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


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
Learning health care systems

In a learning health care system, research influences practice and practice influences research.

Innovations jointly deployed by Google + Verily

Healthy

Diseased

No DR
Neovascular DR
Moderate NPDR
Severe NPDR
Proliferative DR
Hemorrhages
### Admission Risk Prediction Model

- **Input Data Sources:** Claims, EHR
- **Output:** Poisson Deep Factor Network
- **Risk Expression:** 31 Diagnostic Codes
- **Clinical Workflow:** 6-month probability and percentile risk (e.g., 73% and 87th %tile)

### Flagging Acute Inpatient Issues

- **Shorten time to treatment and better patient outcomes**
- **Reduce alarm fatigue**
- **Improve detection**

- **Clinical Workflow**
- **User Interface**
- **Deep Learning Model**
- **Data Infrastructure**
- **EHR**
Generating Evidence to Inform Decisions

1. NIH Roadmap
2. FDA Critical Path
3. Early Translational Steps
4. Data Standards
5. Network Information
6. Empirical Ethics
7. Policies and Processes
8. Use for Feedback on Priorities
9. Clinical Trials
10. Measurement and Education
11. Conflict of Interest Management
12. Transparency to Consumers
13. Pay for Performance
14. Performance Measures
15. Outcomes
16. Discovery Science
17. Evaluation of Speed and Fluency

Which Treatment is Best for Whom?
High-Quality Evidence is Scarce

< 15% of Guideline Recommendations Supported by High Quality Evidence
Across 26 current ACC/AHA guidelines… 8.5% [of recommendations] were classified as LOE A

Across 25 ESC guidelines… 14.2% [of recommendations] were classified as LOE A

This pattern does not appear to have meaningfully improved from 2008 to 2018

**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.
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.

CRNs

- ADVANCE: Accelerating Data Value Across a National Community Health Center Network
- Oregon Community Health Information Network (OCHIN)
- Chicago Area Patient Centered Outcomes Research Network (CAPiCORN)
- The Chicago Community Trust
- Greater Plains Collaborative (GPC)
- University of Kansas Medical Center
- Research Action for Health Network (REACHnet)
- Louisiana Public Health Institute (LPHI)
- Mid-South CDRN
- Vanderbilt University

- National Pedsnet: A Pediatric Learning Health System
- The Children’s Hospital of Philadelphia
- New York City Clinical Data Research Network (NYC-CDRN)
- Weill Medical College of Cornell University
- OneFlorida Clinical Data Research Network
- University of Florida
- PaTH: Towards a Learning Health System
- University of Pittsburgh
HPRNs

HealthCore (a subsidiary of Anthem)

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

Resulting in a national evidence system with unparalleled research readiness

PCORnet represents:
more than
100 million patients
who have had a medical encounter in the past five years

*Some individuals may have visited more than one partner network and would be counted more than once

For clinical trials
For observational studies

Pool of patients

Sex
Female
Male

Race
Missing
Non-White
White

Age
0–4
5–14
15–21
22–64
65+

More than 60 million
More than 100 million

For clinical trials
For observational studies
ADAPTABLE Study Design

15,000 patients with known ASCVD + ≥ 1 “enrichment factor”

- Patients identified by research networks through EHR searches
- Computable phenotype identifies pts via inclusion/exclusion criteria
- Patients able to learn, provide e-consent, and self randomize on a web portal
- Treatment assignment provided directly to patient
- ASA 81 mg QD
- ASA 325 mg QD
- Electronic patient follow-up: Every 3 or 6 months Supplemented with EHR, health plans, Medicare

Primary endpoint:
Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke

Primary safety endpoint:
Hospitalization for major bleeding

To develop and refine the infrastructure for PCORnet to conduct multiple comparative effectiveness trials in the future

ClinicalTrials.gov: NCT02697916

Site Approach and Enrollment

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<tr>
<th>CDRN</th>
<th>Total Number Eligible</th>
<th>Total Number Approached</th>
<th>% of Eligible Approached</th>
<th>Golden Tickets Entered</th>
<th>% Golden Tickets entered per Approached</th>
<th>Total Enrolled</th>
<th>% Enrolled Per Approached</th>
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<td>12,251</td>
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<td>821</td>
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<td>GPC</td>
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<td>Mid-South</td>
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Adaptable