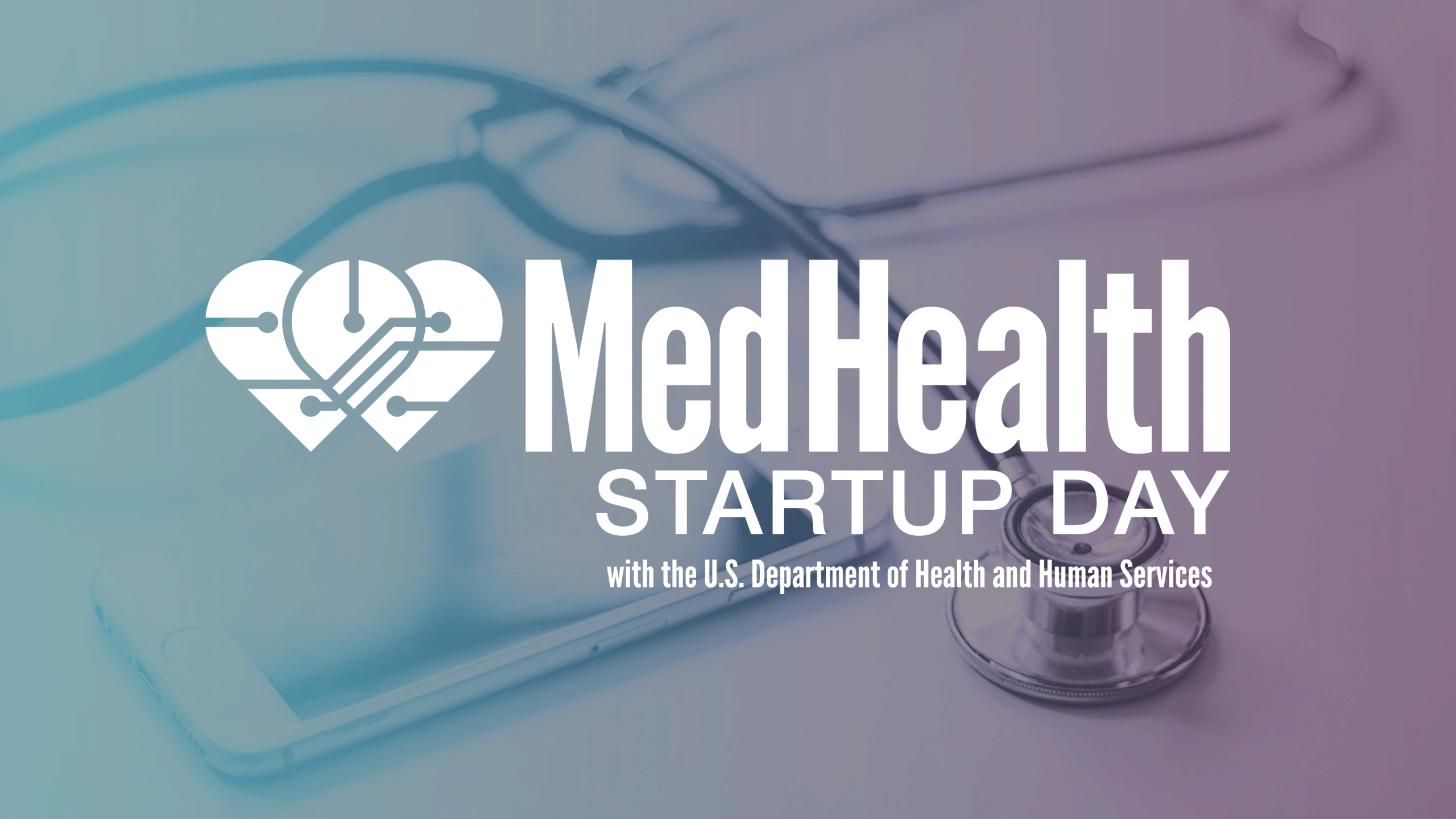


MedHealth

STARTUP DAY

with the U.S. Department of Health and Human Services

Innovating Healthcare Together

Innovation from a Federal Lens

Ed Simcox, Chief Technology Officer, U.S. Department of Health and Human Services

MedHealth

Office of the
CHIEF TECHNOLOGY OFFICER

Detroit Startup Day

Ed Simcox

7/15/2019

HHS At A Glance

Cabinet-Level

$1.1 Trillion budget

80,000+ staff

Mission

To build an innovation-focused culture at HHS that improves health outcomes and reduces costs

"Working in tandem, the Government and the private sector can promote the nation's economic growth through innovation"

- Michael Kratsios, Mick Mulvaney
August, 2017

Principles

1. Open data fuels insight and change
2. Partnerships accelerate mission
3. Consumer focus drives better healthcare

Inter-Agency Innovation Hub

Data

We open data to fuel internal & external innovation

Data Insights Initiative

Talent

We cultivate talent through Ignite, CoLab and EIR

IDEA LAB

Partnerships

We leverage prize authority to address market failures

KIDNEY X
INNOVATION ACCELERATOR

startupdays

Data

Data Insights Initiative

Increasing interagency data access

HHS Opioid Code-a-Thon
Connecting data to *Save lives*

45 teams
3 $10k prizes

Internal Innovation

IDEA LAB

Data Science CoLab
Ignite Accelerator

EIR
ENTREPRENEURS-IN-RESIDENCE

21 EIRs
15 projects

Partnerships

KIDNEY X
INNOVATION ACCELERATOR

Public-private partnership
$25M in prizes

startupdays

5 cities
1000 participants

GLOBAL DIGITAL HEALTH
PARTNERSHIP

36 countries

Innovating Healthcare Together

KidneyX Challenge

Rachel Meyer, Director of Policy and Government Affairs, American Society of Nephrology

MedHealth

Accelerating Innovation in the Prevention, Diagnosis and Treatment of Kidney Diseases

KIDNEY X
INNOVATION ACCELERATOR

Rachel Meyer
Director of Policy and Government Affairs
American Society of Nephrology

MedHealth Start Up Day
Detroit, Michigan
Monday, July 15, 2019

Kidney X Mission:

Accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.

- How public-private partnerships can drive progress in otherwise neglected areas
- How a small organization can create transformative changes
- How realigning incentives can help patient needs come first

ADVANCING AMERICAN Kidney Health

“This executive order encourages private enterprises to partner with government to achieve incredible medical breakthroughs.

We are going to prioritize the development of an artificial kidney.”

—President Donald J. Trump
July 10, 2019

ADVANCING AMERICAN Kidney Health

Goal 1: Reduce risk of kidney failure

Goal 2: Improve access to and quality of person-centered treatment options

Goal 3: Increase access to kidney transplants

OBJECTIVE 3. Catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic and private entities through KidneyX, and coordinating regulatory and payment policies to incentivize innovative product development

700,000
Americans have kidney failure

100,000 START DIALYSIS
every year: >50% of them will **DIE WITHIN 5 YEARS**

1% Medicare population has kidney failure

7% Medicare budget dedicated to their care

$35 BILLION
Annual Medicare Spend

12 Hours

A typical in-center hemodialysis patient spends 12 hours a week attached to a machine

93% Patients

Among patients ages 18-54 years old at the start of dialysis, 93% were classified as disabled

100,000

Each year, more than 100,000 Americans begin hemodialysis as a result of kidney failure

40 Million

40 Million adult Americans are currently classified as having chronic kidney disease

13 Patients

Every day 13 patients die waiting for a kidney transplant

48%

Of Stage 4 CKD patients, 48% were unaware of their severe CKD

3.5 Times

African-Americans are 3.5x more likely to develop kidney failure

1.5 Times

Hispanics are 1.5x more likely to develop kidney failure

SPOTLIGHT ON KIDNEY DISEASES IN MICHIGAN

1,331,312 PATIENTS WITH KIDNEY DISEASES

15,356 PATIENTS ON DIALYSIS

22,969 PATIENTS DIAGNOSED WITH KIDNEY FAILURE*

7,517 PATIENTS WITH A KIDNEY TRANSPLANT

2,437 PATIENTS WAIT-LISTED FOR A KIDNEY TRANSPLANT TODAY

KIDNEY X
INNOVATION ACCELERATOR

ASN Foundation
for Kidney Research
Time for a Cure

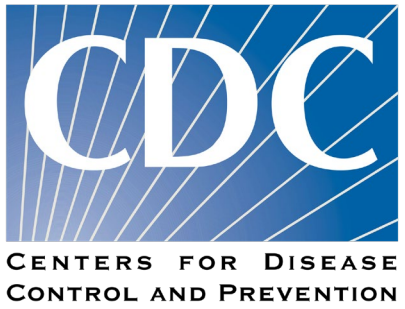
KHI
KIDNEY HEALTH INITIATIVE


ASN
LEADING THE FIGHT
AGAINST KIDNEY DISEASE


NTDS
NEPHROLOGISTS
TRANSFORMING
DIALYSIS SAFETY

KIDNEY
INNOVATION ACCELERATOR

HHS	ASN
Research funder	Nephrology expertise
Market regulator	Global reach
Primary payer	$25 million committed
Public health steward	Fundraising capacity



"There may be no better example than kidney care of how government domination of healthcare discourages innovation from providers...we need to flip that around."

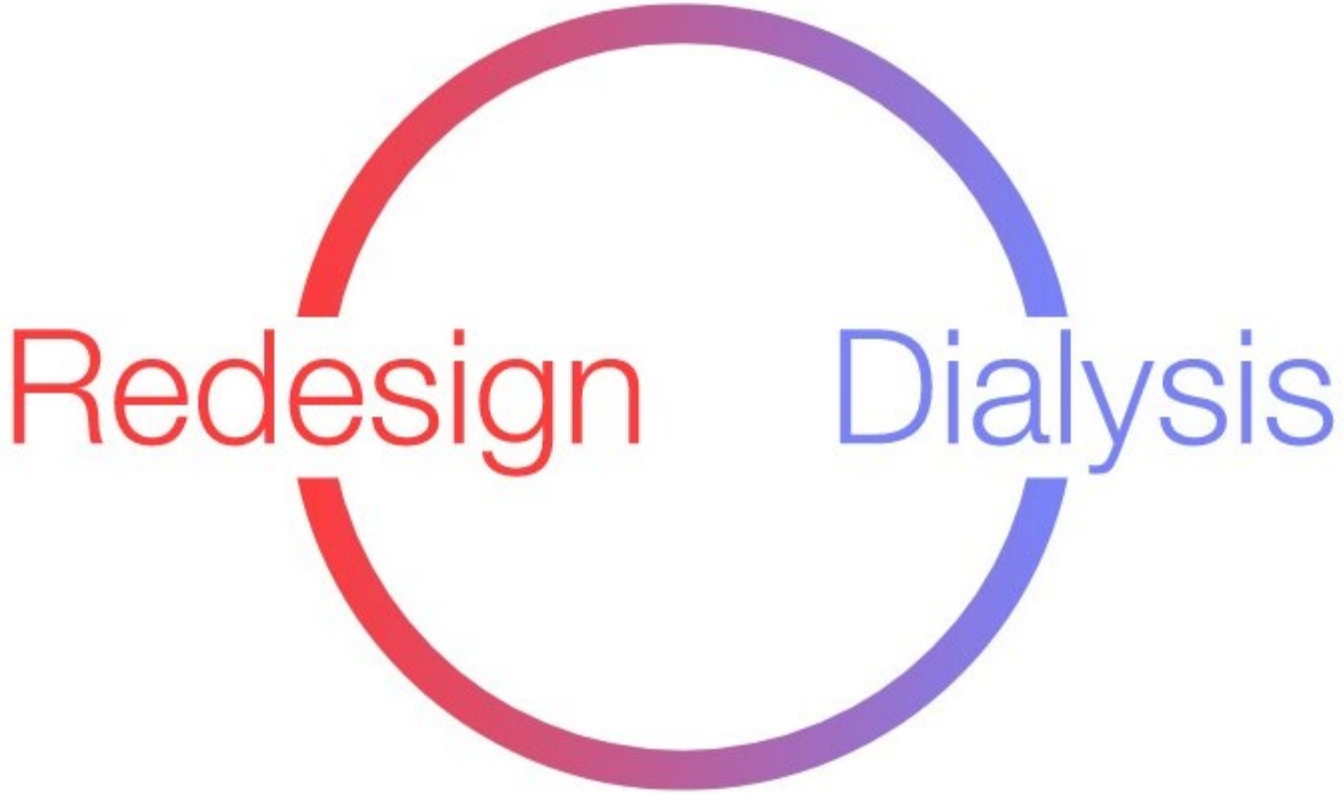
– HHS Secretary Alex M. Azar II
July 10, 2019

“Catalyze the Development of Innovative New Therapies”

1. **Offer funding opportunities**
   Series of prize competitions
2. **Coordinate regulatory and payment policies across HHS**
   Clarify paths to commercialization (FDA, NIH, CMS)
3. **De-risk commercialization**
   Attract outside investment capital
4. **Create a sense of urgency**
   On behalf of people living with kidney diseases

KidneyX Principles

- **Patient-Driven:** Ensure all product development is patient-driven
- **Urgent:** Create a sense of urgency
- **Achievable:** Ground in scientifically-driven technology development
- **Catalytic:** Reduce regulatory and financial risks to catalyze investment
- **Collaborative:** Foster multidisciplinary approaches
- **Additive:** Addresses known barriers to innovation
- **Sustainable:** Invest in a diverse portfolio to balance risk


Redesign
Dialysis

Redesign Dialysis: Solutions Sought

- Replacing kidney functions
- Improving patient quality of life
- Addressing engineering challenges
- Ancillary technologies
- Biomaterials development
- Biological and immunological modulation
- Biosensor development and safety monitoring

Phase One: Design Solutions

- Sought promising ideas *on paper*
- Awarded 15 teams $75,000 in April 2019

"…we got 165 submissions, including a number of proposals that could help advance an artificial kidney…we're thrilled with this level of interest, and it shows what a prize competition can drive."

