Welcome to HHS Startup Day

Presented By:

MACP MASSACHUSETTS COMPETITIVE PARTNERSHIP

MeHI MASSACHUSETTS eHEALTH INSTITUTE

PULSE@ MASSCHALLENGE

Harvard Pilgrim HealthCare

#HHSstartupBOS #HHSstartupday

Office of the
CHIEF TECHNOLOGY OFFICER

Startup Day
Boston, MA

Bruce Greenstein, HHS Chief Technology Officer

CTO
Office of the
CHIEF TECHNOLOGY OFFICER

About HHS

The U.S. Department of Health and Human Services (HHS) is the nation's principal agency for protecting the health of all Americans and providing essential human services. The Department includes CMS, CDC, FDA, NIH, AHRQ, HRSA, SAMHSA

~ 79,540 employees

The Office of the Chief Technology Officer, located in the Immediate Office of the Secretary, provides leadership and direction on **data**, **technology** and **innovation** and across the Department of Health and Human Services

CTO
Office of the
CHIEF TECHNOLOGY OFFICER

The Office of the Chief Technology Officer

Using data to generate better health and human services insights

Driving partnerships across the public, private and international sectors

Testing and validating solutions to solve challenging problems in the delivery of health and human services

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Aim of HHS Startup Day

- Open the doors to the startup and entrepreneur community.
- Our aim is to demystify HHS, by making our vision, priorities, processes and ways to engage very simple, and immediately actionable.
- Nothing we will share today is not already general public knowledge.

Office of the CHIEF TECHNOLOGY OFFICER

What We've Heard

As the hub for innovation at HHS, we are constantly looking for ways to learn from fellow innovators.

- "HHS is an unnecessary barrier to innovation, not an enabler of it."
- "More lines of communication needed."
- "Startups are not aware of all the funding and collaboration opportunities from HHS."
- "HHS does not provide clear points of contact or guidance to discuss regulatory barriers."

Digital Health 2017 Landscape

More money, follow-on funding, mega deals

- Deals surpassing $5B+ for the first time ever
- 345 deals; avg. deal $16.7 M
- Most mega deals greater than $100M to date
- Avg. deal size of Series D increased by 60%

Segments of Digital Tech

- Consumer Health Information
- Clinical Decision Support and Precision medicine
- Fitness and Wellness
- Monitoring of Disease
- Diagnosis of Disease
- Non-clinical workflow

Sources: Health tech data source - Rock Health 2017 Research report, CB Insights 2016 report

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> There is no turning back to an unsustainable system that pays for procedures rather than value. In fact, the only option is to charge forward — for HHS to take bolder action, and for providers and payers to join with us. This administration and this President are not interested in incremental steps. We are unafraid of disrupting existing arrangements simply because they're backed by powerful special interests.
>
> SECRETARY AZAR

The White House
Office of the Press Secretary

Presidential Memorandum on The White House Office of American Innovation

MEMORANDUM FOR THE SENIOR ADVISOR TO THE PRESIDENT
THE ASSISTANT TO THE PRESIDENT AND CHIEF OF STAFF

HOME - BLOG

Fueling American Innovation and Economic Growth with Open Data

AUGUST 11, 2017 AT 5:18 PM ET BY OSTP

On July 25, 2017, the Executive Office of the President Office of Management and Budget (OMB) hosted the Roundtable on Open Data for Economic Growth to explore the role of government datasets as a driver of the American economy. Open data leaders from the government and the private sector attended the White House event as a part of the Administration's long-term commitment to modernizing government.

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Connect with us

Twitter: @HHSIDEALab

Twitter: @HHSCTO

Website: HHS.Gov/IDEALab

Email: IDEALab@HHS.Gov

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Office of the CHIEF TECHNOLOGY OFFICER

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

HHS Startup Day – Boston

Ray Hurd

CMS Deputy Consortium Administrator & Regional Administrator, Regions 1 & 2

Centers for Medicare & Medicaid Services

FY '18 Requested Budget:	$737.9 billion
Total Staff:	Close to 6,000
Headquarters:	Baltimore, MD
Regional Offices:	10

CMS Basics and Programs

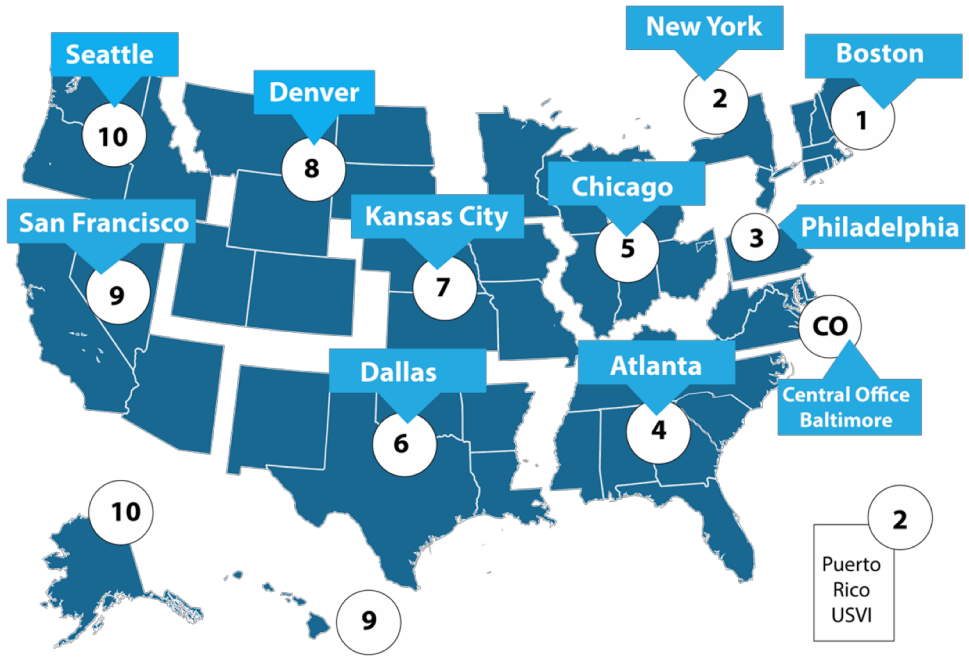
- Over **143 million people in the U.S.** get health coverage through one of these programs or roughly 1in every 3 Americans.
- CMS is the largest health insurer in the nation and the largest purchaser of health care in the world.
- 17.9% of GDP *(Calendar Year 2016)*

Medicare.gov

Medicaid.gov
Keeping America Healthy

HealthCare.gov

CMS Field Offices



What We Do At CMS

- **Oversee and Administer**
  - Medicare
  - Federally-facilitated Health Insurance Marketplace
- **Work with states to administer**
  - Medicaid
  - Children's Health Insurance Program (CHIP)
  - State-Partnership Marketplaces
- **Maintain and monitor quality standards to assure quality health care through accountability and public disclosure**
- **Fight fraud and abuse**
- **Explore quality-improvement and cost-saving advances by funding or leading studies, demonstrations, and pilots**

3 Strategic Goals for 2018

- Patients over Paperwork
- Eliminating Opioid Overdoses and Misuse
- Interoperability – putting data in the hands of patients

Top Priority

OUR TOP PRIORITY AT CMS IS PUTTING PATIENTS FIRST

CMS is committed to:

- reducing unnecessary burden
- increasing efficiencies
- improving the beneficiary experience

Working With CMS

Coverage

- Medicare's authority to cover or exclude certain items or services is governed by the Social Security Act (the Act) and implementing regulations.
  - Benefit Category: Does the new technology fall into at least one defined benefit category or categories under the Act?
  - Statutory Exclusion: Does the new technology involve an item or service that is specifically excluded by the Act?
  - Reasonable and Necessary: Is the new technology "reasonable and necessary"

Working With CMS

- Is it Meaningful to the Patient?
  - Improved activities of daily living
  - Playing with Grandkids again
  - Walk Faster
  - Fewer Hospitalizations and ER Visits

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Beneficiaries Agree 3 Most Important Issues

1. Independence
2. Quality of Life
3. Functional Status

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Working With CMS

- Centers for Clinical Standards
- Center for Medicare
- Center for Program Integrity
- Center for Medicare and Medicaid Innovation (Innovation Center)
- Center for Technology and Innovation

Working With CMS - DATA

- MyHealthEData initiative is leading by example:
  - **BLUE BUTTON 2.0**

  Blue Button 2.0 represents a major step towards giving patients control of their health information.

Working With CMS - BLUEBUTTON2.0

- Value and Use Cases
  - Reduce patient burden
  - Streamline information about different kinds of care over time
  - Uncover new insights that can improve health outcomes
  - Access and monitor health information in one place

Working With CMS

CMS.gov

Centers for Medicare & Medicaid Services

Thank you

Federal Food and Drug Administration

HHS START-UP DAY

MARCH 30, 2018

ESTHER WB BLEICHER, JD, MPH

SENIOR POLICY ADVISOR

What does FDA do?

- Assure safety, effectiveness, quality, and security of:

human and veterinary drugs,

vaccines and other biological products, and

medical devices

What does FDA do?

- Responsible for safety and security of:

food,

cosmetics,

dietary supplements, and

products that emit radiation.

- Reduce public health harm from:

tobacco products.

How does FDA do it?

Risk-based oversight

- Premarket review
- Regulations
- Guidance
- Outreach and Engagement
- Enforcement

How does FDA do it?

Risk-based oversight

- Premarket review
  - New drugs (including generics)
  - Moderate and high risk devices
  - Biologics
- Regulations
- Guidance
- Outreach and Engagement
- Enforcement

How does FDA do it?

Risk-based oversight

- Premarket review
- Regulations
  - *require* manufacturers of FDA regulated products to do things
  - Title 21 CFR, divided by product area
- Guidance
  - *recommend* manufacturers of FDA regulated products to do things
  - FDA's website (http://www.fda.gov)
- Outreach and Engagement
- Enforcement

How does FDA do it?

