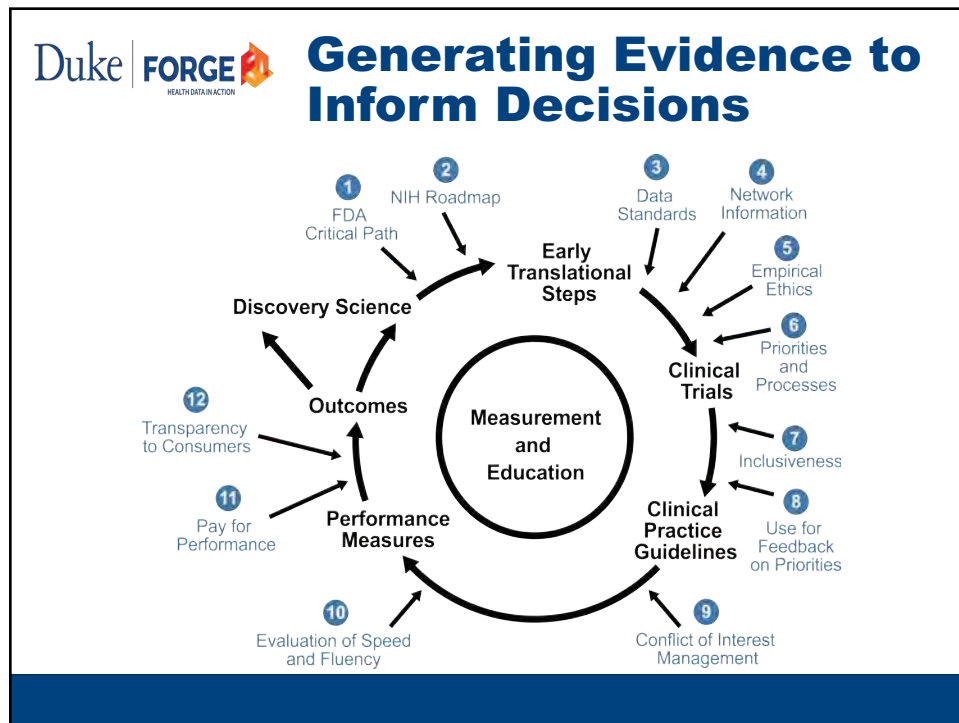
32



33



34



35

Which Treatment is Best for Whom?

High-Quality Evidence is Scarce

< 15% of Guideline Recommendations Supported by
High Quality Evidence

ORIGINAL CONTRIBUTION

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Pierluigi Teerarat, MD, MHS, PhD
Joseph M. Allen, MA
Judith M. Kramer, MD, MS
Robert M. Califf, MD
Sidney C. Smith Jr, MD

Context The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

Objective To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.

Data Sources and Study Selection Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division. Fifty-three guidelines on 22 topics, including a total of 7136 recommendations, were abstracted.

Clinical Practice Guidelines are systematically developed statements to assist practitioners with decisions about appropriate health care for spe-

36

JAMA | Original Investigation
Levels of Evidence Supporting American College of Cardiology/American Heart Association and European Society of Cardiology Guidelines, 2008-2018
 Alexander C. Fanaroff, MD, MPH, Robert M. Galt, MD, Stephen Winkler, MD, Sidney C. Smith Jr, MD, Renato D. Lopes, MD, PhD, MS

IMPORTANCE: Clinical decisions are largely based on evidence supporting guideline recommendations.

OBJECTIVE: To determine the levels of evidence (LOE) supporting current ACC/AHA and ESC guidelines (2008-2018) as identified in these guideline documents.

STUDY SELECTION: Current ACC/AHA and ESC guidelines (2008-2018) were organized by class and LOE.

DATA EXTRACTION AND MAIN RESULTS: LOE (A) (supported by data from observational studies) was determined for each guideline recommendation.

RESULTS: Across 26 current ACC/AHA guidelines, 130 recommendations (8.5%) were classified as LOE A. The median proportion of LOE A recommendations was 0.0% (range, 0.0%-15.2%). Across 25 current ESC guidelines, 142 recommendations (14.2%) were classified as LOE A. The median proportion of LOE A recommendations was 0.0% (range, 0.0%-14.2%). When comparing current guidelines with prior versions, the proportion of recommendations that were LOE A did not increase in either ACC/AHA (median, 0.0% [current] vs 11.7% [prior]) or ESC guidelines (median, 15.7% [current] vs 17.6% [prior]).