– HHS Secretary Alex M. Azar II

March 4, 2019


Announcement of
Redesign Dialysis – Phase I
Prize Recipients
Ed Simcox, HHS
Mark Rosenberg, ASN
KidneyX Summit
US Institute of Peace
Washington, DC
April 28-30, 2019
KIDNEY
INNOVATION ACCELERATOR


INNOVATION ACCELERATOR
OpticLine
Utilizing Optical Interrogation Methods for Early Diagnosis of Peritonitis in Peritoneal Dialysis Patients
.Outset
Development of an Automated Multimodal Sensor to Improve Patient Outcomes in Hemodialysis
www.KidneyX.org


KIDNEY


KIDNEY
INNOVATION ACCELERATOR

Phase Two: Develop Solutions

- Seek prototype or component technology
- Up to 3 prizes of $500,000
- Submissions accepted Nov. 2019 – April 2020

Phase Three: Test Solutions in Human Trials

- Advancing American Kidney Health Initiative mandate
- Launch prize competition in 2020

REDESIGN DIALYSIS: October 2018 - Q2 2020

Wearable or implantable dialyzers, bio-artificial kidneys, xenotransplant technology, etc.

MEDICATIONS

Drugs specifically designed to treat and slow progression of kidney diseases, as well as encompass the needs of kidney transplant patients

DEVICES

Devices that support the management and treatment of kidney diseases that are not dialyzers (such as vascular access technologies, etc.)

DIAGNOSTICS

Point-of-care or at home testing kits, real time kidney monitoring, etc.

PATIENT-CENTERED TOOLS

Tools designed to identify and track disease, applications to empower patients to manage kidney diseases (e.g., apps)

Patient Innovator Prize: Announced July 10

- Seek hacks and creative solutions from patients themselves
- Call for new ideas to address patient needs
- Run August 1 – September 16, 2019

“KidneyX has given me hope. As I watch my husband's quality of life decline, I want to do more and proceed in a positive direction.

We devote about 32 hours/week to home hemodialysis. It is like having a full-time job again. We are searching for newer and better ways to treat my husband's kidney failure before he succumbs to it.

Please keep us informed about KidneyX.”

–Wife of dialysis patient

KIDNEY X

INNOVATION ACCELERATOR

Public-private Partnerships

Partnering with the Food and Drug Administration

Kevin Go, Center for Devices and Radiological Health Innovation and Payor Communication Task Force, U.S. Food and Drug Administration

MedHealth

U.S. FOOD & DRUG ADMINISTRATION

FDA as a Driver of Medical Device Innovation

MedHealth Start-Up Day

Kevin Go
CDRH Innovation
July 15, 2019

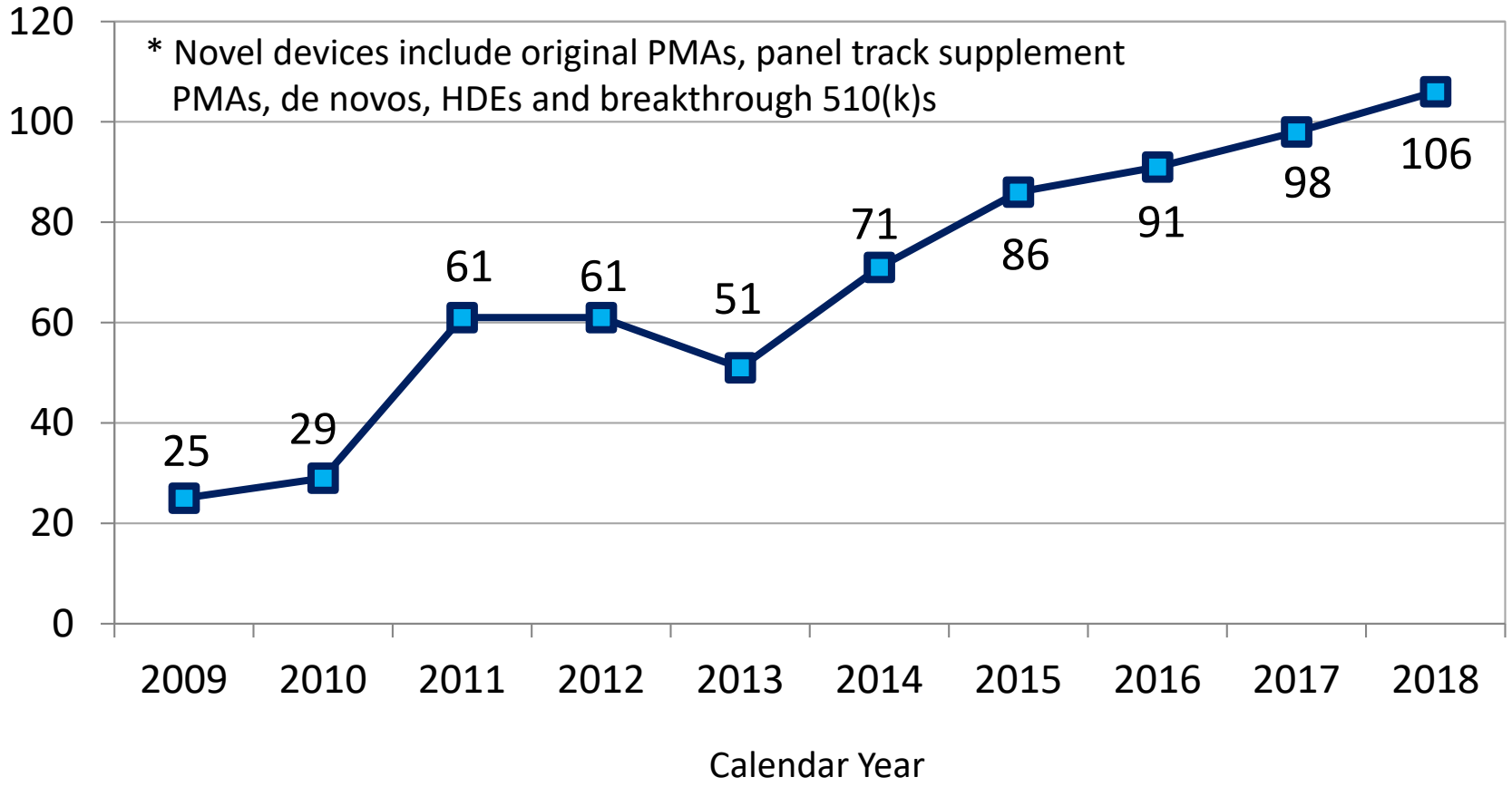
Patients are at the Heart of What We Do

CDRH Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

Novel Device Approvals

>4-fold Increase in # of Novel Device Approvals



Early Feasibility Studies

- Voluntary, informal program that allows devices in the early stages of development to be evaluated in a small human clinical study in the US
- Intended to support the initiation of these trials in the US, providing access to US patients and physicians
- Pre-Submission interactions encouraged
- No formal request or designation process
- Additional **flexibility** and tools (e.g., Device Evaluation Strategy) support FDA's review
- Program support and division representatives

[Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies]

Early Feasibility Studies: Perceptual Shifts in Ease of Conduct

	2014	2015	2016	2018
1	Australia	Australia	Australia	Australia
2	New Zealand	New Zealand	New Zealand	United States
3	Central America	Canada	Canada	Central America
4	Germany	Netherlands	Netherlands	New Zealand
5	Denmark	Germany	Denmark	Canada
6	Netherlands	United States	United States	Germany
7	Canada	Central America	Central America	Brazil
8	Brazil	Denmark	Germany	Netherlands
9	United Kingdom	United Kingdom	Brazil	France
10	United States	Brazil	United Kingdom	United Kingdom

*Data provided by Aaron Kaplan/Dartmouth Device Development (3D) Symposium Annual Survey of 3D Participants

Breakthrough Devices Pathway
(Formerly Expedited Access Pathway)

142 devices accepted into the program since April 2015

1st breakthrough device approved December 2017

11 breakthrough devices granted marketing authorization

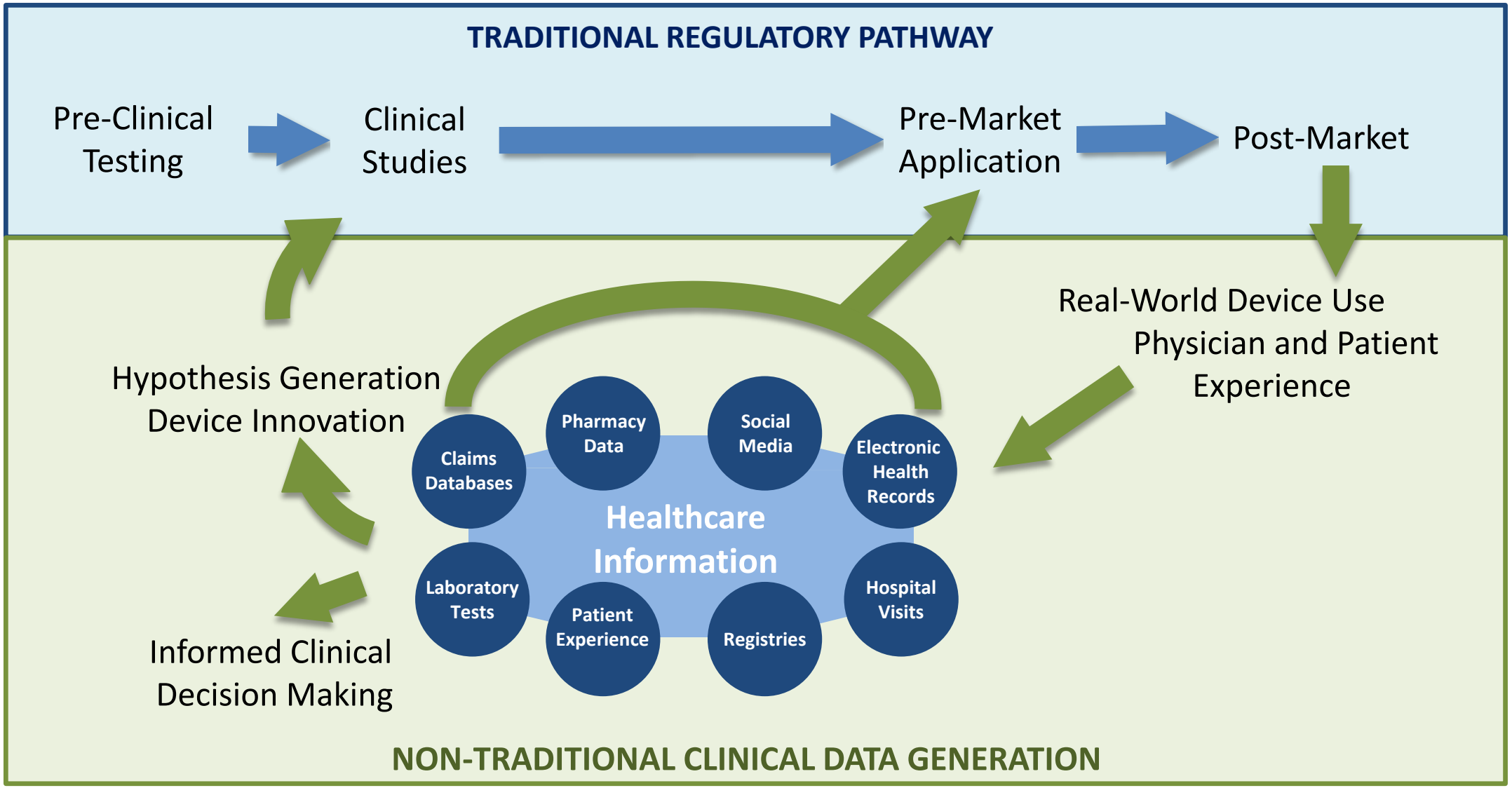
Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