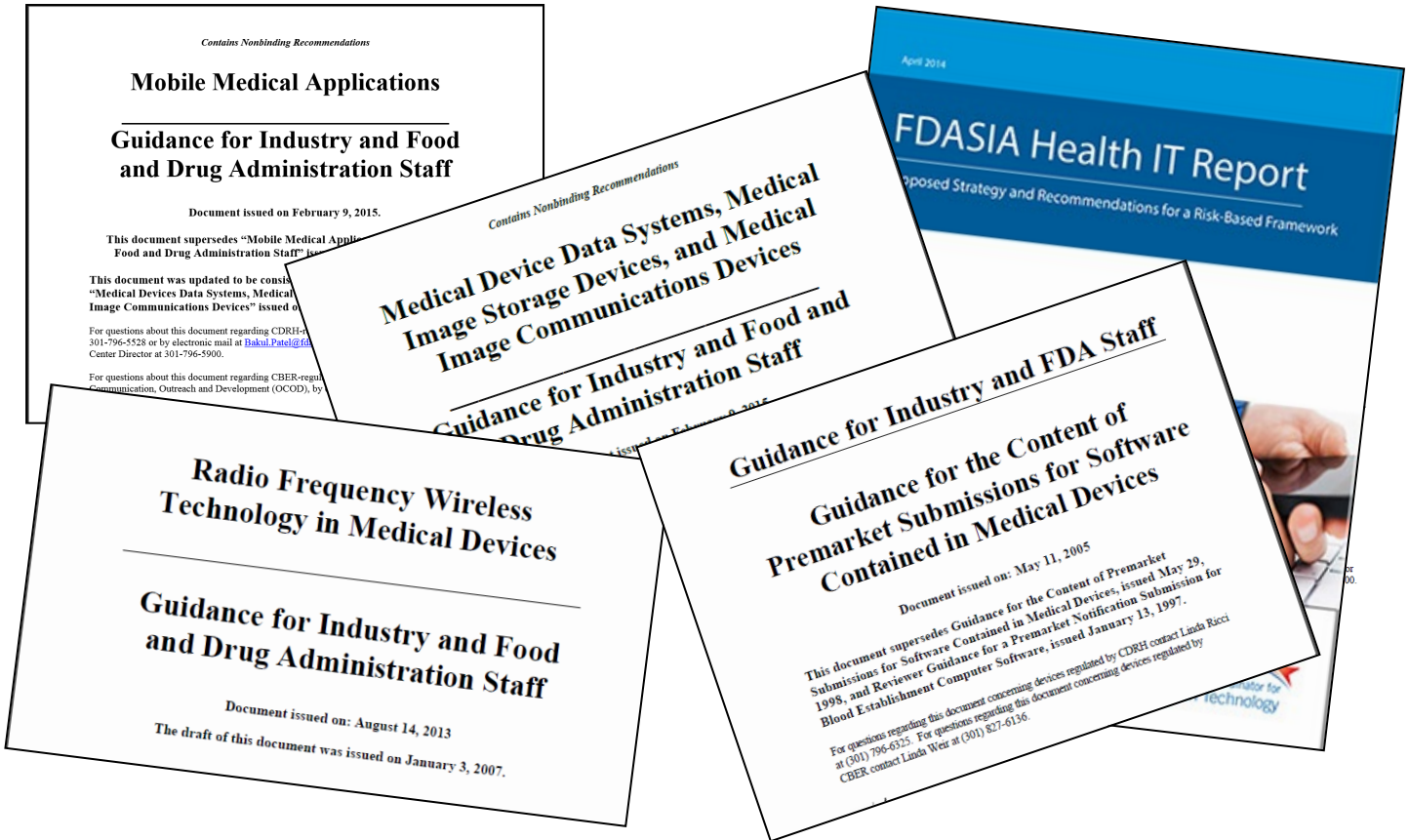
Risk-based oversight

- Premarket review
- Regulations
- Guidance
- Outreach and Engagement
  - Digital health website: https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm
  - Software Precertification Pilot Program
  - Email with questions: digitalhealth@fda.hhs.gov
- Enforcement

Digital Health

33

Clarifying expectations



Digital Health Innovation Action Plan

Implement medical software provisions of 21st Century Cures

- Clean up guidance and regulations for products that are no longer devices
  - Clinical decision support software
- Multifunctionality

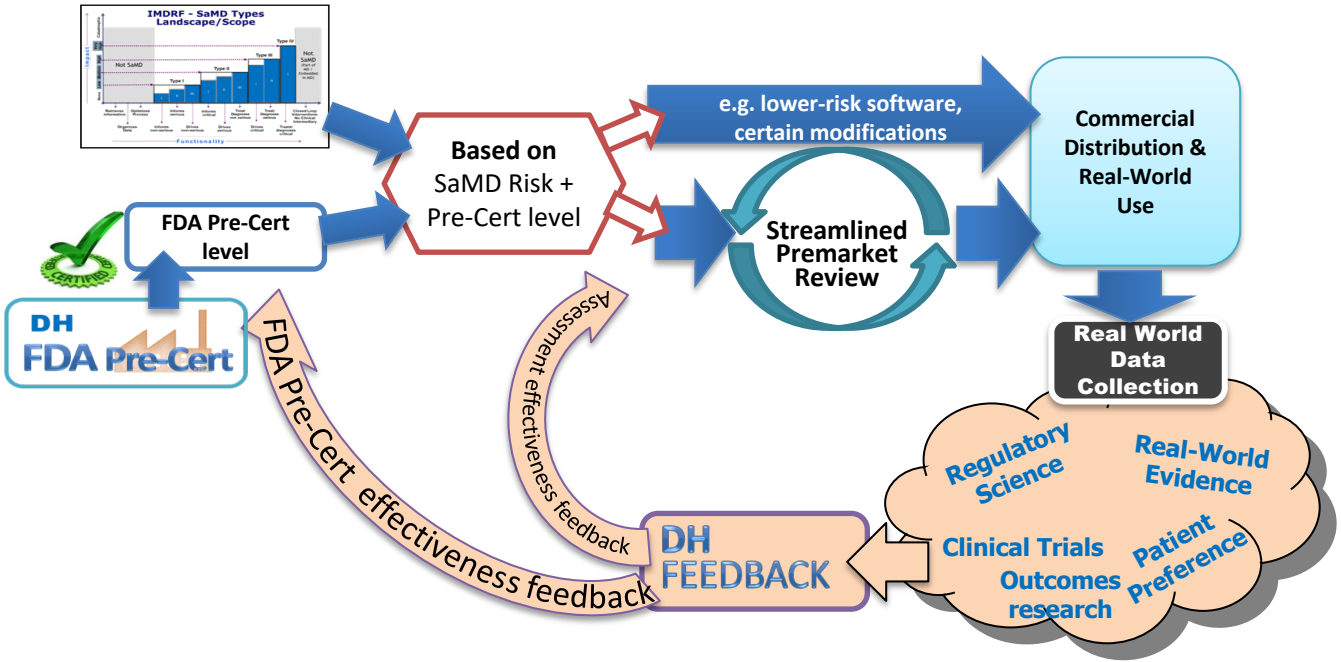
Build bench strength and expertise

- Hiring
- Training

Launch pilot Pre-Cert program

- To develop innovative, fit-for-purpose approach to digital health oversight
- Public meeting
- Open docket

FDA Pre-Cert Working Model



FDA
U.S. FOOD & DRUG
ADMINISTRATION

The National Institutes of Health

HHS StartUp Day - Boston

Jessica Mazerik, PhD

The National Institutes of Health

The Nation's Steward of Medical & Behavioral Research

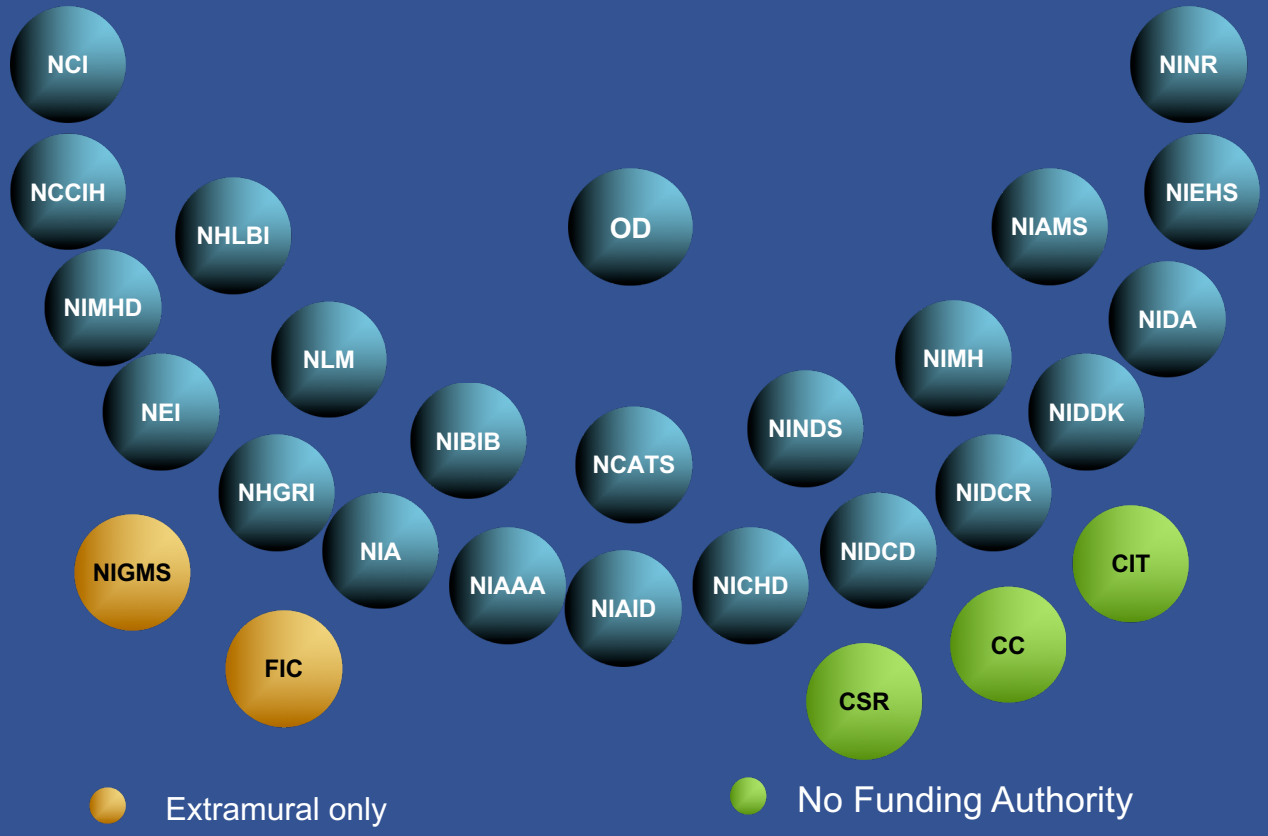
"Science in pursuit of fundamental knowledge about the nature and behavior of living systems ... and the application of that knowledge to extend healthy life and reduce illness and disability."

NIH ACTIVITIES

- Conducts research in its own laboratories
- Supports research of non-Federal scientists
  - In universities, medical schools, hospitals, and research institutions throughout United States and overseas
- Helps train research investigators
- Fosters communication of medical information
- 153 NIH-supported researchers have become Nobel Laureates*

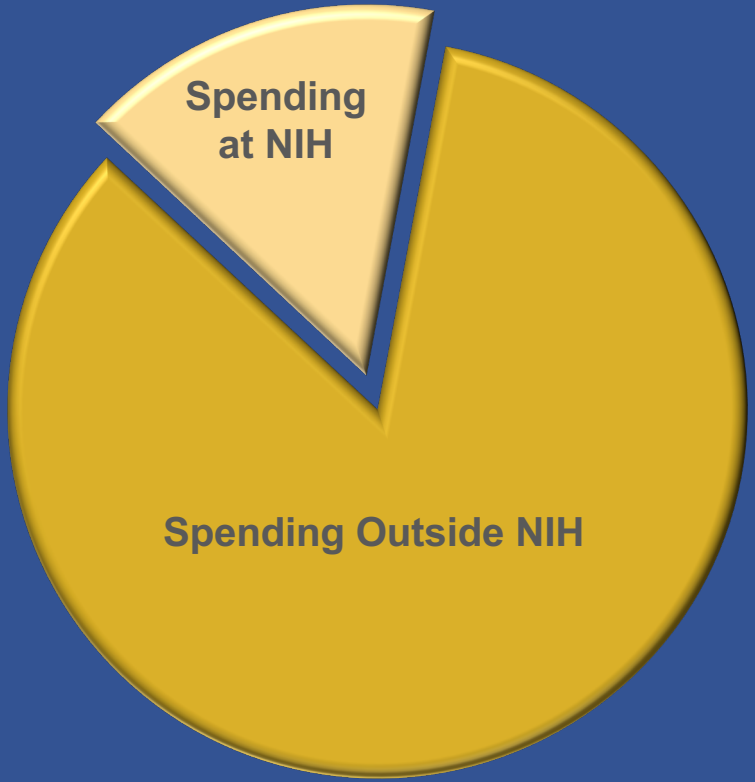
* As of 10/04/2017

The National Institutes of Health



NIH Extramural & Intramural Funding

FY 2018 Budget: $37 Billion



Researcher

NIH Grant Proposal

Initiates grant proposal:
- New project
- Continuing project

Scientific Review Panel

Scientists evaluate scientific merit of grant proposal

Program Officer

Main contact for applicant
Helps interpret review results

Institute National Advisory Councils

Assess programs
Approve applications
Public members

Congress

Funds

Institute Director

Makes final decision
Allocates funds
Provides annual justification to Congress

The NIH Clinical Center: Our Unique Hospital

- The largest clinical research center in the world
- The NIH CC only admits patients as part of clinical studies
- Patients can be referred to a study by their physician or they can self-refer by visiting – www.clinicaltrials.gov
- There are currently about 1,500 clinical studies in progress at the Clinical Center
- 40 languages translated to support the global audience of patients, staff, visitors