CONCLUSIONS AND RELEVANCE: Among recommendations in major cardiovascular society guidelines, only a small percentage were supported by evidence from multiple RCTs or a single, large RCT. This pattern does not appear to have meaningfully improved from 2008 to 2018.

Duke Clinical Research Institute
 Fanaroff, Lopes et al. J Am Med Assoc 2019;321:1069-1080

37

PCORnet®: the National Patient-Centered Clinical Research Network



An innovative initiative funded by the Patient-Centered Outcomes Research Institute (PCORI), PCORnet is **a large, highly representative, national patient-centered clinical research network**.

Our **vision** is to support a learning U.S. healthcare system and to enable **large-scale clinical research** conducted with **enhanced quality and efficiency**.

Our **mission** is to enable people to make informed healthcare decisions by efficiently conducting clinical research relevant to their needs.

38

38

PCORnet® embodies a “network of networks” that harnesses the power of partnerships



9 Clinical Research Networks (CRNs) + 2 Health Plan Research Networks (HPRNs) + Patient Partners + 1 Coordinating Center = A national infrastructure for people-centered clinical research



39

39

CRNs

ADVANCE	Accelerating Data Value Across a National Community Health Center Network (ADVANCE) Oregon Community Health Information Network (OCHIN)	PEDSnet A Pediatric Learning Health System	National PEDSnet: A Pediatric Learning Health System The Children's Hospital of Philadelphia
CAPriCORN	Chicago Area Patient Centered Outcomes Research Network (CAPriCORN) The Chicago Community Trust	NYC-CDRN New York City Clinical Data Research Network	New York City Clinical Data Research Network (NYC-CDRN) Weill Medical College of Cornell University
GPC Greater Plains Collaborative	Greater Plains Collaborative (GPC) University of Kansas Medical Center	OneFlorida Clinical Research Consortium	OneFlorida Clinical Data Research Network University of Florida
REACHnet	Research Action for Health Network (REACHnet) Louisiana Public Health Institute (LPHI)	PaTH Network Patient Health Information Network	PaTH: Towards a Learning Health System University of Pittsburgh
Mid-South CDRN	Mid-South CDRN Vanderbilt University		



40

40

HPRNs



HealthCore (a subsidiary of Anthem)

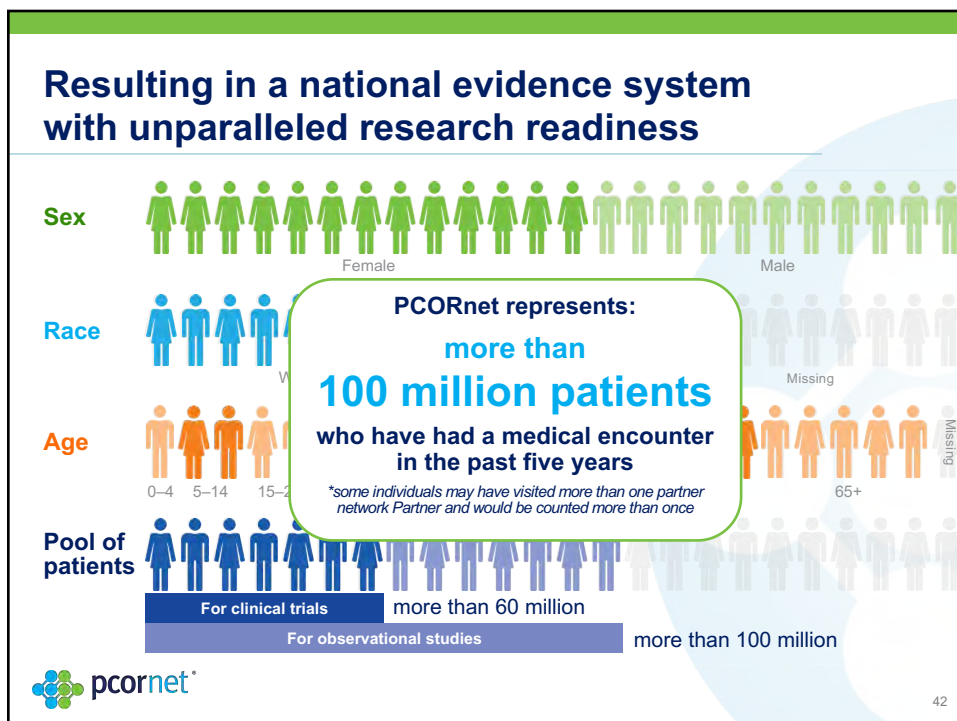


Humana – Comprehensive Health Insights
(CHI; a subsidiary of Humana Pharmacy Solutions)