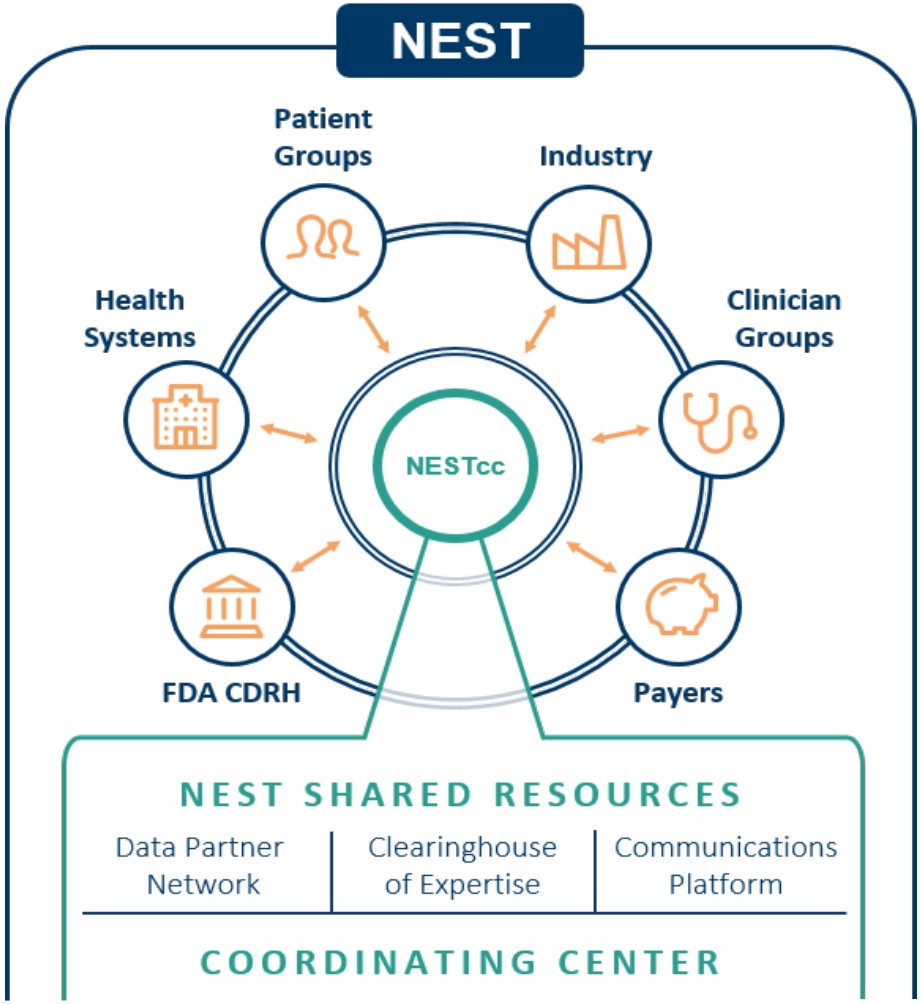
Document issued on December 18, 2018.

- Interactive & Timely Communication
- Pre-Postmarket Balance
- Flexible Clinical Study Design
- Senior Management Engagement
- Priority Review

Evidence in Regulatory Decisions



National Evaluation System for Health Technology

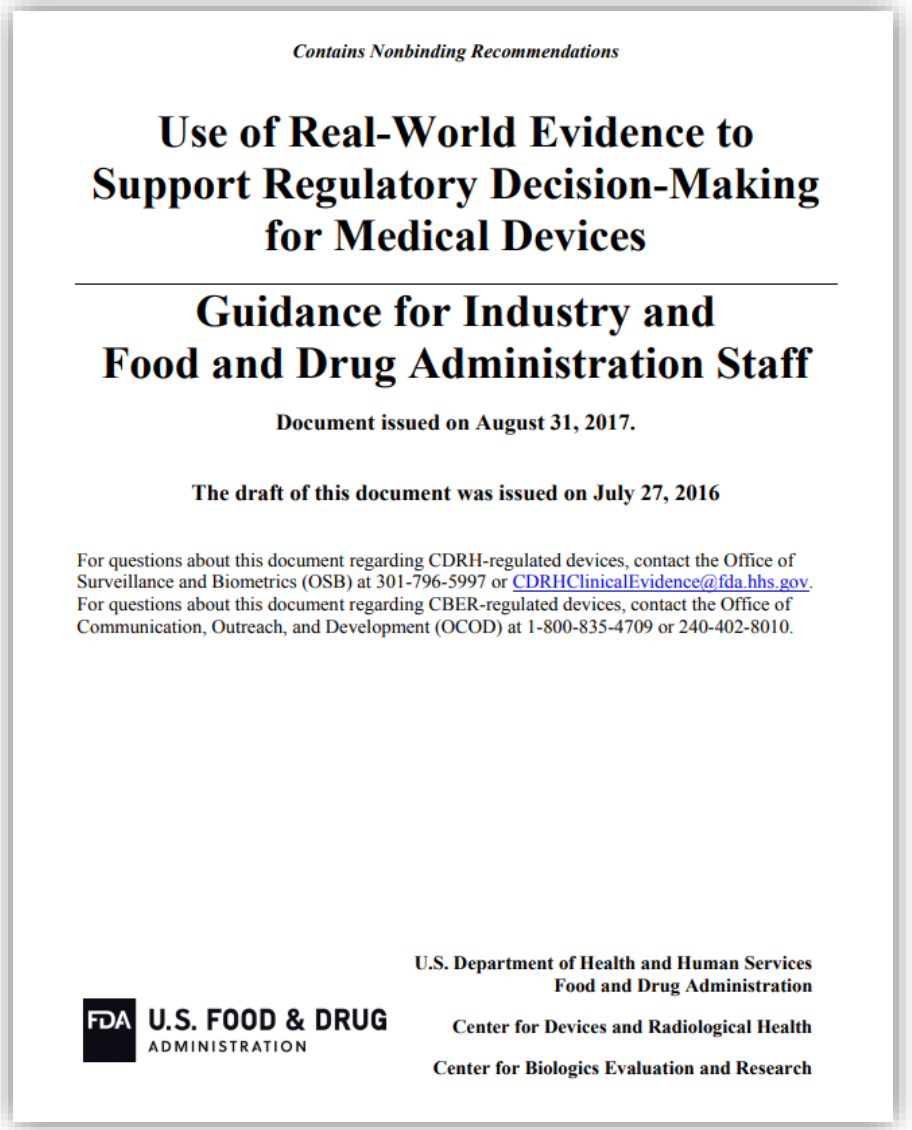


NEST
National Evaluation System for health Technology
Coordinating Center

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Clinical Trial Design Innovation:
Real-World Evidence

August 31, 2017



Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Surveillance and Biometrics (OSB) at 301-796-5997 or CDRHClinicalEvidence@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

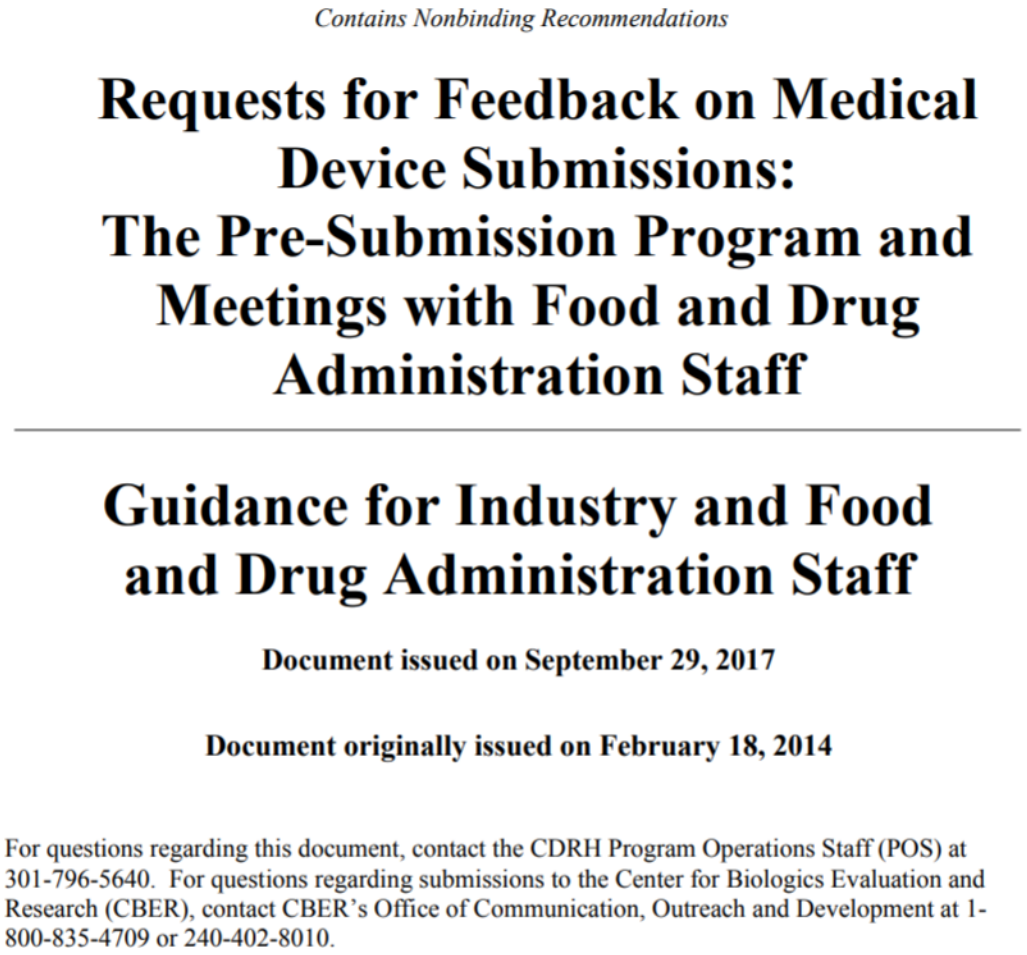
U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Communicating with FDA



Contains Nonbinding Recommendations

Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff

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Guidance for Industry and Food and Drug Administration Staff

Document issued on September 29, 2017

Document originally issued on February 18, 2014

For questions regarding this document, contact the CDRH Program Operations Staff (POS) at 301-796-5640. For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-8010.