NIH's Impact on U.S. Health and Medicine

- Cardiovascular disease death rates have fallen more than 70% in the last 60 years
- Cancer death rates now falling more than 1% per year; each 1% drop saves ~$500 billion
- HIV therapies enable people in their 20s to live to age 70+

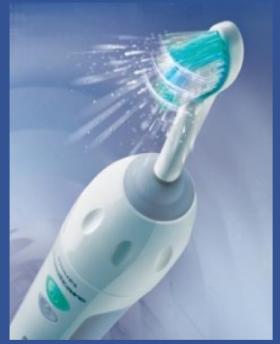
Impact of NIH-Supported Research On U.S. Economy

- In 2017, NIH research supported more than 402,000 jobs at more than 2,500 institutions, small businesses nationwide
- In 2017, NIH funding generated $69 billion in new economic activity—double taxpayers' investment
- NIH serves as foundation for entire U.S. medical innovation sector that:
  - Employs 1 million U.S. citizens
  - Generates $84 billion in wages, salaries
  - Exports $90 billion in goods, services

Source: NIH's Role in Sustaining the U.S. Economy, 2018 Update
United Medical Research

NIH

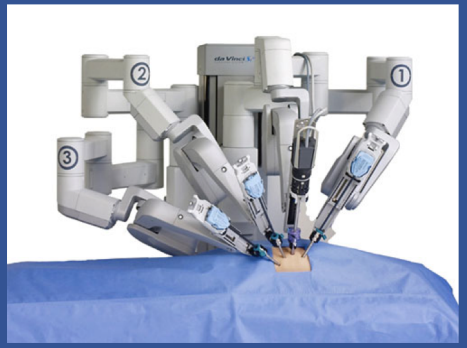
Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)



THERMEDICAL

SERF Ablation System

Genentech
IN BUSINESS FOR LIFE



MENSSANA
RESEARCH, INC.

Heartsbreath™ Heart Transplant Rejection point-of-care breath test

MedImmune

illumina®

NIH Small Business Program:
Supporting and Enabling Research Output

$37 Billion

Basic and applied biomedical science

>$980 Million

Non-dilutive funding just for small businesses

NIH SBIR/STTR: 3-Phase Program

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Commercialization
Phase III

Phase I → *Phase II*

Fast-Track

NIH SBIR/STTR Website

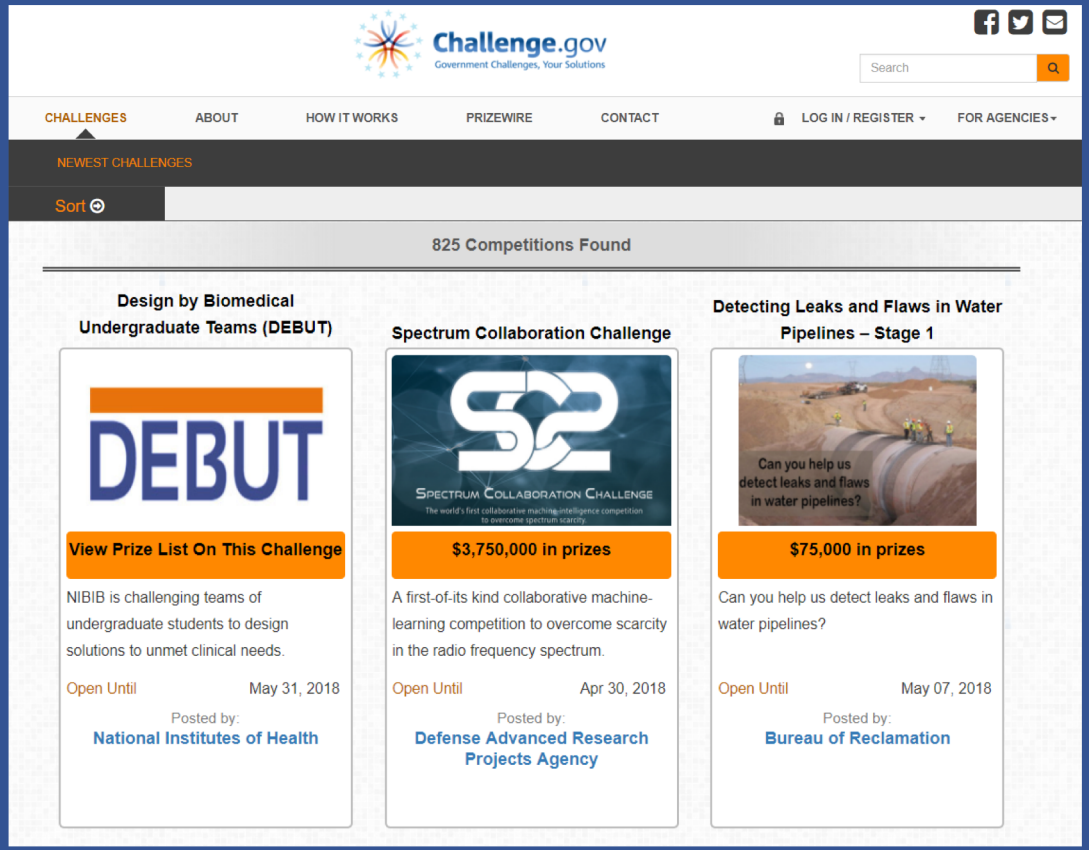
http://sbir.nih.gov

What is a challenge?

A competition in which a prize is offered to participant(s) whose solution meets the criteria set by organizers.

Success depends on meeting the challenge's defined scientific goals and stimulating innovation that has the potential to advance the agency's mission.

America COMPETES Act of 2010
American Competitiveness and Innovation Act of 2016



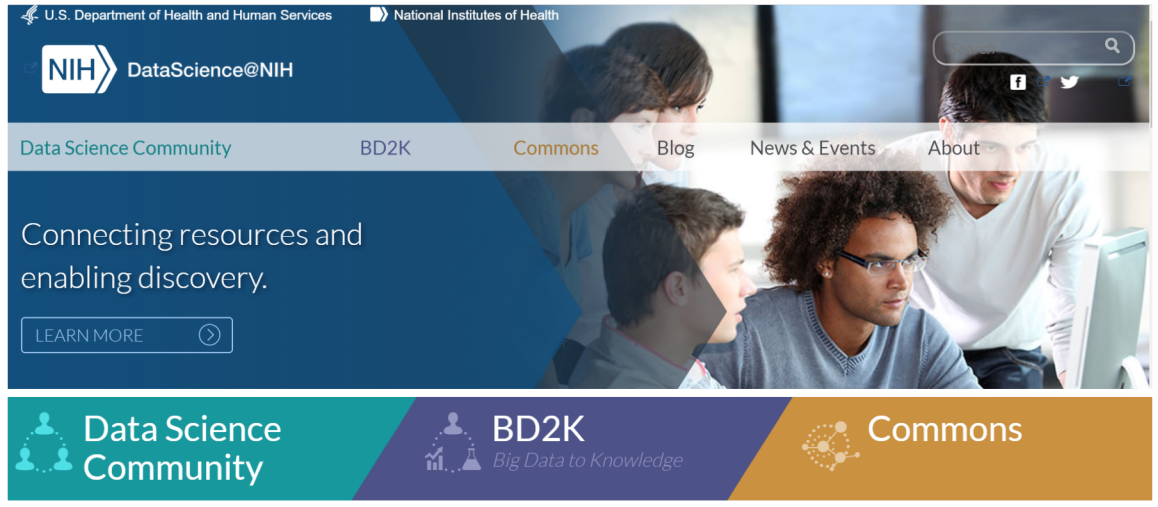
- Give fed agencies prize authority to stimulate innovation and develop creative solutions
- Encourages public-private partnerships, commercialization & cross-discipline interactions
- Eligibility to win cash: US Citizen/Permanent Residents & US-based companies

Prize Competitions @ NIH

- 3-D Retina Organoid Challenge ($1.1M)
  - Idea challenge: winner announced in September 2017
  - Implementation: currently underway; multiple opportunities to win
- Single Cell Analysis Challenge ($500k)
  - Phase I: Concept proposals; five winners and 11 finalists selected
  - Phase II: 2 winners selected June 2017; developed new tools to predict and analyze behavior of a single cell in complex tissue over time
- Wearable Alcohol Biosensor ($300k)
  - BACtrack Skyn: worn on the wrist and offers continuous and non-invasive monitoring of a user's BAC
- Up For a Challenge: Stimulating Innovation in Breast Cancer Epidemiology ($50k)
  - Two winners, a second place team, and two runners-up
  - Solvers used NCI genomic datasets for innovative approaches to identify novel pathways involved in breast cancer susceptibility

NIH Strategic Plan for Data Science - RFI

- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-134.html



NIH...

Turning Discovery Into

The Office of the National Coordinator for Health Information Technology

Office of the National Coordinator for Health Information Technology

Teresa Zayas-Cabán, PhD, Chief Scientist
Stephen Konya, Senior Innovation Strategist
HHS Startup Day, Boston - March 30, 2018

Mission and Priorities

FEDERAL HEALTH IT MISSION

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

2017-2018 ONC PRIORITIES

ONC will work to make health information more accessible, decrease the documentation burden, and support EHR usability under 21st Century Cures and MACRA.

ONC Implementation of 21st Century Cures Act

- Primary Responsibility is in Title IV – Delivery

Section	Short Title
4001	Improving Quality of Care for Patients: Burden Reduction
4002	EHR Transparency: Conditions of Certification
4003	EHR Transparency: Trusted Exchange Framework and Common Agreement and Health IT Advisory Committee
4004	Information Blocking
4005	Leveraging EHRs to Improve Patient Care
4006	Empowering Patients and Improving Patient Access to Electronic Health Information
4007 & 4008	GAO Studies on Patient Matching, Patient Access to Health Information

ONC Implementation of 21st Century Cures Act

- Primary Responsibility is in Title IV – Delivery

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Office of the Chief Scientist Overview

- **Responsible for**
  - developing and evaluating ONC's overall scientific efforts and activities and, as necessary, develops, establishes, or recommends scientific policy to the National Coordinator; and
  - identifying, tracking, and anticipating innovations in health care technology across the ONC organization.
- **Priority Areas**
  - Precision Medicine Initiative (PMI)
  - Patient-centered outcomes research (PCOR) projects
  - Coordinating on relevant scientific endeavors with other HHS operating divisions and other Federal agencies

The Precision Medicine Initiative (PMI)

A federal effort launched in 2015

MISSION: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care.