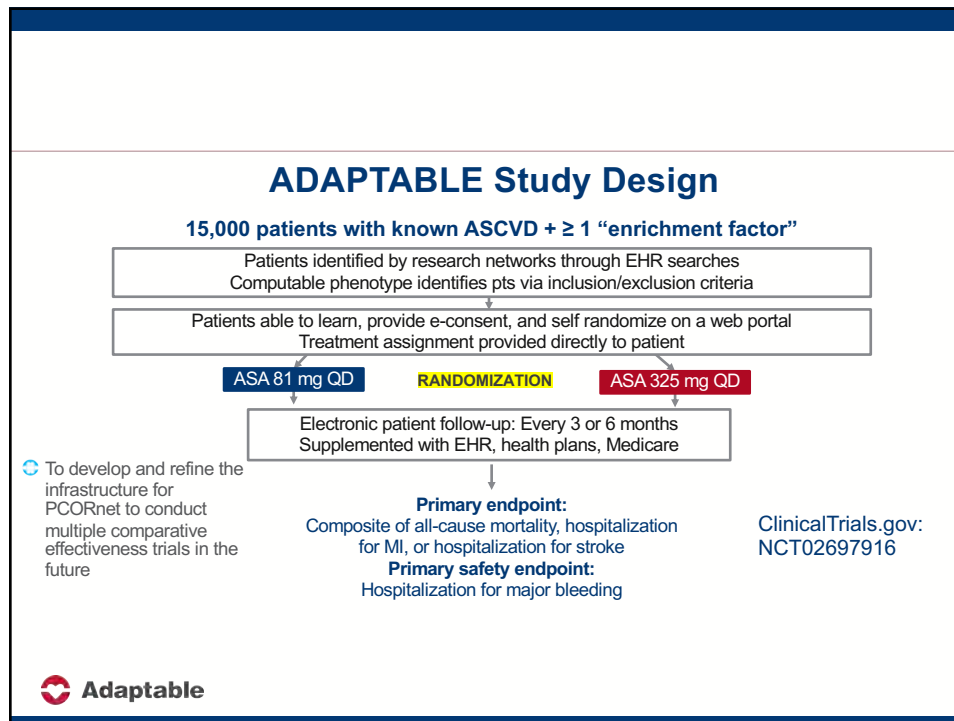



41

41



42




43

Sept 30, 2018

Site Approach and Enrollment

CDRN	Total Number Eligible	Total Number Approached	% of Eligible Approached	Golden Tickets Entered	% Golden Tickets entered per Approached	Total Enrolled	# Non-internet Enrolled	% Enrolled Per Approached	% Enrolled Per Golden Ticket Entered
CAPriCORN	18,389	12,251	67%	821	7%	516	203	4%	63%
GPC	92,053	62,365	68%	3594	6%	1690	119	3%	47%
HPRN	160,914	160,914	100%	1,551	1%	358	2	0%	23%
LHSNet	128,981	35,342	27%	1493	4%	865	115	2%	58%
Mid-South	92,714	43,629	47%	7,283	17%	3942	491	9%	54%
NYC-CDRN	22,141	6,575	30%	1339	20%	710	253	11%	53%
OneFlorida	59,373	5,220	9%	749	14%	593	154	11%	79%
PaTH	47,594	41,187	87%	3682	9%	1279	58	3%	35%
pScanner	15,669	6,855	44%	253	4%	131	8	2%	52%
REACHnet	33,299	20,583	62%	1801	9%	773	240	4%	43%
TOTAL	671,133	394,921	59%	22,566	6%	10,857	1,643	3%	48%

 **Adaptable**

44