- Covers informational meetings to explain device concepts to FDA
- To obtain guidance/advice prior to submitting a device application.
- Knowing as much as possible prior to a formal device submission benefits both FDA and the sponsor

FDA Approval ≠ Patient Access

New Program with Payors Aims to Accelerate Patient Access to Medical Devices

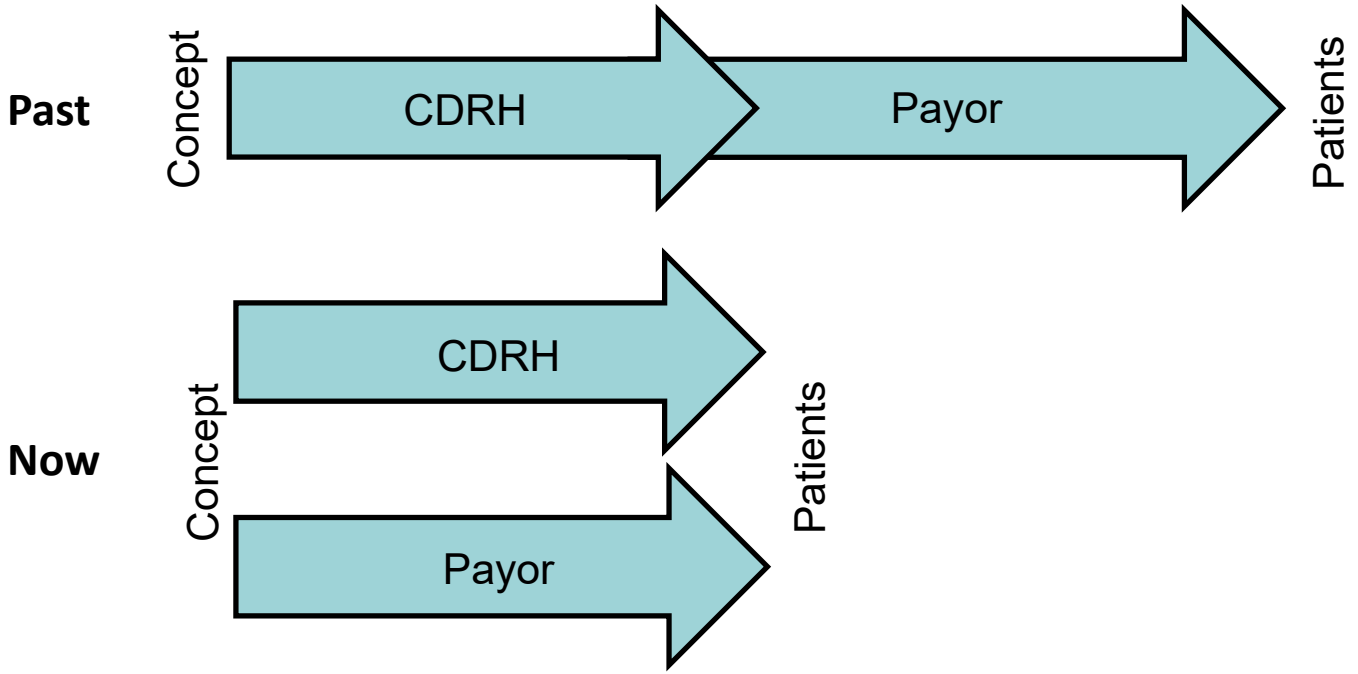
Posted on **September 5, 2018** by **FDA Voice**

By: Scott Gottlieb, M.D.

Advancing the public health means helping to make sure patients have access to safe, effective medical products. Access is a matter of public health. And our commitments to patients don't stop at the time of a product's approval. We take many steps to make sure products can be safely accessed in the post-market setting, and that new innovations continue to deliver their anticipated benefits. We actively monitor for safety findings in the post-approval period. We have updated labeling to provide modern guidance to providers and patients. And as part of our dedication to the promotion of public health, we also look for opportunities to help advance wider access to safe and effective innovations.

Patients may not have access to an FDA approved or cleared device in the absence of adequate coverage. So, the FDA recognizes the importance of working collaboratively with the payor community to streamline the path from FDA market authorization to payor coverage and reimbursement.

Over the past few years, we've sought creative solutions to decreasing the gap between the FDA's decision to advance a product to the market and the time it takes both public (e.g., Medicare, Medicaid) and private payors to determine whether and how they will provide coverage.



Payor Programs

- **Private or Public Payor Pre-Submission Participation**: manufacturers may request payer input (public or private payer/HTA) on clinical trial design and other considerations. For questions email: CDRHPayerCommunications@fda.hhs.gov

- **Parallel Review**: a mechanism for FDA and the Centers for Medicare & Medicaid Services (CMS) to simultaneously review the submitted clinical data. For questions email: parallel-review@fda.hhs.gov

See our website for more details: https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhinnovation/ucm456149.htm

U.S. FOOD & DRUG
ADMINISTRATION
& Devices

Thank You

Public-private Partnerships

Partnering with the Centers for Disease Control and Prevention

Paula Braun, Entrepreneur in Residence, Centers for Disease Control and Prevention

MedHealth

Public Health for Startups

Paula Braun
Entrepreneur-in-Residence
Centers for Disease Control and Prevention

July 2019


CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION
DEPARTMENT OF HEALTH & HUMAN SERVICES · USA


NHS
Policy
Health Inequalities
Social Determinants
Housing
Statistics
Wellbeing
Ageing
Notify
Infectious Disease
Big Data
Environmental Hazards
Toxins
Mental Health
Public Health
Employment
Occupational Health and Safety
Smoking
Family
Pollution
Demography
Equality
Addiction
Cardiovascular Disease
Leadership
Risk
Vital Statistics
Injuries
Oral Health
Reproduction
Education
Healthy Cities
Education
Obesity
Epidemiology
Influenza
Global Health
Alcohol
Social Policy
Chronic Disease
Food Safety
Healthcare
Environmental
Monitor
Prevention
Economics


Smaller Impact
Counseling and Education
Examples: Eat Healthy and Exercise
Clinical Interventions
Examples: Medicine for High Blood Pressure, Diabetes
Long-lasting, Protective Interventions
Examples: Vaccines, Smoking Cessation, Colonoscopy
Changing the Context to Make Individuals'Default Decision Healthy
Examples: Flouridation, Smoke-Free Laws, Tobacco Tax
Socioeconomic Factors
Examples: Poverty, Education, Housing, Inequality
Larger Impact

A SET OF DATA CLASSES TO SUPPORT NATIONWIDE INTEROPERABILITY

The USCDI Version 1 (USCDI v1) is proposed as a standard (§ 170.213). It reflects the same data classes referenced by the CCDS definition and includes new required data classes and data elements, noted below.

If adopted, health IT developers will need to update their certified health IT to support the USCDI for all certification criteria affected by this change.

USCDI v1

Assessment and Plan of Treatment

Care Team Members

Clinical Notes *NEW
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns

Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications
- Medication Allergies

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (including middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Address *NEW
- Phone Number *NEW

Problems

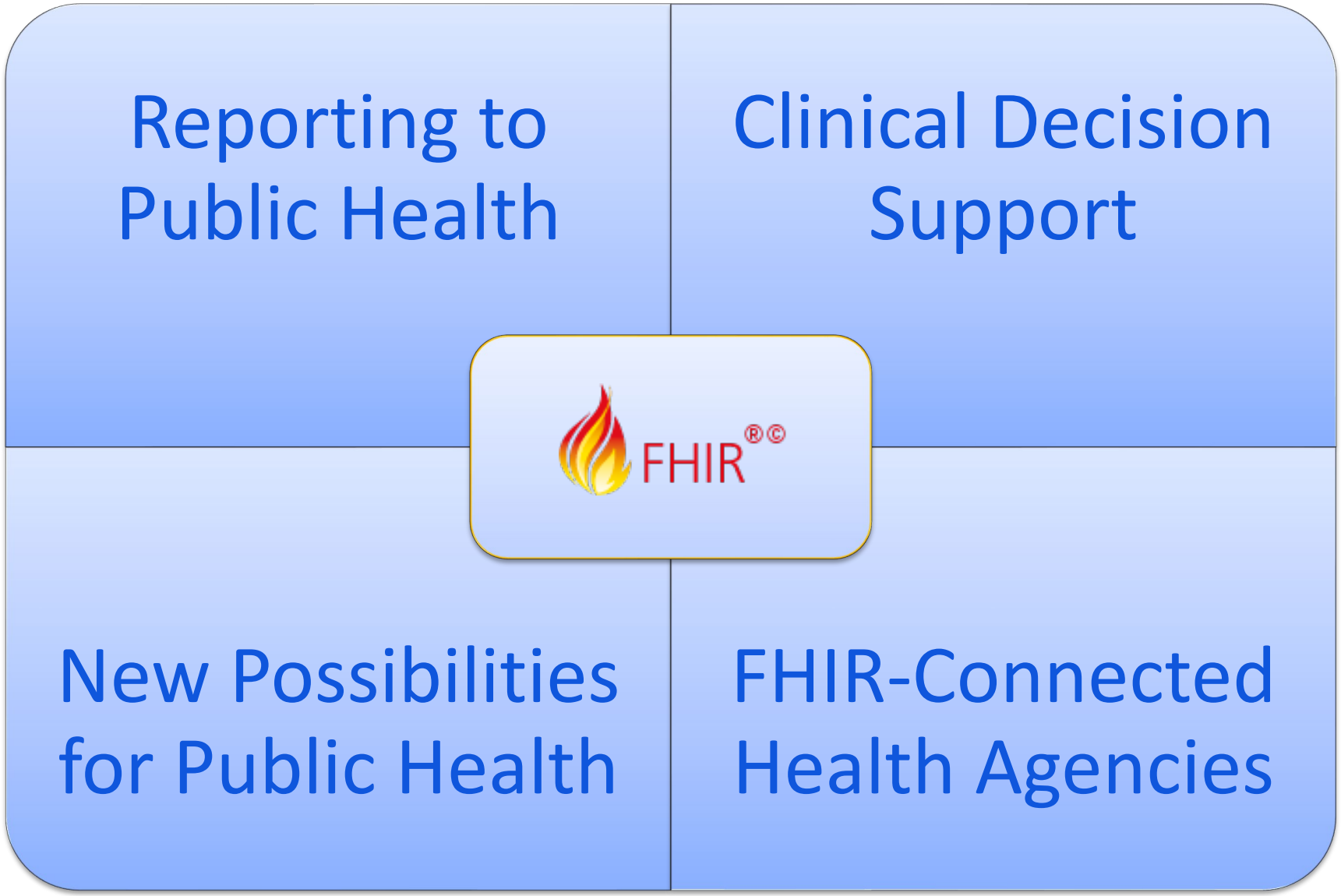
Procedures

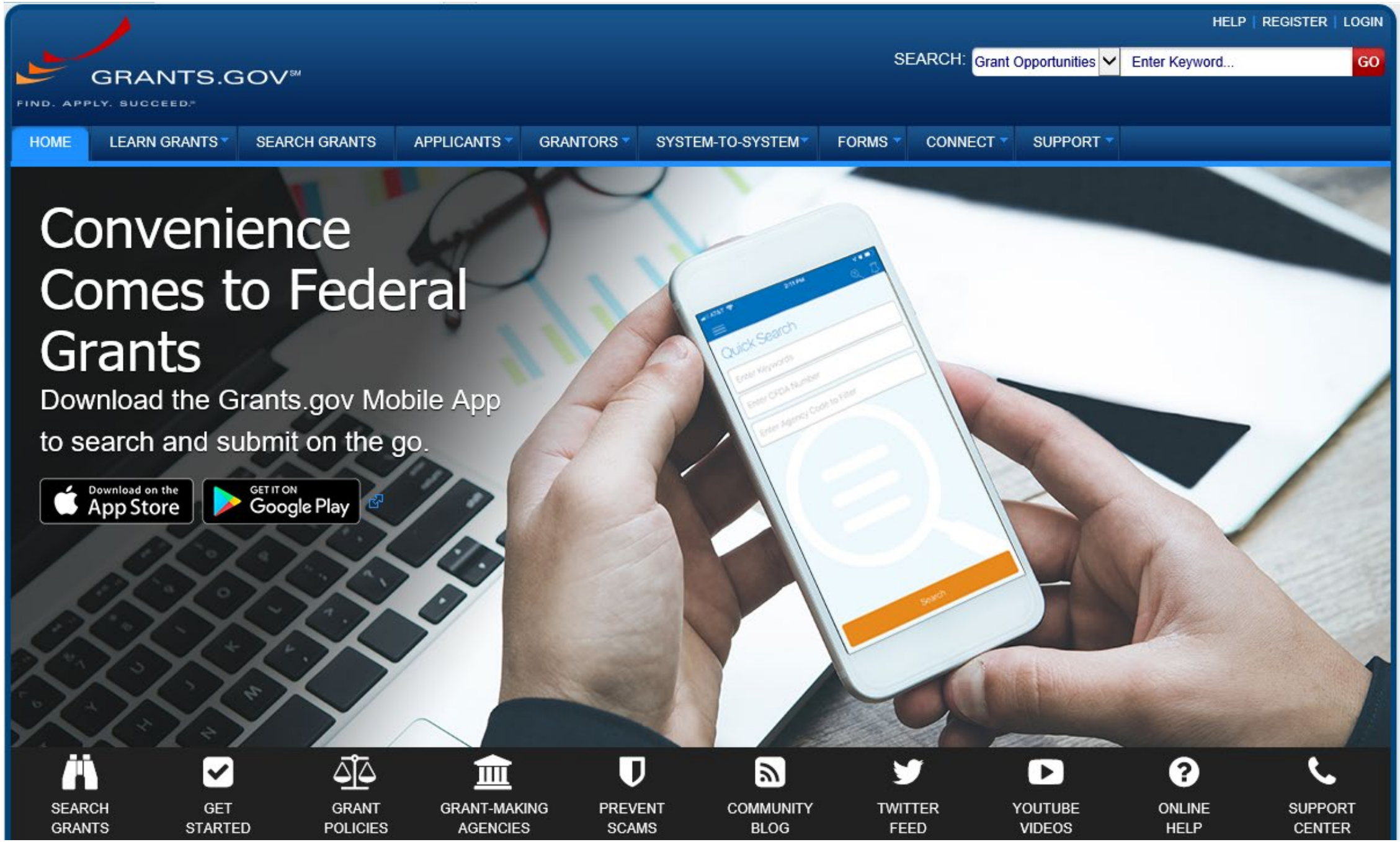
Provenance *NEW
- Author
- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory rate
- Body Temperature
- Pulse oximetry
- Inhaled oxygen concentration
- Pediatric Vital Signs *NEW
  - BMI percentile per age and sex for youth 2-20
  - Weight for age per length and sex
  - Occipital-frontal circumference for children < 3 years old


Reporting to Public Health
Clinical Decision Support
FHIR®©
New Possibilities for Public Health
FHIR-Connected Health Agencies


HELP | REGISTER | LOGIN
GRANTS.GOV
FIND. APPLY. SUCCEED.
SEARCH: Grant Opportunities Enter Keyword... GO
HOME
LEARN GRANTS
SEARCH GRANTS
APPLICANTS
GRANTORS
SYSTEM-TO-SYSTEM
FORMS
CONNECT
SUPPORT
Convenience Comes to Federal Grants
Download the Grants.gov Mobile App to search and submit on the go.
Download on the App Store
GET IT ON Google Play
SEARCH GRANTS
GET STARTED
GRANT POLICIES
GRANT-MAKING AGENCIES
PREVENT SCAMS
COMMUNITY BLOG
TWITTER FEED
YOUTUBE VIDEOS
ONLINE HELP
SUPPORT CENTER

Questions?