ONC Role in the PMI

- Accelerate innovative collaboration around pilots and testing of standards that support health IT interoperability for research
- Adopt policies and standards to support privacy and security of cohort participant data
- Advance standards that support a participant-driven approach to patient data contribution

ONC PMI Activities

- **Sync for Science Pilot**
  - » Demonstrate the feasibility of open, standardized, API-based individual access to and donation of data for research, such as the *All of Us* Research Program
- **Sync for Science Application Programing Interface (API) Privacy and Security**
  - » Technical and administrative testing, analysis, and assessment of APIs developed under the S4S Pilot Project
- **Sync for Genes**
  - » Develop and pilot resources for standards for genomics information

https://beta.healthit.gov/topic/precision-medicine

Artificial Intelligence (Ai) for Health and Health Care

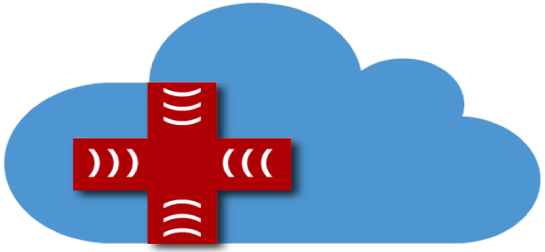
- Collaboration with the Agency for Healthcare Research and Robert Wood Johnson Foundation
- Asked JASON to study the impact Ai can have on health and health care, specifically:
  - How can Ai shape the future of public health, community health, and health care delivery from a personal level to a system level?
  - Understand the *opportunities* and *considerations* that can better prepare and inform developers and policy makers and promote the general welfare of health care consumers and the public

Blog: https://healthit.gov/buzz-blog/jason

Report: https://healthit.gov/jason

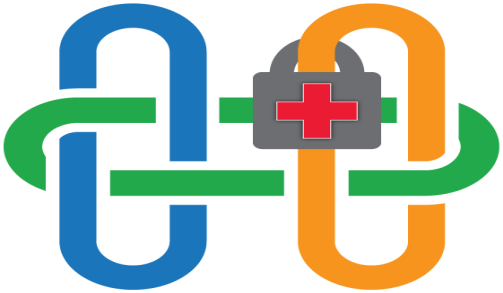
National App & Idea Challenges

Consumer Health Data Aggregator Challenge



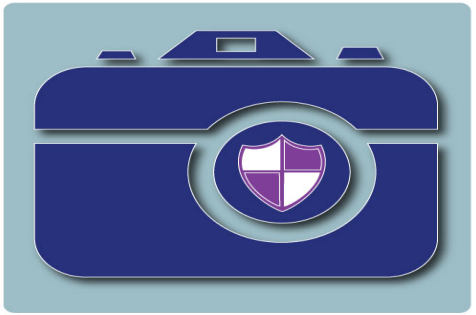
Provider User Experience Challenge

Blockchain Challenge

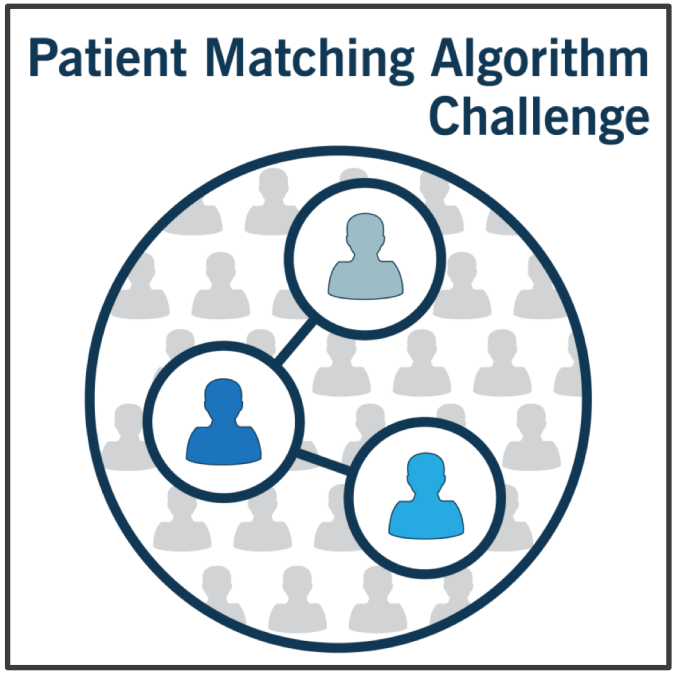


MHDFC
MOVE HEALTH DATA FORWARD CHALLENGE

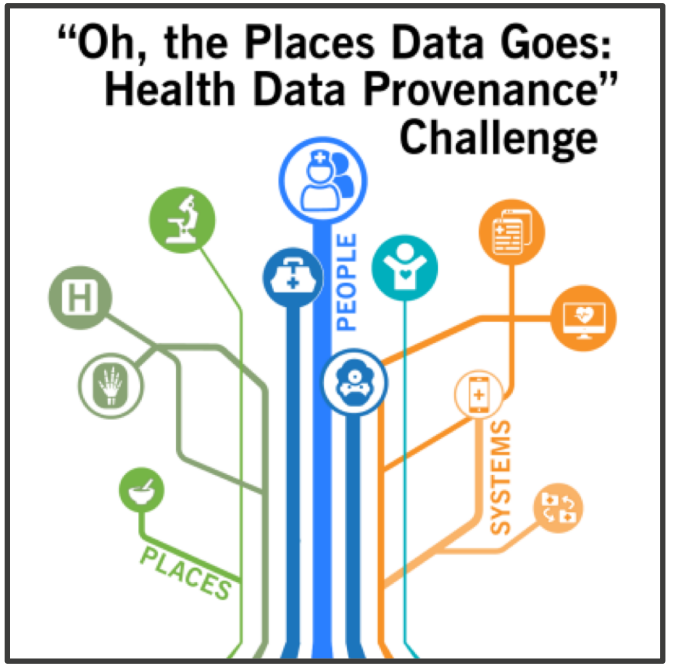
Privacy Policy Snapshot Challenge



Challenges Launched in 2017



Closed for submissions:
October 12th, 2017



Phase 2 Just Closed

Challenges Launched in 2017

www.challenge.gov

- Up to $50,000 in prizes
- Deadlines for submissions;
  - Stage #1: Closed
  - Stage #2: May 25th, 2018
- Secure, "ready to use"/"turn-key" FHIR server code development

***

Informational Resources / Tools

Mobile Health Apps Interactive Tool

WHICH LAWS APPLY TO MY MOBILE HEALTH APP?

1. Do you create, receive, maintain, or transmit identifiable health information?

- YES
- NO

2. Are you a health care provider or health plan?

- YES
- NO

3. Do consumers need a prescription to access your app?

- YES
- NO

4. Are you developing this app on behalf of a HIPAA covered entity (such as a hospital, doctor's office, health insurer, or health plan's wellness program)?

One Stop “Shopping” for Resources

Standards Implementation & Testing Environment (SITE)

"Learn, Collaborate, and Test!"

CONSOLIDATED CDA (C-CDA) SANDBOX

This sandbox contains resources and test tools related to the Consolidated Clinical Document Architecture standard.

DIRECT TRANSPORT SANDBOX

The sandbox contains resources and test tools related to the Direct project and Direct systems registered by health IT developers that can be used by implementers to test interoperability.

PROVIDER DIRECTORY SANDBOX

This sandbox contains resources and test tools related to the IHE Healthcare Provider Directory (HPD) standard.

QUALITY REPORTING STANDARD SANDBOX

This sandbox contains resources and test tools related to the Quality Reporting Document Architecture (QRDA) Category I and QRDA Category III standards.

CLINICAL QUALITY MEASURES (CQM) SANDBOX

This sandbox contains resources and tools related to evaluating the accuracy of clinical quality measure calculations with Cypress.

PUBLIC HEALTH REPORTING SANDBOX

This sandbox contains resources and tools related to the Public Health Reporting Initiative.

LABORATORY STANDARDS SANDBOX

This sandbox contains resources and test tools related to Laboratory Standards.

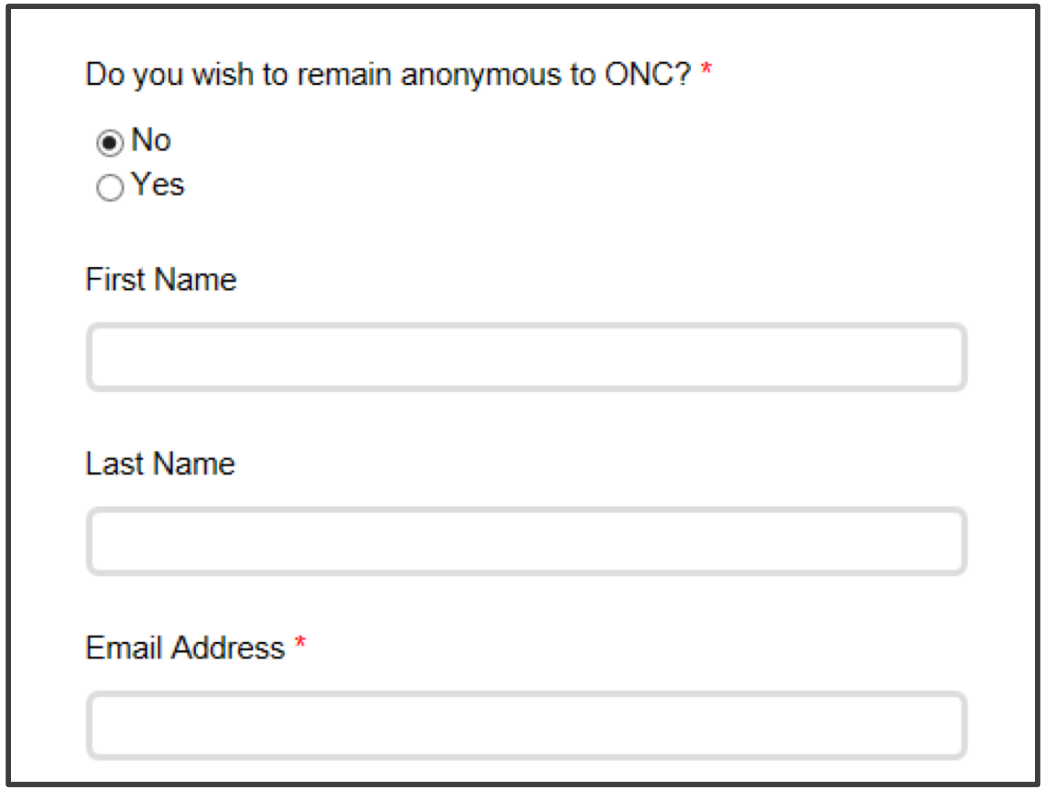
ELECTRONIC PRESCRIBING SANDBOX

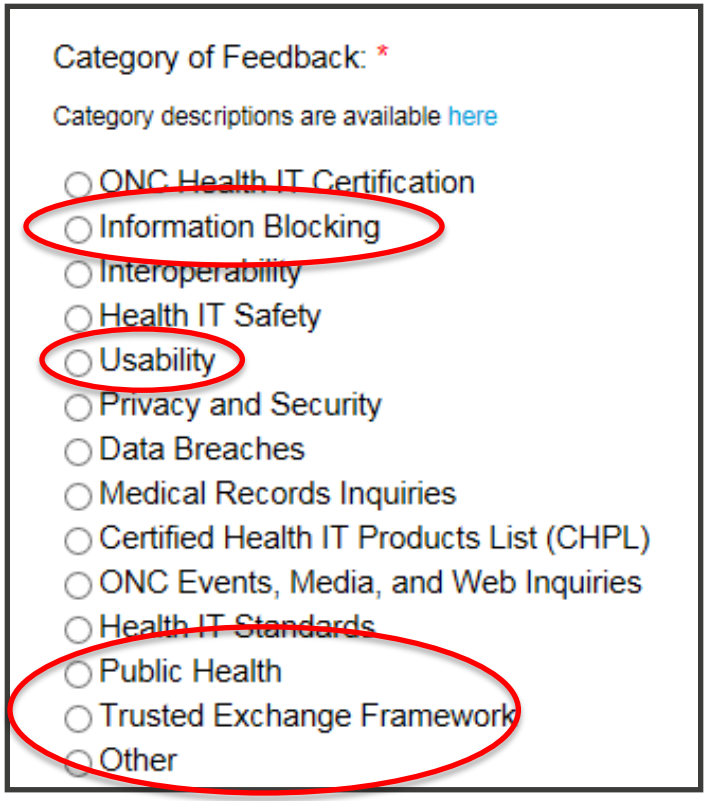
This sandbox contains resources and tools related to Electronic Prescribing.

SOAP TRANSPORT SANDBOX

This sandbox contains resources and tools related to SOAP Transport.

Health IT Feedback Form





The Office of the National Coordinator for Health Information Technology

Let's connect!

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@StephenKonya

@ONC_HealthIT @HHSONC HealthIT.gov

MeHI
MASSACHUSETTS eHEALTH INSTITUTE
at the MassTech Collaborative

MASS DIGITALHEALTH

The Massachusetts eHealth Institute at MassTech (MeHI)

& the Massachusetts Digital Health Initiative

Mass Digital Health Initiative

Announced in January 2016, the Massachusetts Digital Health Initiative, or **Mass Digital Health**, is a public-private partnership building a stronger and more competitive digital health ecosystem across the Commonwealth.

MACP
MASSACHUSETTS COMPETITIVE PARTNERSHIP

MeHI
MASSACHUSETTS eHEALTH INSTITUTE
at the MassTech Collaborative

BOSTONIA. CONDITA A.D. 1630.

PULSE@ MASSCHALLENGE

TechSpring
THE BAYSTATE HEALTH TECHNOLOGY INNOVATION CENTER

MASS DIGITAL HEALTH

Mass Digital Health Goal

MASS DIGITALHEALTH

The Mass Digital Health Cluster

Mass Digital Health Council

The role of the Mass Digital Health Council is to advise the Governor regarding the digital health industry, and to develop a growth plan to achieve the goal of creating the leading global ecosystem for digital health in Massachusetts.

OFFICE OF THE GOVERNOR
COMMONWEALTH OF MASSACHUSETTS
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CHARLES D. BAKER
GOVERNOR

KARYN E. POLITO
LIEUTENANT GOVERNOR

By His Excellency

CHARLES D. BAKER
GOVERNOR

EXECUTIVE ORDER NO. 574

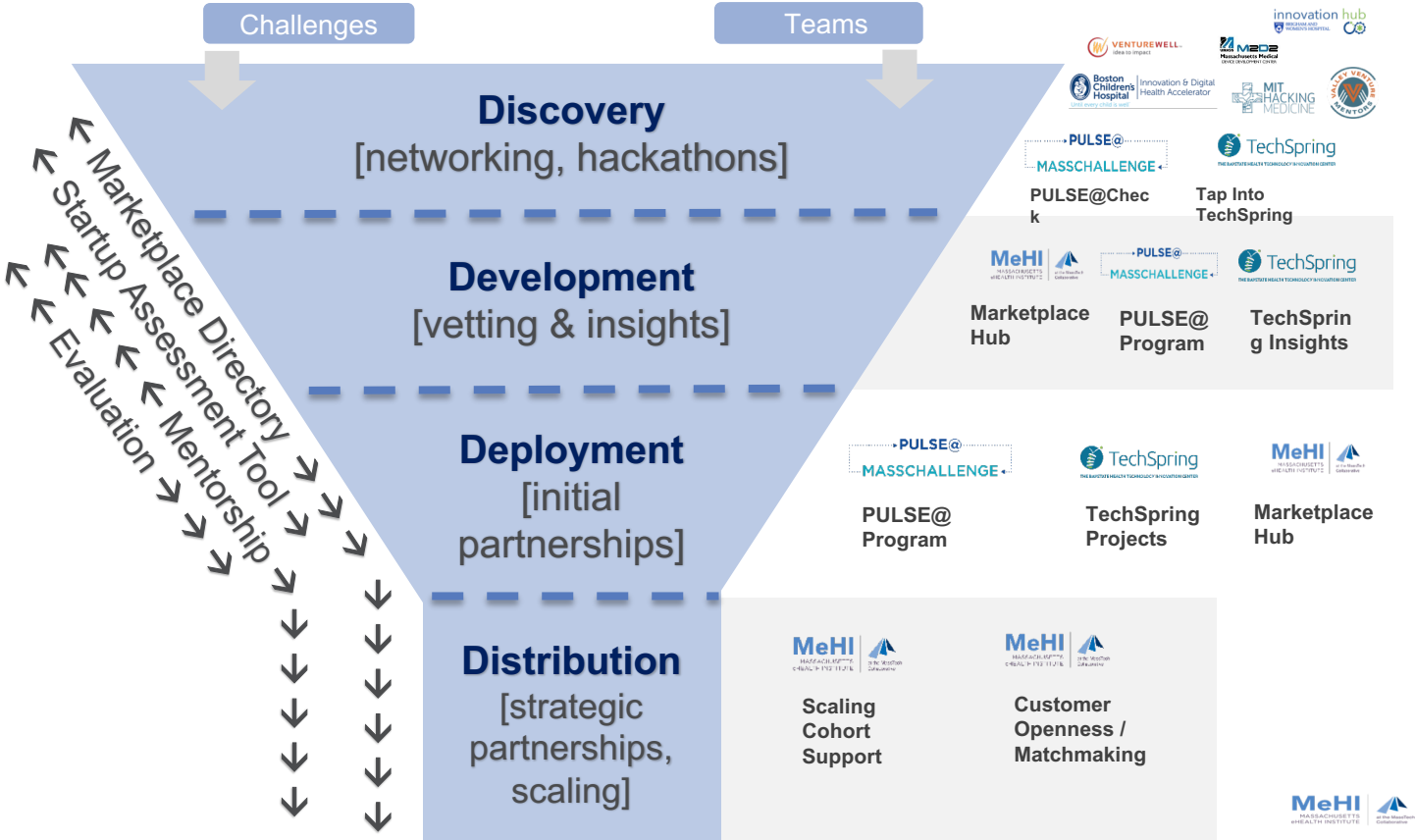
ESTABLISHING THE MASSACHUSETTS DIGITAL HEALTHCARE COUNCIL

WHEREAS, the digital healthcare industry is a rapidly growing industry with the potential to significantly improve healthcare delivery and contain costs;

WHEREAS, Massachusetts's strong base of established and startup healthcare companies, robust investment community, high rate of use of electronic health records, and unparalleled healthcare providers, universities, and research institutions uniquely position the Commonwealth to lead in the growth of the worldwide digital healthcare industry;

WHEREAS, private sector innovators, leaders and mentors are partnering with institutional researchers to create the nation's top innovation economy, and a globally-leading life sciences sector;

Mass Digital Health: Marketplace



Current Action Agenda

Mass Digital Health Council:

- Strategic Plan Development
  - Data
  - Piloting and Product Validation
  - Ecosystem

Marketplace Program:

- Marketplace Directory and Startup Assessment Tool
- Aging & Caregiving Marketplace
- Support Regional ‘development’ pipeline
- Exploring ways to expand the ‘customer’ pool (CHCs, regional hospitals, BH, LTPAC, MassHealth/ACOs)

Connection and Promotion:

- MassDigitalHealth.org & #MassDigitalHealth
- PULSECheck Meetup Series
- Tap into TechSpring Meetup Series
- Innovation Managers Meetup Group

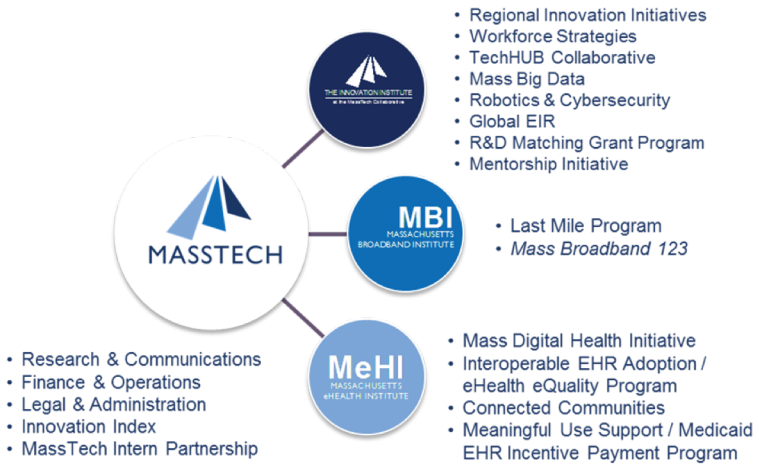
PULSE@MassChallenge:

- Monitor and learn from partnership process
- Executive Office of Elder Affairs as Champion for PULSE 2018

TechSpring

- Leverage TechSpring Insights into Greater Boston to build mentor/education networks for startups

MeHI Overview



MeHI is a division of the Massachusetts Technology Collaborative, a state economic development agency

MeHI is the designated state agency for:

- Coordinating health care innovation, technology and competitiveness
- Accelerating the adoption of health information technologies
- Promoting health IT to improve the safety, quality and efficiency of health care in Massachusetts
- Advancing the dissemination of electronic health records systems in all health care provider settings

Connect with Us

Laurance Stuntz

Director

Massachusetts eHealth Institute at the MassTech Collaborative

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(617) 371-3999 x201

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www.MassDigitalHealth.org

@MassEHealth

#MassDigitalHealth

LinkedIn: Mass Digital Health

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engage@masstech.org

Alice Bonner

Secretary, Massachusetts Executive Office of Elder Affairs

#HHSstartupBOS #HHSstartupday

LUNCH

Presented By:

MACP MASSACHUSETTS COMPETITIVE PARTNERSHIP

MeHI MASSACHUSETTS eHEALTH INSTITUTE

PULSE@ MASSCHALLENGE

Harvard Pilgrim HealthCare

#HHSstartupBOS #HHSstartupday

BREAKOUTS

1. **Kevin McTigue, HHS** – What challenges can HHS solve with your help?
2. **Jessica Mazerik, NIH** – How to use big data to make an impact on health
3. **Ray Hurd, CMS** – How to work with CMS
4. **Mona Siddiqui, HHS** – How to use data effectively in your work
5. **Robin Lipson, MA Executive Office of Elder Affairs** – How is the Commonwealth thinking about issues facing an aging population?
6. **Rebecca Love, Northeastern** – How to engage nurses, the end users of nearly every medical product
7. **Josie Elias, Brigham and Women's Hospital** – Avoiding pilot purgatory by defining key ways to a collaborative environment between startups and clinicians
8. **Patricia Forts, Harvard Pilgrim Health Care** – When is the right time to work with a payor and how can you prove value?
9. **Laurance Stuntz** – How to work with the Commonwealth of Massachusetts on your digital health solution
10. **Teresa Zayas-Cabán and Stephen Konya, ONC** – Interoperability, usability, and the 21st Century Cures Act. How innovation can improve research and improve care
11. **Margie Zuk, MITRE & Esther Bleicher, FDA** – How to know when your technology is secure enough to work with the federal government and how to work with the FDA

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SHARK TANK

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JUDGES

1. **Bruce Greenstein** – Chief Technology Officer, US Department of Health and Human Services
2. **Jessica Mazerik** – Special Assistant, Immediate Office of the Director, National Institutes of Health
3. **Esther Bleicher** – Senior Policy Advisor, US Food and Drug Administration
4. **Mona Siddiqui** – Chief Data Officer, US Department of Health and Human Services
5. **Laurance Stuntz** – Director, Massachusetts eHealth Institute
6. **Peter Sherlock** – Senior Vice President & Director of Bedford Operations, MITRE Corporation
7. **Michael Crawford** – Chief of Staff for the CEO, Unity Health Care System
8. **Michael Palantoni** – Director, Platform Strategy and Operations, Athenahealth

#HHSstartupBOS #HHSstartupday

Bringing Health Home

March 2018

Our *Mission*

PRIVATE &
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To **empower older adults** living **with chronic conditions** to live healthier and more independent lives

Problem

MOST OLDER ADULTS WANT TO AGE INDEPENDENTLY AT HOME

MILLION
109
U.S. Adults over 50

+65%
65+ Growth By 2030

90%
Want To Age At Home

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BUT...