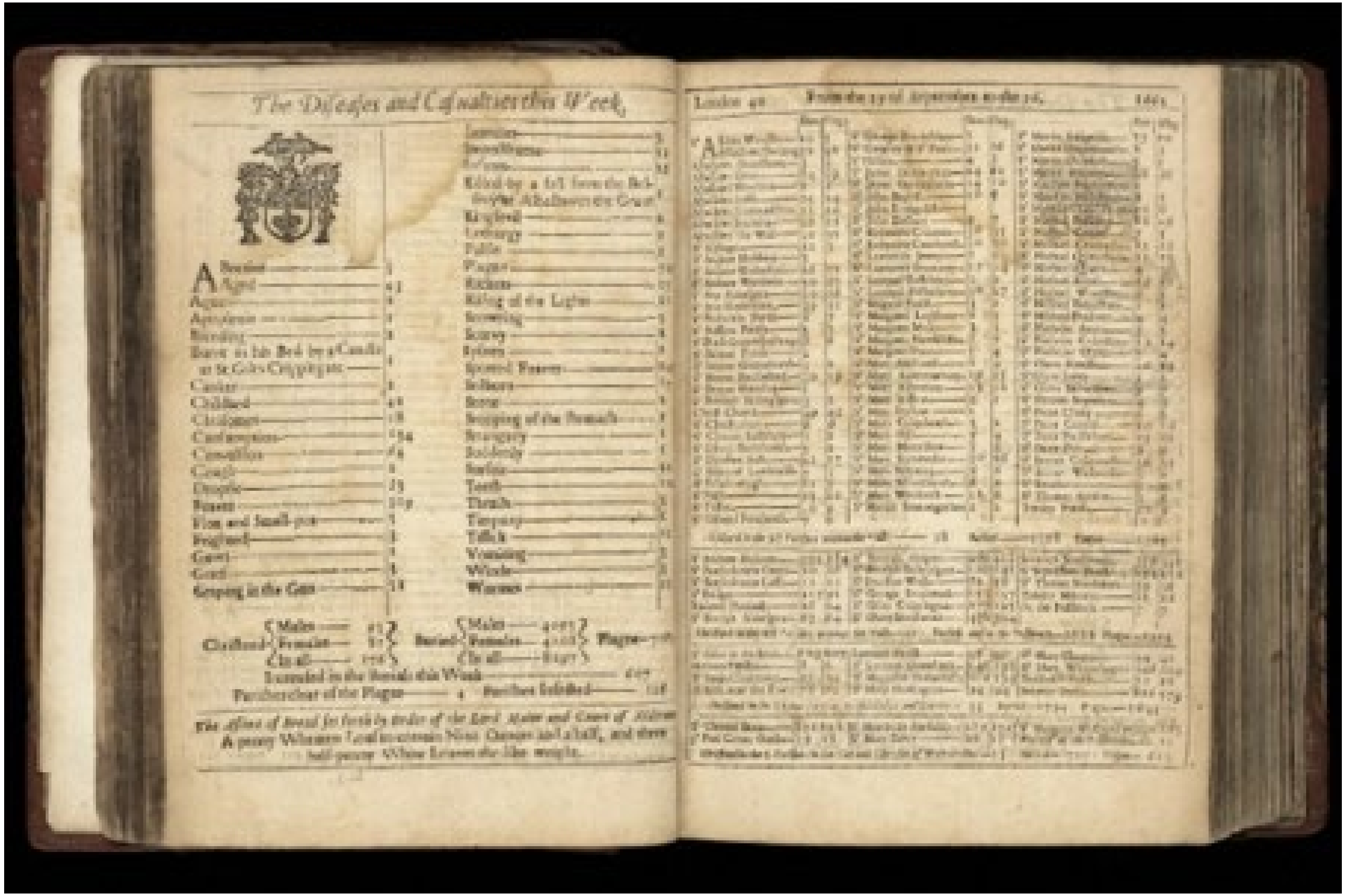
Paula Braun

Phone: 404-498-6809

pabraun@cdc.gov

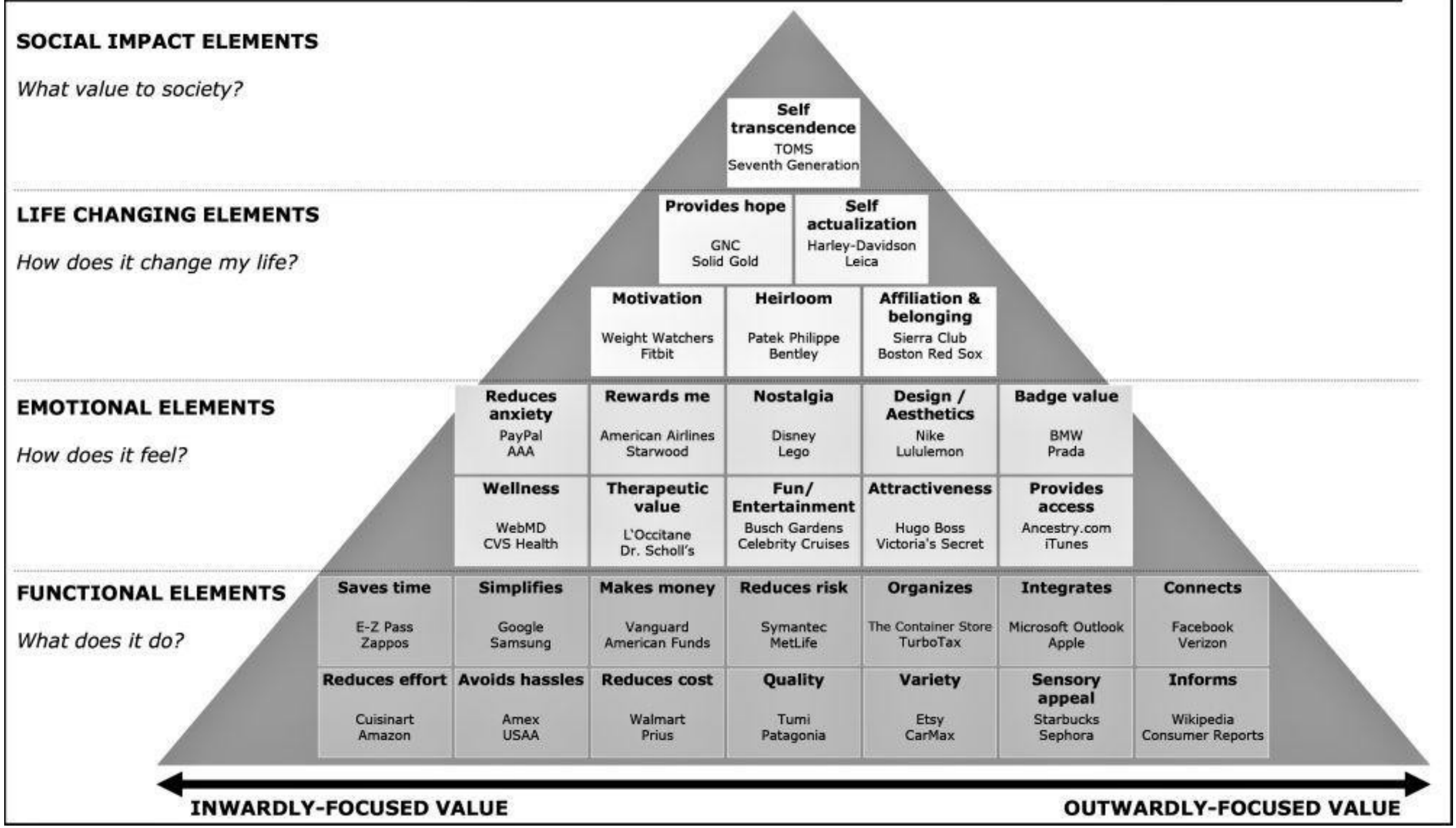
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.


The Diseases and Casualties this Week.
Aged
Ague
Childbed
Consumption
Dropsie
Feaver
Plague
Rickets
Rising of the Lights
Spotted Feaver
Teeth
Worms

Potential to Transform Public Health Surveillance

FHIR®©


SOCIAL IMPACT ELEMENTS
What value to society?
Self transcendence
TOMS
Seventh Generation
LIFE CHANGING ELEMENTS
How does it change my life?
Provides hope
GNC
Solid Gold
Self actualization
Harley-Davidson
Leica
Motivation
Weight Watchers
Fitbit
Heirloom
Patek Philippe
Bentley
Affiliation & belonging
Sierra Club
Boston Red Sox
EMOTIONAL ELEMENTS
How does it feel?
Reduces anxiety
PayPal
AAA
Rewards me
American Airlines
Starwood
Nostalgia
Disney
Lego
Design / Aesthetics
Nike
Lululemon
Badge value
BMW
Prada
Wellness
WebMD
CVS Health
Therapeutic value
L'Occitane
Dr. Scholl's
Fun/ Entertainment
Busch Gardens
Celebrity Cruises
Attractiveness
Hugo Boss
Victoria's Secret
Provides access
Ancestry.com
iTunes
FUNCTIONAL ELEMENTS
What does it do?
Saves time
E-Z Pass
Zappos
Simplifies
Google
Samsung
Makes money
Vanguard
American Funds
Reduces risk
Symantec
MetLife
Organizes
The Container Store
TurboTax
Integrates
Microsoft Outlook
Apple
Connects
Facebook
Verizon
Reduces effort
Cuisinart
Amazon
Avoids hassles
Amex
USAA
Reduces cost
Walmart
Prius
Quality
Tumi
Patagonia
Variety
Etsy
CarMax
Sensory appeal
Starbucks
Sephora
Informs
Wikipedia
Consumer Reports
INWARDLY-FOCUSED VALUE
OUTWARDLY-FOCUSED VALUE

FHIR Projects in Public Health: Collaboration with GT

https://cs6440.gatech.edu/

Public-private Partnerships

Partnering with the Office of the National Coordinator for Health Information Technology

Stephen Konya, Senior Innovation Strategist, Office of the National Coordinator for Health Information Technology

MedHealth

The Office of the National Coordinator for Health Information Technology

Partnering to Support National Health IT Innovation

MedHealth Startup Day w/ HHS
July 15th, 2019

Stephen Konya, Senior Innovation Strategist, HHS-ONC

ONC's Mission

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration's health IT efforts and is a resource to the entire health system

"...to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care."

ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS).