DOING SO WITHOUT PROPER SUPPORT CAN BE DANGEROUS

CARE MANAGEMENT

4:5 seniors living with **multiple chronic illnesses**

MEDICATION ERRORS

28% of hospitalizations in seniors are medication related

SOCIAL ISOLATION

Loneliness & isolation negatively impact health

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CONFIDENTIAL

A DIGITAL HEALTH COMPANION &
CARE MANAGEMENT PLATFORM FOR THE HOME

FRIENDLY & EASY TO USE

Voice interface that proactively engages with users using facial recognition

PATENT PENDING PROCESS

REDUCES MEDICATION ERRORS

Stores & dispenses 28 days of medication, orders refills, and delivers therapy reminders

IMPROVES CARE DELIVERY

Delivers relevant and personalized care plans and performs health check-ins

CONNECTS THE HOME TO CARE

Video calls, drop-ins, and alerts to care team members via the Pillo Mobile App

A Care Management Platform

OPTIMIZE THE PATIENT EXPERIENCE

with our interface dedicated to healthcare

EXTRACT ACTIONABLE HEALTH & CONTEXTUAL DATA

from inside of the home (via API)

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PROVIDE A PLATFORM FOR HEALTH ORGANIZATIONS TO DELIVER CONTENT & VALUE ADDED HEALTH SERVICES

into the home

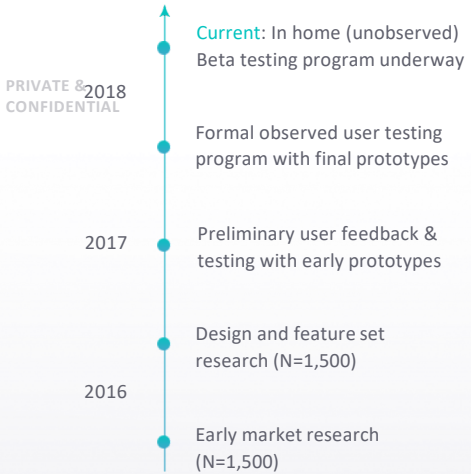
INFORM AND ASSIST PROVIDERS OF CARE

with alerts & remote monitoring tools

Market Validation

USERS LOVE PILLO & PROVIDERS OF CARE ARE WILLING TO PAY FOR THE SOLUTION

USER CENTRIC APPROACH



USERS LOVE PILLO

10 beta testers
56 - 77 years old

ENGAGEMENT	Avg. 5 interactions per day
INTERACTION TYPE	Weather Time Calories General Health
FAVORITE FEATURES	Daily Care plan Dispensing Video calling

CAREGIVERS WILL PAY

FEMALE	60%
AVG AGE	49 Yrs
WOULD SPEND OUT OF POCKET (OOP)	82%
ANNUAL "OOP" SPEND ON CARE (1)	$6,954

PURCHASE INTENT FOR SOLUTION

PRICE	TOP 2 BOX
$499	72%
$399	77%
$299	83%
$199	88%

(1) AARP - "Family Caregiving and Out-of-Pocket Costs: 2016 Report."

Go To Market (B2B2C)

REPLICABLE MODEL THAT LEVERAGES PARTNERS FOR EFFICIENT LEAD GENERATION AND RAPID DISTRIBUTION

Current	Proof of Concept	Lead Generation	Distribution	Services	Leads
PRIVATE & CONFIDENTIAL AARP	• 4-Week diabetes pilot	• Pillo featured as preferred AARP solution • Placement on website (38Mn members)	• AARP to drive traffic to Pillo Health website	• AARP branded content featured on Pillo device	American Heart Association | American Stroke Association VA U.S. Department of Veterans Affairs Home Care Assistance Microsoft American Diabetes Association
STANLEY Healthcare	• 4-Week aging in place pilot	• Stanley marketing support	• Wholesale • Direct sales to independent living (11,000 communities)	• Stanley specific device branding • Stanley branded software on device	BEST BUY CVS pharmacy Walmart Walgreens
FRESENIUS MEDICAL CARE	• Multi-month in-home peritoneal dialysis pilot	• Fresenius dialysis patients (300,000 patients worldwide)	• Devices purchased by or leased to Fresenius	• Customized Fresenius renal care experience • Population analytics & full platform access	AstraZeneca MERCK Boston Scientific ERT Innovating Better Health Humana. CareMore

Case Study: Senior Living & Aging in Place

- Medication Storage
- Video Chat /Drop-In
- Community Calendar
- Disease Care Plans
- Fall Monitoring/ PERS
- Wander Prevention

Our Vision

A Digital Health Hub For The Home

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HHS Startup Day

March 30, 2018 • Boston, MA

ACT.md

Act together. Make health happen.

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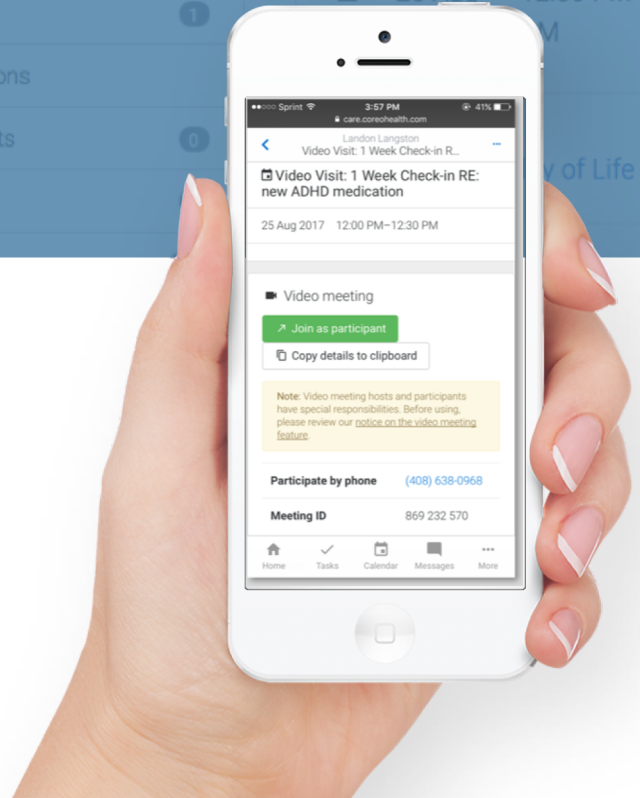
Simplifying Technology



Impacting outcomes that matter

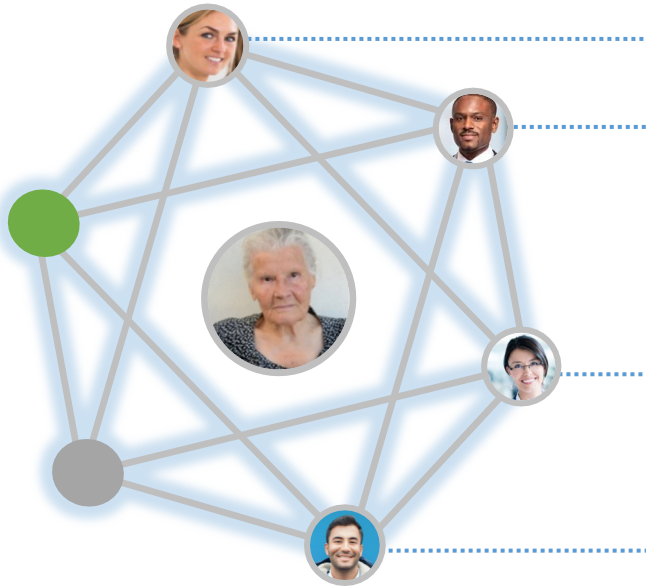
Giving care teams, including patients and families, the tools to automate and debug care processes across their community

ACT.md

A Platform for Care Design

Automating Personal Care Processes Across the Community

- Hospital Data
- Risk Stratification
- Pharmacy Data
- Claims Data
- Health Info Exchange



Schedule Annie appt with SUD counselor

Hospital & HIE Alerts More

27 Mar 6:00 PM Emergency Department Discharge

Adherence to Refills and Medications Scale (ARMS-7) Assessment

Goal: Secure Stable Housing More

Access to this section is restricted to 3 people. Permissions

Goal was Achieved today

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Partners in Innovation

ACROSS THE COUNTRY

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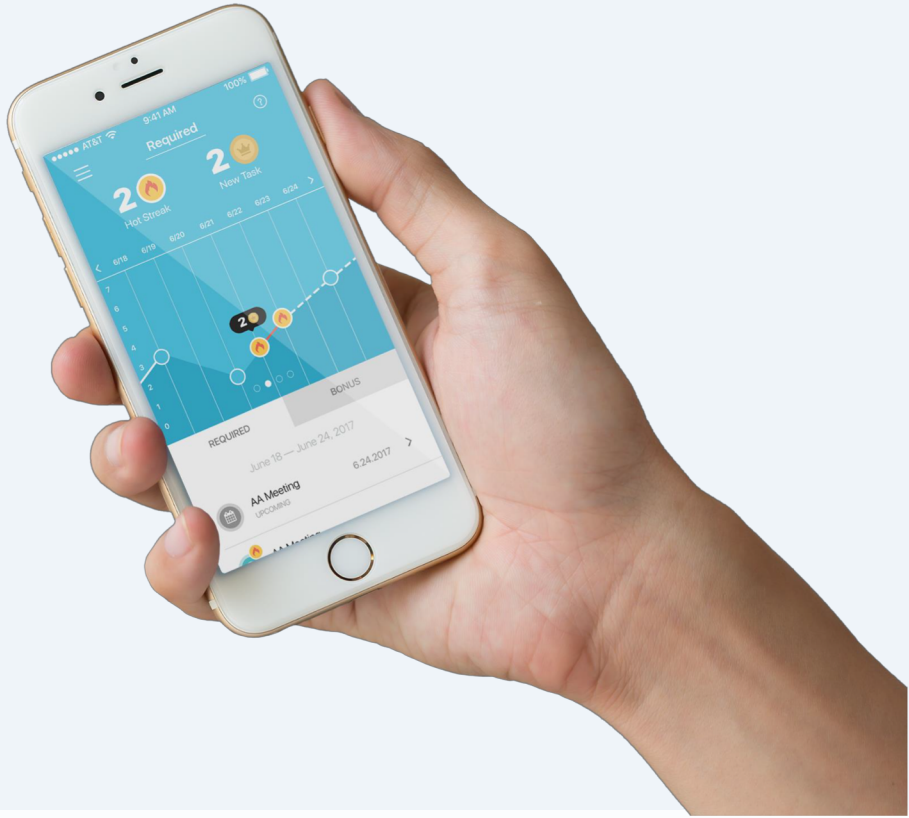
DynamiCare HEALTH

The digital platform for monitoring & rewarding recovery from addiction



info@dynamicarehealth.com

PULSE@ MASSCHALLENGE

Champions

aetna

Harvard Pilgrim HealthCare

MGH 1811

ENTERING EST. 1630 BOSTON

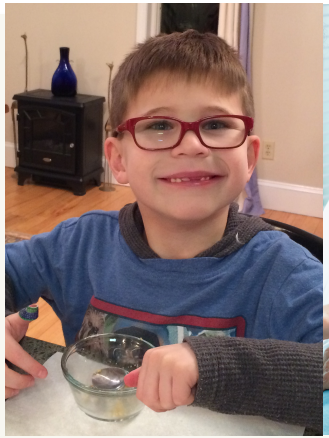
MeHI MASSACHUSETTS eHEALTH INSTITUTE

Neuroelectrics:

Personalized brain therapy

Ana Maiques
CEO
HHS Startup Day
March 30th,2018

Brain Disorders Affect One in Five People



YOUR NEIGHBOR WITH EPILEPSY

(50M PATIENTS WORLDWIDE)

YOUR GRANDMA WITH ALZHEIMER'S

(90M PATIENTS WORLDWIDE)

YOUR FRIEND WITH DEPRESSION

(240M PATIENTS WORLDWIDE)

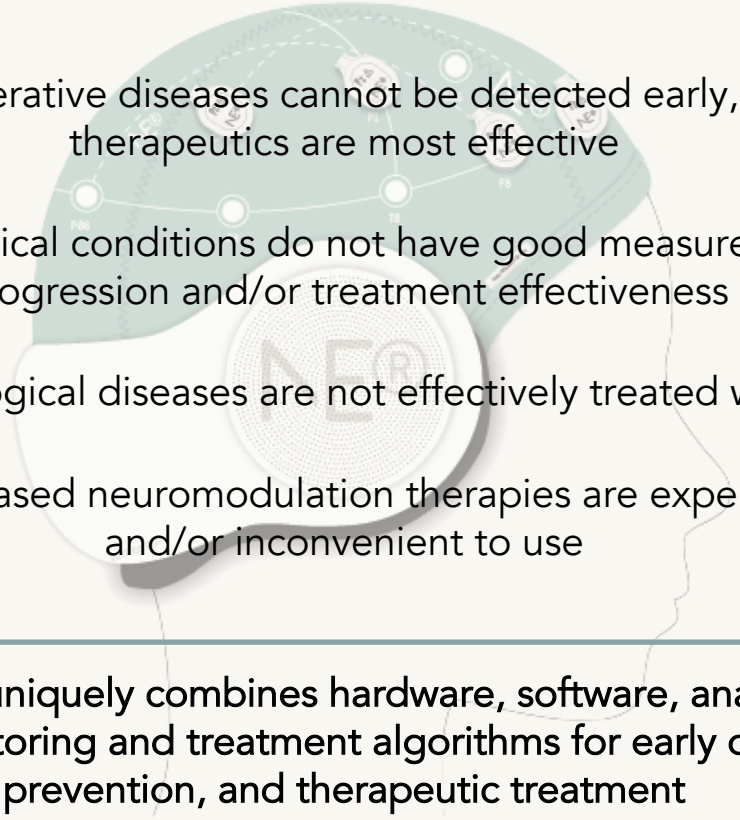
YOUR DAD WITH PARKINSONS

(5M PATIENTS WORLDWIDE)

YOUR SON WITH ADHD

(120M PATIENTS WORLDWIDE)

Significant Needs in $165B Brain Health Markets
Major Gaps in Diagnosis, Prevention, and Effective Treatments



Neurodegenerative diseases cannot be detected early, when new therapeutics are most effective

Many neurological conditions do not have good measures of disease progression and/or treatment effectiveness

Many neurological diseases are not effectively treated with a drug

Existing device-based neuromodulation therapies are expensive, invasive, and/or inconvenient to use

Neuroelectrics uniquely combines hardware, software, analytics, cloud-based monitoring and treatment algorithms for early diagnosis, prevention, and therapeutic treatment

Our approach: Read/Write the Brain

Lead Clinical Program: Drug Resistant Epilepsy

One third of 50 Million epilepsy patients are refractory to drugs.

Only alternatives are surgery or invasive implants.

Neuroelectrics is sponsoring an FDA-approved clinical trial for multidose therapy and device approval

Expected FDA approval in 2020

Pilot Study Sep. 2017 to Feb. 2018	**Pivotal Study** May 2018 to June 2019
Single site (BCH, referrals from BIDMC)	Est. four sites, including BCH and BIDMC
Co-Principal Investigator **Alexander Rotenberg, MD, PhD** Boston Children's Hospital Associate Professor of Neurology, Harvard Medical School	***Co-Principal Investigator*** ***Mouhsin Shafi, MD, PhD*** Beth Israel Deaconess Medical Center Assistant Professor of Neurology, Harvard Medical School

Boston Children's Hospital
Until every child is well™

Beth Israel Deaconess Medical Center
HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Our second clinical program: dementia and early Alzheimer's disease

- Our elderly population has reduced capacity to activate brain networks involved in motor and cognitive skills
- 30-40% people older than 65 suffer a fall per year (10% will cost $34 billion)

- 40 elderly subjects (10 already completed)
- With symptoms or cognitive decline and falls
- Endpoint: Quantified improvement in cognition and balance

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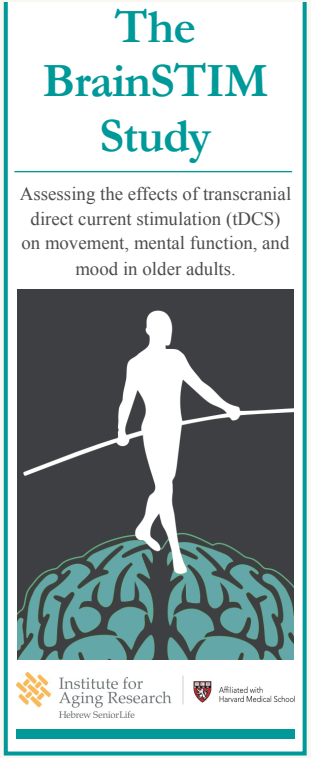
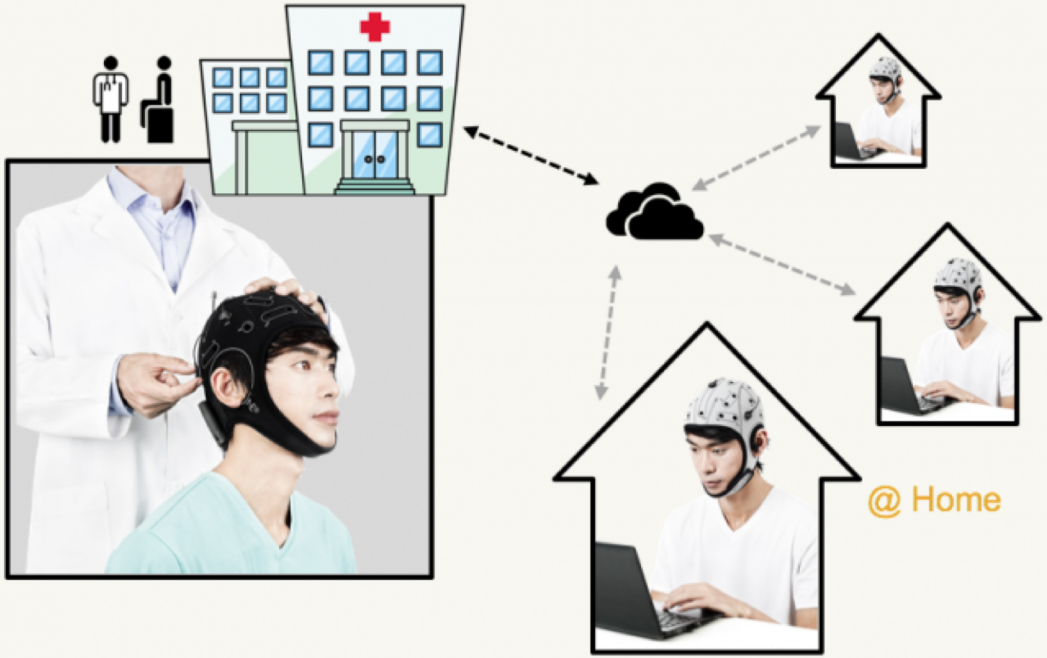
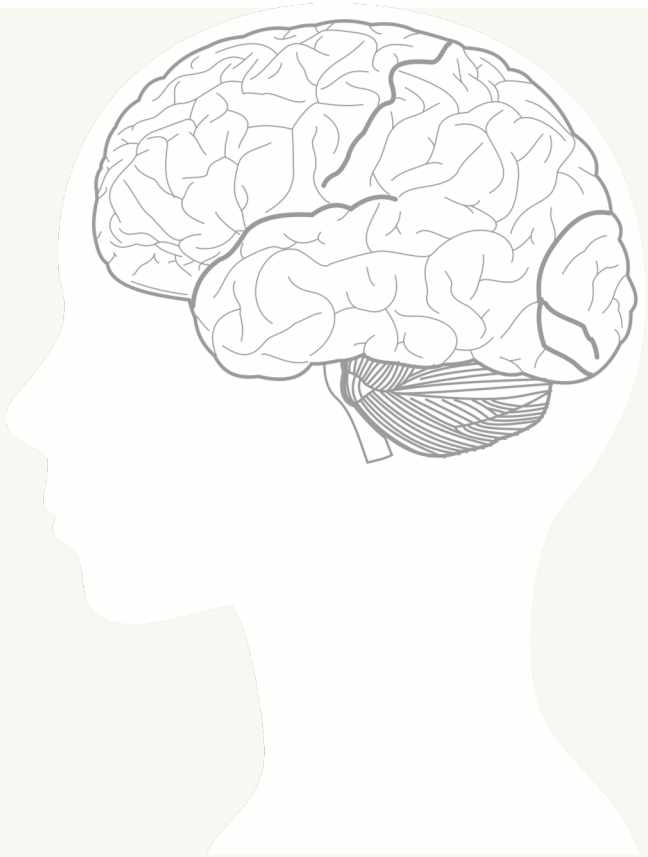


Principal Investigator
Dr. Bradley Manor, PhD
Director, Mobility and Brain Function, Institute for Aging Research
Professor of Medicine,BIMDC
Harvard Medical School

Delivering Prescription Treatments at Home



Transformational digital therapeutics are here!



- New digital therapies to be deployed at home required a new reimbursement model
- Current regulatory and reimbursement silos drugs/diagnostics/devices must be broken
- Combination therapies drug/digital will be patient centered, with better constant patient follow up
- We need to start building the new regulatory/reimbursement/healthcare provision models now

Thank you for your attention!