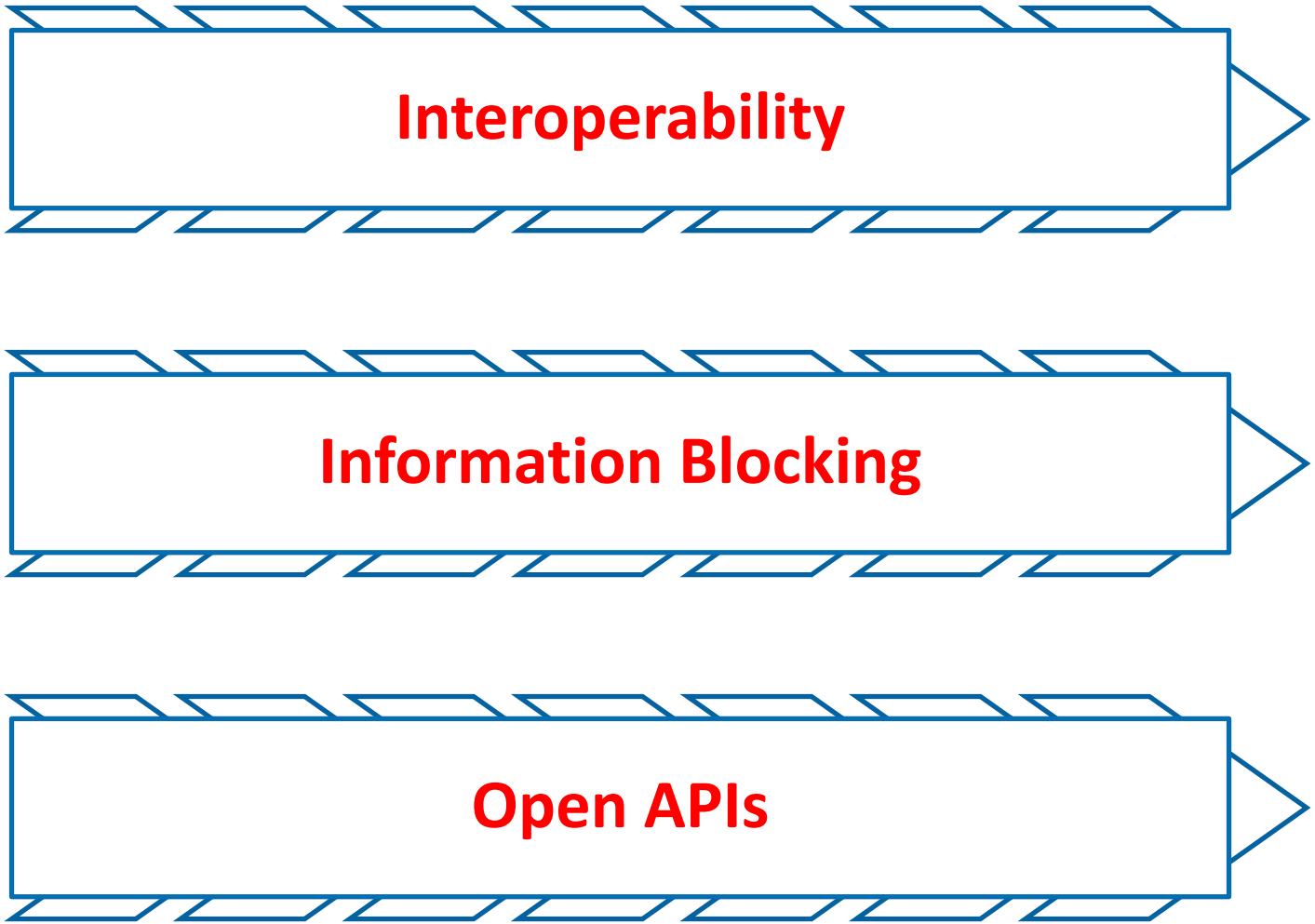
ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.

HITECH Act (3001(b)(10))

Among many duties, the National Coordinator is tasked with promoting:

- *"…a more effective marketplace*
- *greater competition*
- *greater systems analysis*
- *increased consumer choice, and*
- *improved outcomes in health care services"*

21st Century Cures Act



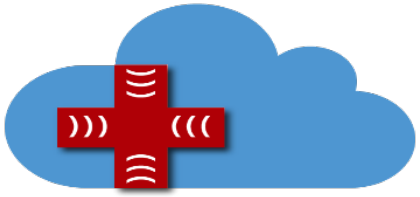
How does ONC support innovation?

#1: Direct ($)	#2: Indirect
Challenge competitions	Toolkits / guides / technical resources
Cooperative agreements and grants	Role as a “National Coordinator”

Innovation
ONC TECH LAB

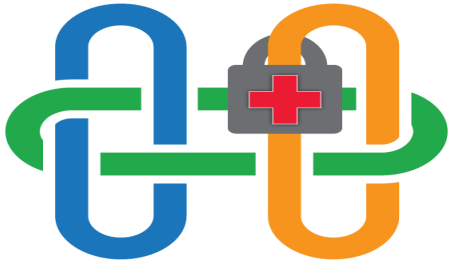
National App & Idea Challenges

Consumer Health Data Aggregator Challenge

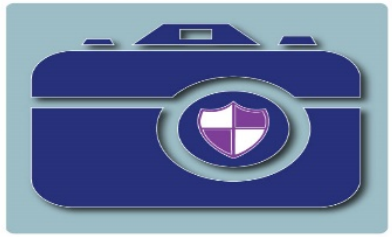


Provider User Experience Challenge

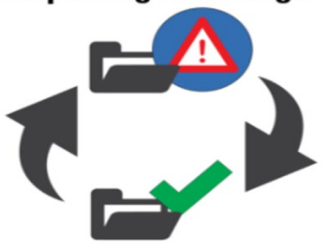
Blockchain Challenge



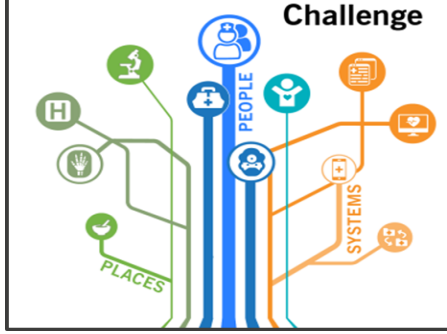
Privacy Policy Snapshot Challenge



Easy EHR Issue Reporting Challenge



"Oh, the Places Data Goes: Health Data Provenance" Challenge



Secure API Server Showdown Challenge

Patient Matching Algorithm Challenge

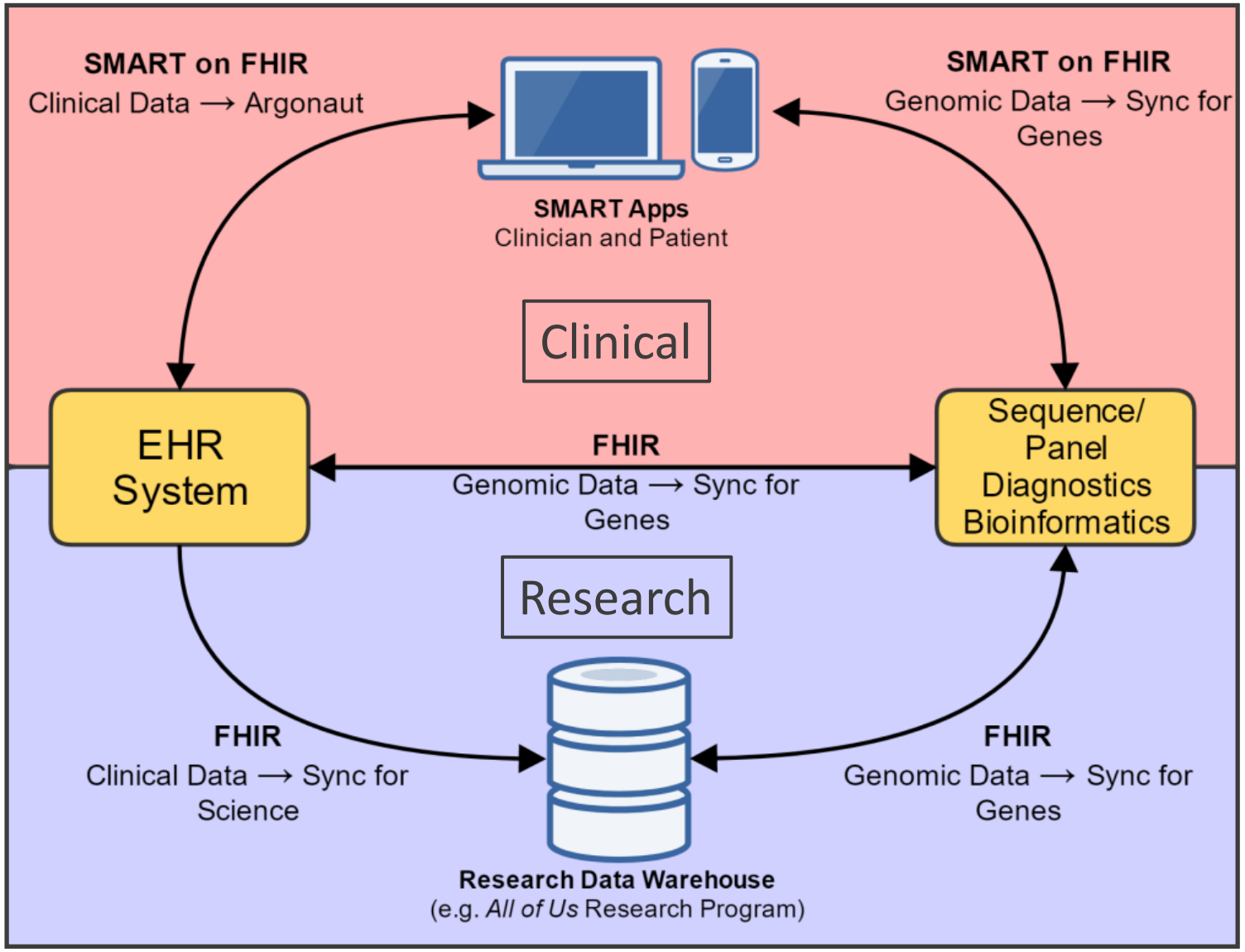
MHDFC
MOVE HEALTH DATA FORWARD CHALLENGE

Precision Medicine and Genomics

Sync 4 Science / Sync 4 Genes

- **ENABLING CLINICAL GENOMICS FOR PRECISION MEDICINE**
- **VIA HL7® FAST HEALTHCARE INTEROPERABILITY RESOURCES®**

*Click here for the Sync for Genes Final Report! (Nov2017)

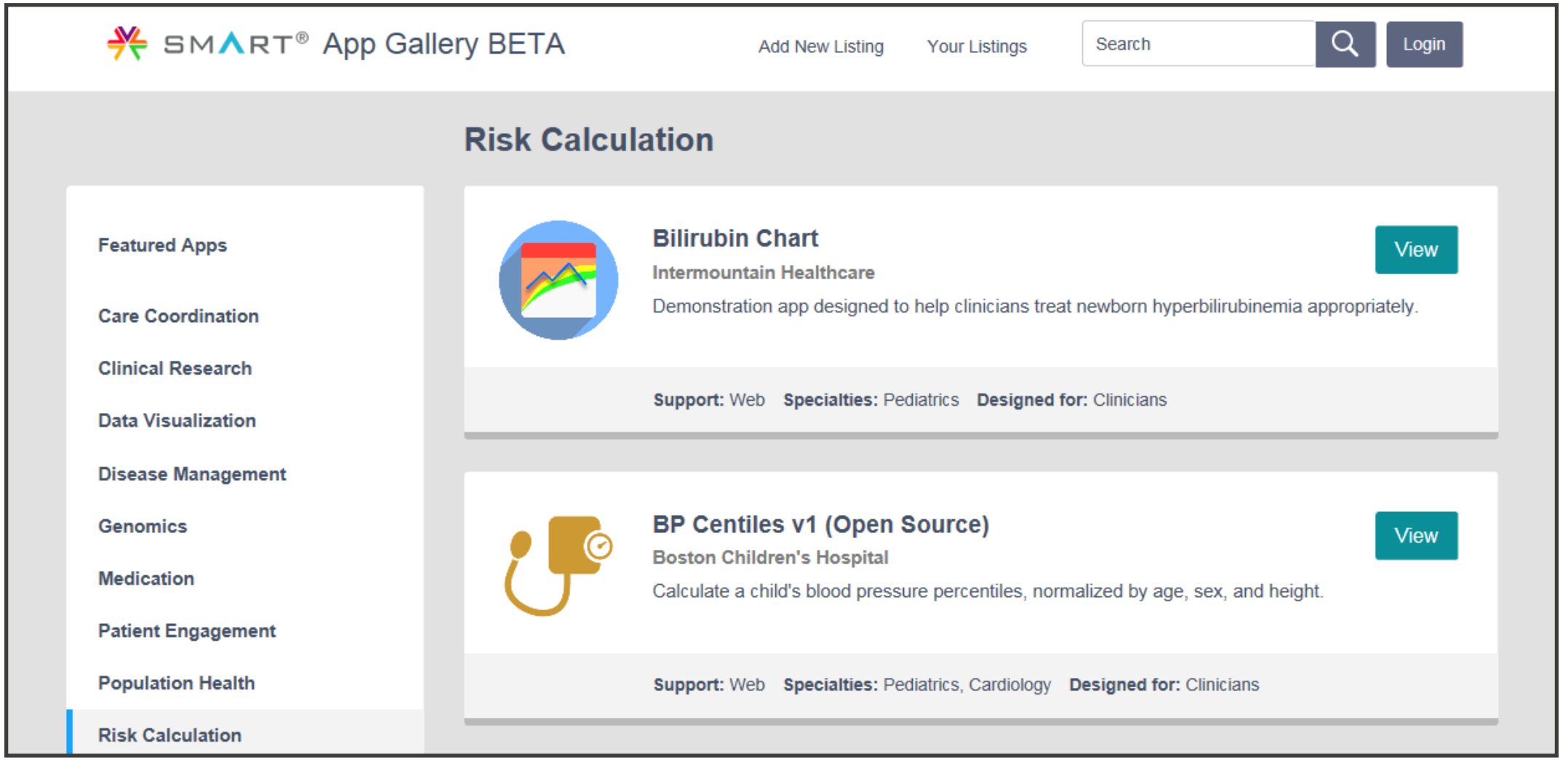


Artificial Intelligence (Ai) for Health

- 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

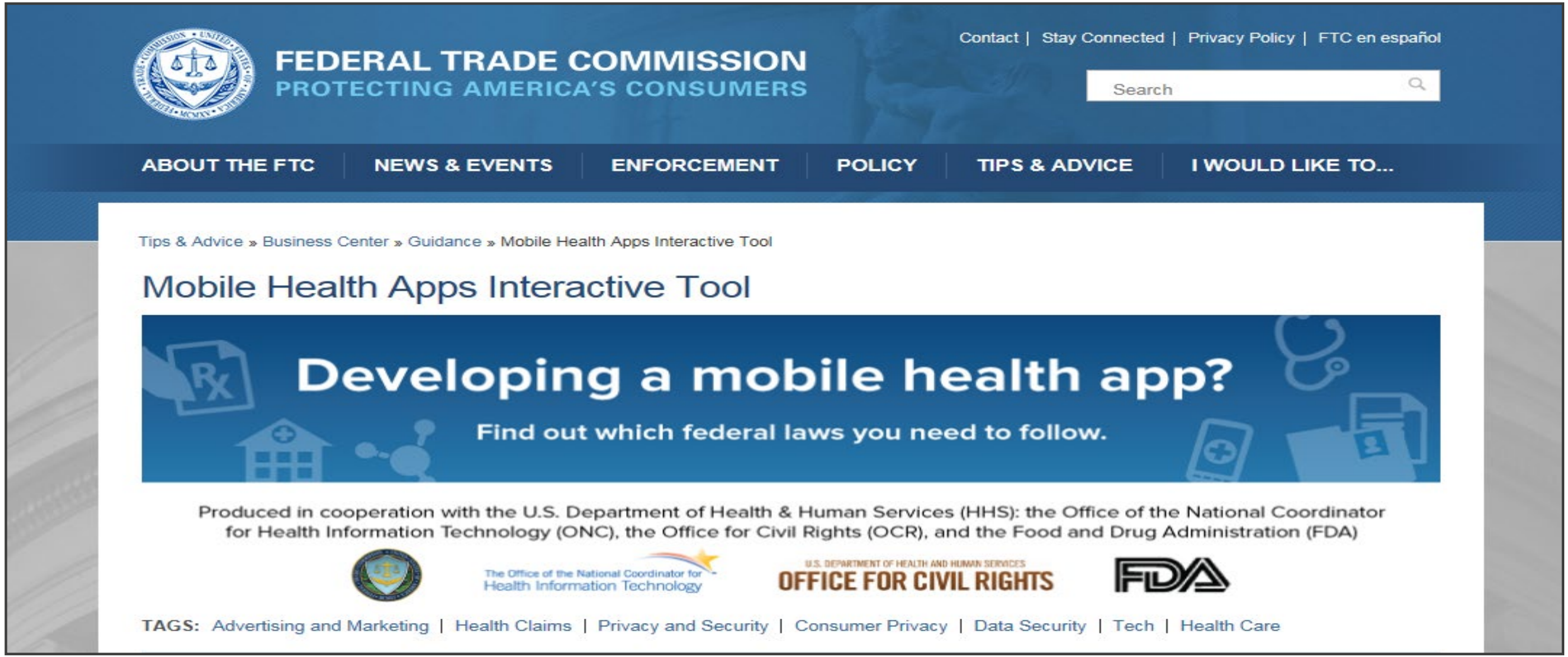
Blog Post: https://healthit.gov/buzz-blog/jason
Full Report: https://healthit.gov/jason

SMART App Gallery and Data Sandbox



https://apps.smarthealthit.org

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

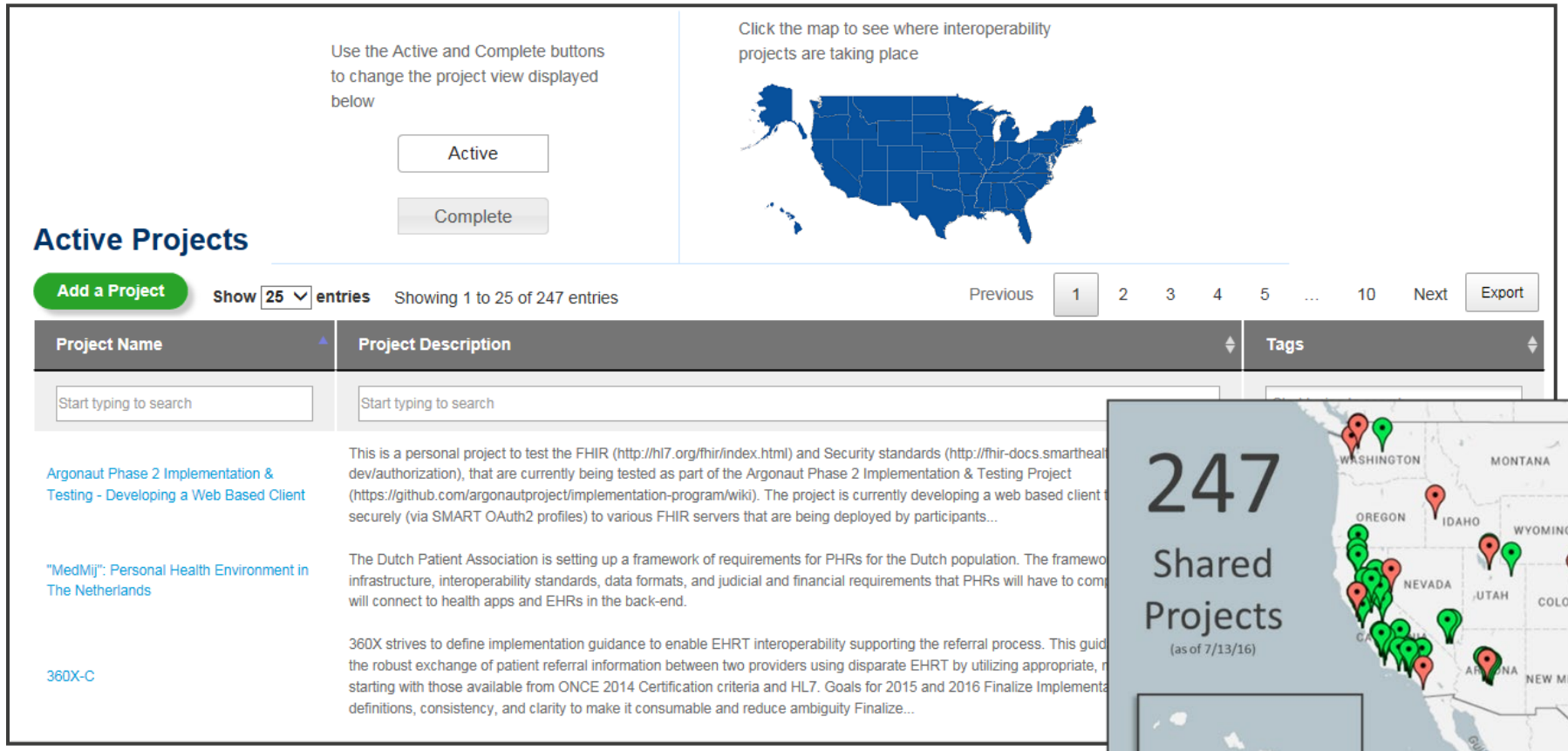
3. Do consumers need a prescription to access your app?

- 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 Policies

Interoperability Proving Ground (IPG)



…share, learn, and be inspired!

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.

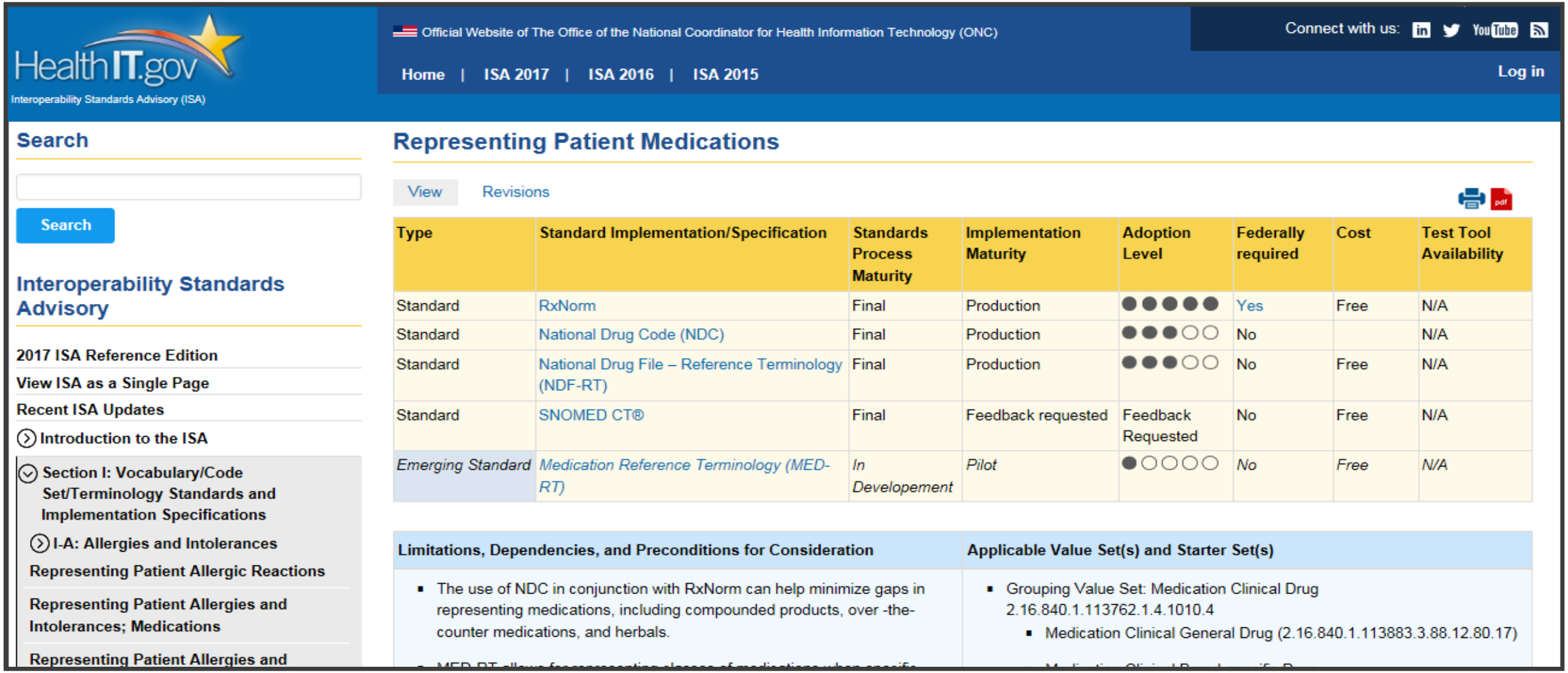
SOAP TRANSPORT SANDBOX

This sandbox contains resources and tools related to SOAP Transport.