Ana Maiques, Co-Founder and CEO
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Paul Pyzowski, Corporate Development
paul.pyzowski@neuroelectrics.com

PATIENTPING CARE COORDINATION

PATIENTPING

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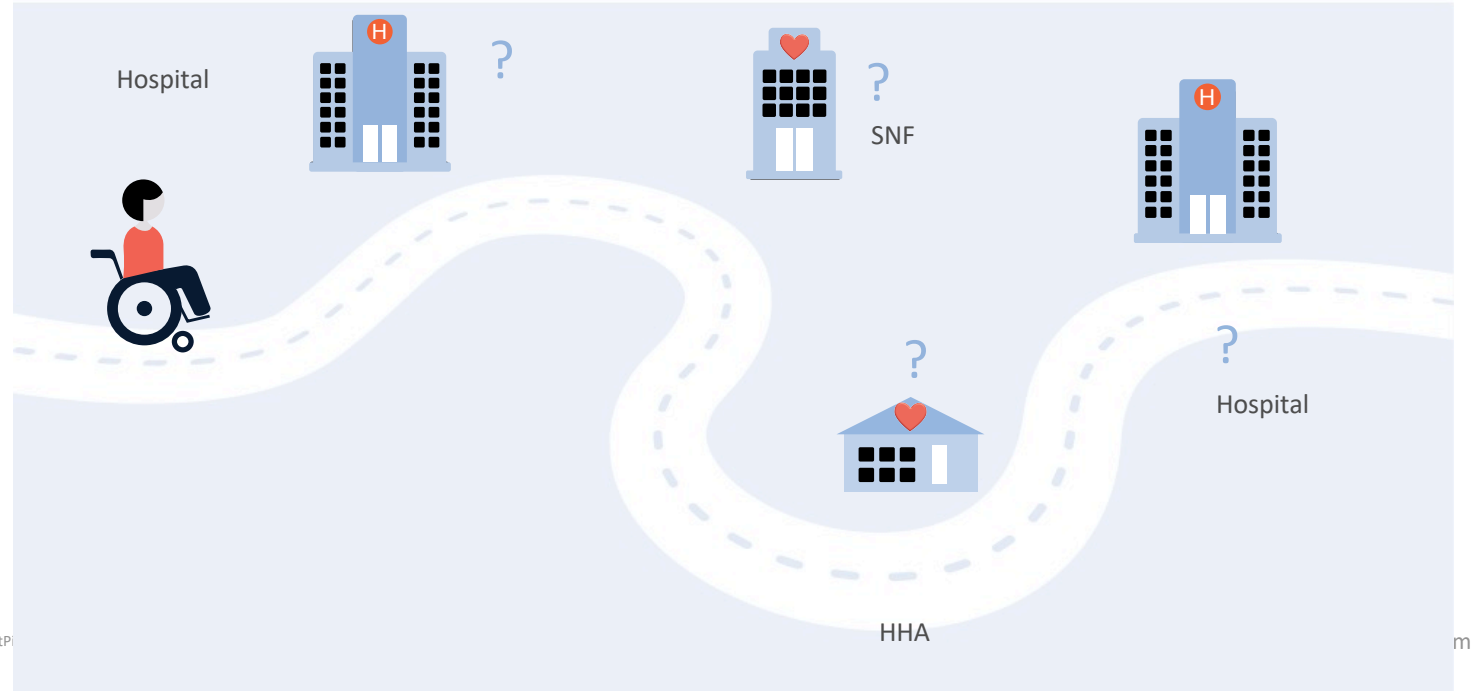
FRAGMENTED CARE

A disjointed healthcare system

Patients see multiple providers across various healthcare settings each year, resulting in fragmented data, unnecessary spending, and patient harm.



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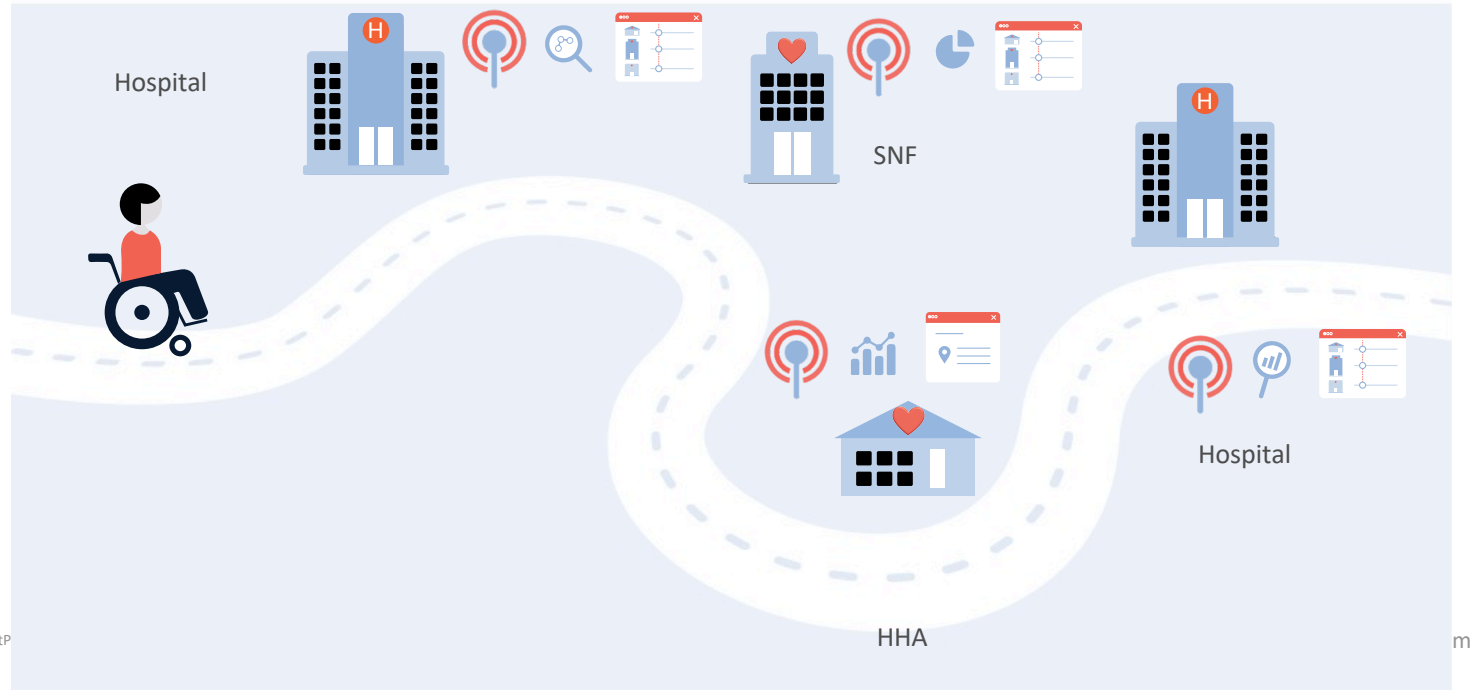
PATIENTPING SOLUTION



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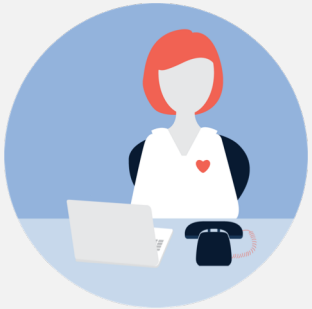
PATIENTPING PRODUCTS AND PROVIDERS WE SERVE

Pings

ROLE	PRODUCT
	
MANAGING PROVIDER	PINGS
Provider or organization responsible for overall patient care	Real-time messages when patients present to the ED, are admitted, transferred or discharged anywhere
PINGS let MANAGING PROVIDERS know in real time when their patients receive care and help them better manage and coordinate care	

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PATIENTPING PRODUCTS AND PROVIDERS WE SERVE

Stories

ROLE	PRODUCT
TREATING PROVIDER Providers with the patient during a clinical encounter	STORIES Clinical and administrative context upon presentation and/or admission
STORIES equip TREATING PROVIDERS with valuable information on patients they treat	

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WHO WE PARTNER WITH

Our value to providers across the care continuum

ACO →

Use PatientPing to: Identify high-utilizing patients, Send important patient context to treating providers, Achieve PAC visibility, Apply timely interventions, Monitor utilizations, Improve patient engagement and follow ups, Reduce leakage post-SNF stay

Hospitals →

Use PatientPing to: View in-and out-of-network patient utilization information, Quickly identify patient care programs, Increase ED throughput, Identify inactive and recent post-acute providers, Connect patients with appropriate community resources

SNF →

Use PatientPing to: Increase census, Apply timely interventions, Receive important patient context, Recapture patients and direct admits back to your facility, View patient utilization, Strengthen partnerships, Monitor patients 90 days post-discharge

HHA →

Use PatientPing to: Receive important patient context, Strengthen partnerships, Receive ED and readmission notifications, Appropriately allocate staffing resources

Providers →

Use PatientPing to: Receive real-time notifications, Send important patient care instructions, Monitor out-of-network hospital utilization, Use lightweight clinical and utilization data

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PATIENTPING ADDRESSING THE OPIOID CRISIS

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A PUBLIC HEALTH CRISIS

Addressing the nationwide opioid epidemic

115

Americans die each day from an opioid overdose

$78.5B

The amount spent annually on prescription opioid misuse

Emergency providers often lack context when patients walk through the doors of the ED. They waste valuable resources doing detective work to figure out the patient's story. But what if that patient's story presented alongside them?

Source: 2018. National Institute on Drug Abuse. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis

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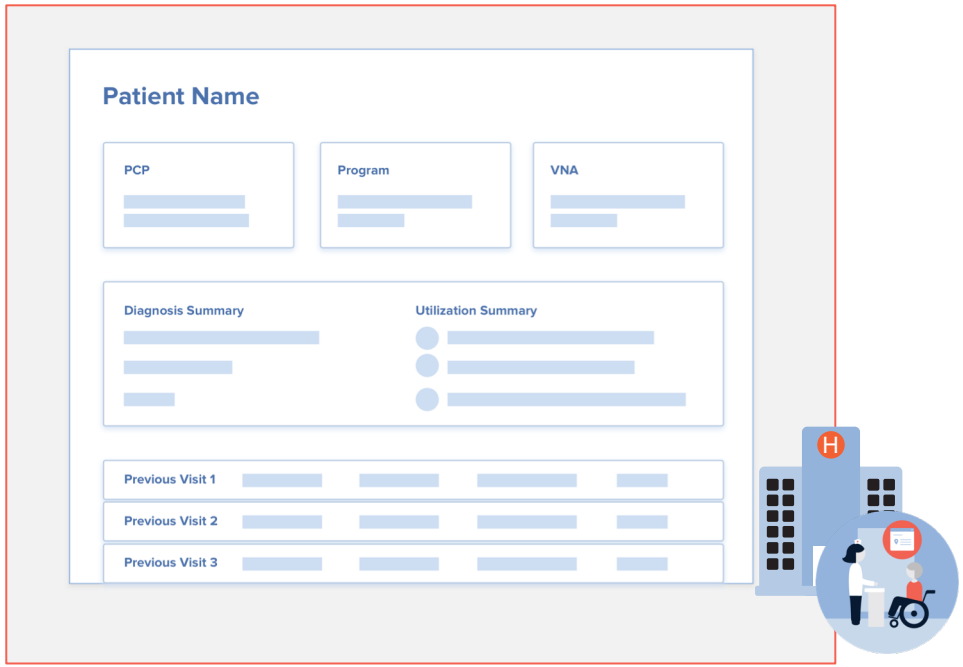
STORIES FOR HOSPITALS

Critical patient context at the point of care

- Utilization patterns
- Intelligent flags
- Program affiliation
- Care team contact information
- Dx Info
- Social determinants of health
- Rx info
- Customized filters



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STORIES FOR HOSPITALS

Summary

- ✓ Identify high-utilizing patients and those exhibiting drug-seeking behavior to apply interventions
- ✓ Access care team contact information to connect with existing resources
- ✓ Identify inactive and recent post-acute providers to streamline patient discharges
- ✓ Identify non-clinical ailments (e.g. food insecurity, housing, etc.) and connect patient to appropriate community resources

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PATIENTPING

THANK YOU!

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CONGRATS STARTUPS!

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Office of the
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Startup Day
Boston, MA

Bruce Greenstein, HHS Chief Technology Officer

Chicago Startup Day

- May 24th
- HealthBox
- Matter
- 7wire Ventures
- Prtizker Group
- Sandbox Industries

CTO
Office of the
CHIEF TECHNOLOGY OFFICER

HEALTH DATAPALOOZA®

April 26-27, 2018

Washington Hilton, Washington, D.C.

AcademyHealth

HHS Entrepreneurs in Residence

"We have saved over $100 million and improved the turn-around time for creating and implementing measures that doctors and other providers use to report Medicare quality." – Patrick Conway, formerly of CMS

Office of the CHIEF TECHNOLOGY OFFICER

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Email: IDEALab@HHS.Gov

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NETWORKING

SAVE THE DATE
PULSE FINALE JUNE 5th

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