New "INFERNO" FHIR Testing Suite

- Open source tool (via GitHub)
- Tests conformance to SMART on FHIR requirements for;
  - app registration
  - app launch
  - authentication
- Tests conformance to the Argonaut Data Query Implementation Guide
- Inferno Quick Start Guide available on GitHub

Interoperability Standards Advisory (ISA)



HealthIT.gov
Interoperability Standards Advisory (ISA)

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

Connect with us:

Home | ISA 2017 | ISA 2016 | ISA 2015

Log in

Search

Search

Interoperability Standards Advisory

2017 ISA Reference Edition
View ISA as a Single Page
Recent ISA Updates
Introduction to the ISA
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications
I-A: Allergies and Intolerances
Representing Patient Allergic Reactions
Representing Patient Allergies and Intolerances; Medications
Representing Patient Allergies and

Representing Patient Medications

View | Revisions

Type	Standard Implementation/Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●●	Yes	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●○○	No		N/A
Standard	National Drug File – Reference Terminology (NDF-RT)	Final	Production	●●●○○	No	Free	N/A
Standard	SNOMED CT®	Final	Feedback requested	Feedback Requested	No	Free	N/A
Emerging Standard	*Medication Reference Terminology (MED-RT)*	*In Developement*	*Pilot*	●○○○○	*No*	*Free*	*N/A*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ The use of NDC in conjunction with RxNorm can help minimize gaps in representing medications, including compounded products, over -the-counter medications, and herbals.	▪ Grouping Value Set: Medication Clinical Drug 2.16.840.1.113762.1.4.1010.4 ▪ Medication Clinical General Drug (2.16.840.1.113883.3.88.12.80.17)

21st Century Cures – Notice of Proposed Rule Making (NPRM)

- **ONC's Primary Landing Page:** www.HealthIT.gov/NPRM
- **Key ONC Presentations:**
  - » API Conditions of Certification (and more!) [PDF - 9.1 MB]
  - » 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (HIMSS Presentation) [PDF -1.9MB]

9 Fact Sheets Provided by ONC

Implementation of Cures Act and Executive Orders [PDF - 1.4 MB]	Application Programming Interface (API) Permitted Fees [PDF - 405 KB]	U.S. Core Data for Interoperability (USCDI) [PDF - 776 KB]
Conditions and Maintenance of Certification Requirements [PDF - 805 KB]	API Certification Criterion and Associated Condition of Certification [PDF - 1.1 MB]	Electronic Health Information Export for Patient and Provider Access [PDF - 1.6 MB]
Health IT for Pediatric Care and Practice Settings [PDF - 477 KB]	Standards Version Advancement Process [PDF - 442 KB]	Information Blocking – Summaries of the 7 Exceptions [PDF - 578 KB]

It Takes A Village…

Health IT Feedback Form

Do you wish to remain anonymous to ONC? *

- (•) No
- ( ) Yes

First Name

Last Name

Email Address *

Category of Feedback: *

Category descriptions are available here

- ( ) ONC Health IT Certification
- ( ) Information Blocking
- ( ) Interoperability
- ( ) Health IT Safety
- ( ) Usability
- ( ) Privacy and Security
- ( ) Data Breaches
- ( ) Medical Records Inquiries
- ( ) Certified Health IT Products List (CHPL)
- ( ) ONC Events, Media, and Web Inquiries
- ( ) Health IT Standards
- ( ) Public Health
- ( ) Trusted Exchange Framework
- ( ) Other

The Office of the National Coordinator for Health Information Technology

Let's connect!

Stephen.Konya@hhs.gov

@StephenKonya

@ONC_HealthIT @HHSONC HealthIT.gov

Pop-up Lunch

Connect with agency representatives over lunch at pop-up tables. Our program will resume at 1PM in this room.

MedHealth
STARTUP DAY
with the U.S. Department of Health and Human Services

Detroit-Windsor DNA

Moderator: Justin Robinson

Senior Vice President, Business Development, Detroit Regional Partnership

Irek Kusmierczyk

Director of Partnerships, WEtech Alliance

Dr. Anne Snowdon

Scientific Director and CEO, Supply Chain Advancement Network in Health

Virginia Wilkinson

Director of Business Intelligence, Detroit Economic Growth Corporation

Phillip Olla

CEO, Audacia Bioscience

MedHealth

Public-private Partnerships

Partnering with the National Institute of Health

Todd Merchak, Program Specialist, National Institute of Health Small Business Innovation Research

MedHealth

The National Institutes of Health

Todd Merchak
Program Manager, Small Business Programs
National Institute of Biomedical Imaging and Bioengineering
Todd.Merchak@nih.gov

Detroit Startup Day with HHS
July 15, 2019

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."

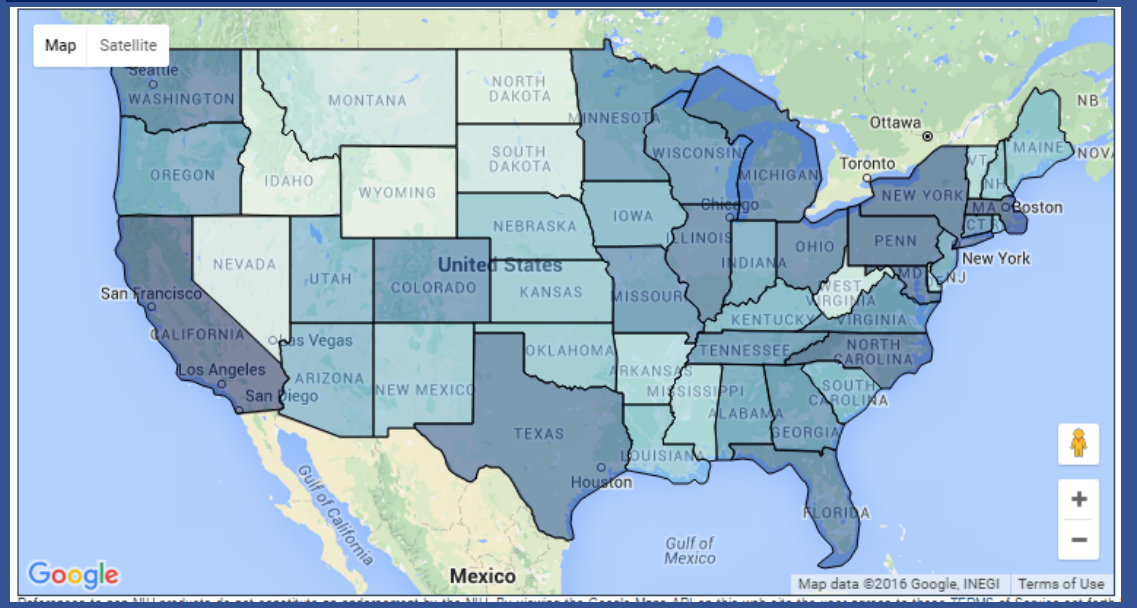
Understanding the Unique Nature of NIH

NIH *is* an institution

(Intramural Research)

- ~ 6,000 scientists

Fiscal Year 2017 Research Funding
across the United States



NIH *supports* institutions & people

(Extramural Research)

- >2,500 institutions
- >300,000 scientists & research personnel

What the NIH can offer to Biomedical Innovators

Expertise and Resources

- Product Development Support
- Clinical Trial Networks

NIH-developed technologies

- Over 1500 technologies and research tools available for licensing
- Special licensing terms for start-ups

Non-Dilutive Investment

- $1 Billon dollars in SBIR/STTR grants for U.S.-owned small businesses
- Technical Assistance

NIH SBIR/STTR: A Multi-Phased Program

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Commercialization
Phase

Phase I → ***Phase II***

Fast-Track

Direct-to-Phase II

Concept to Clinic: Commercializing Innovation (C3i)

Goal

Provide NIH grantees with essential business tools and specialized mentoring for successful translation of biomedical technologies from lab to market

Objectives

1) Validate an unmet market need
2) Validate a viable business opportunity
3) Build a compelling pitch to secure support from investors and partners

Outcomes

- ✓ 37 SBIR/STTR companies and 17 R01 teams have participated over the past 4 years
- ✓ $15M received in Phase II SBIR/STTR grants with success rate of 66%
- ✓ >$94M raised in private capital to date
- ✓ 2 products received FDA 510(k) clearance

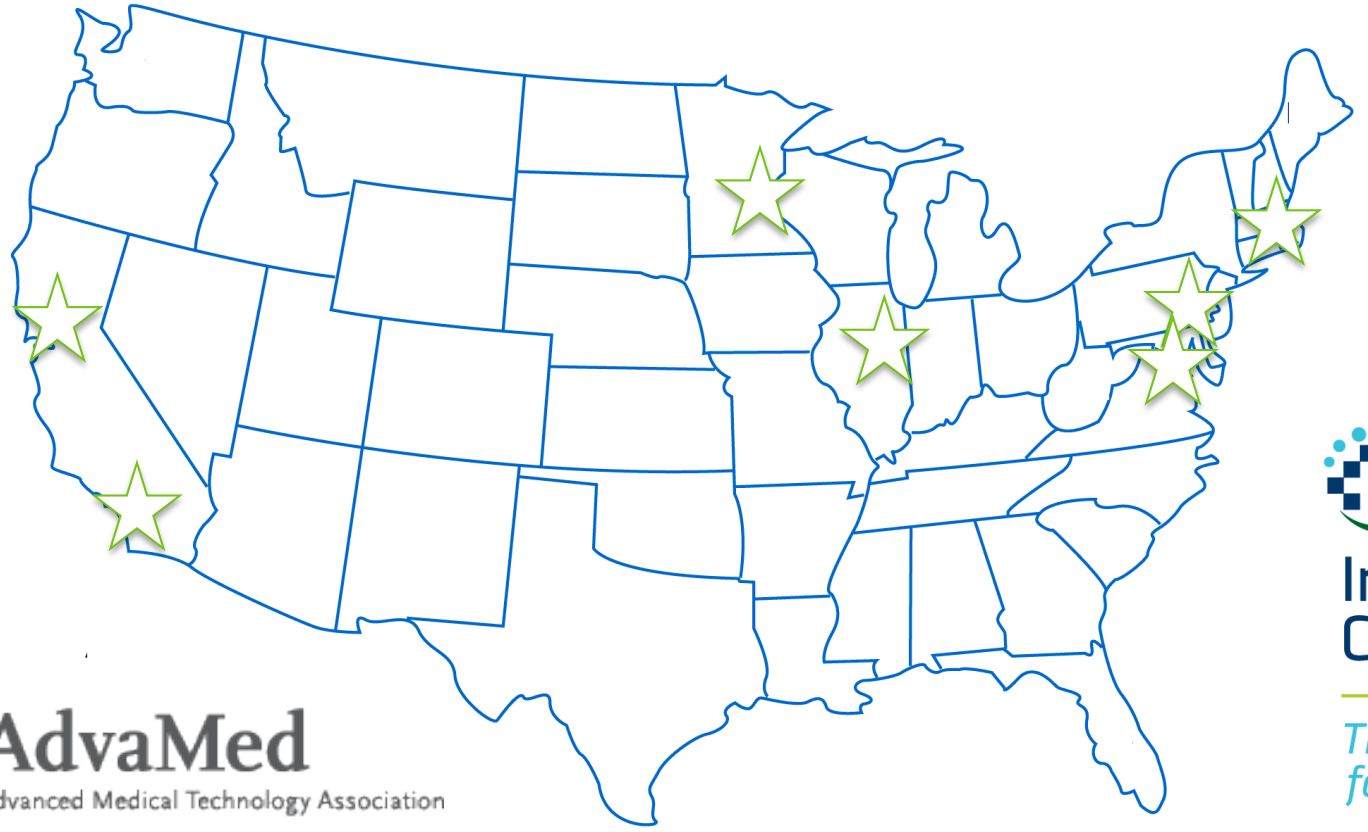
https://www.nibib.nih.gov/research-funding/c3i

Facilitating Partnerships

ACA
ANGEL CAPITAL ASSOCIATION

RESI
REDEFINING EARLY STAGE INVESTMENTS

LIFESCIENCES™ SUMMIT



MEDTECH INNOVATOR

AdvaMed
Advanced Medical Technology Association

BIO International Convention
The Global Event for Biotechnology

Research Funding

Scientific Program Areas

- Division of Applied Science & Technology +
- Division of Discovery Science & Technology (DDST) +
- Division of Health Informatics Technologies (DHIT) +
- Division of Interdisciplinary Training (DIDT)

Funding

- Funding Opportunities
- Grant Programs & Mechanisms
- Grants Process
- NIH-wide and Trans-NIH Initiatives
- Funding Policies
- Funding Notices

Related Links

- NIH Guide
- NIH Parent Announcements
- NIH Submission Dates
- NIH RePORTER
- Research Resources
- NIBIB and the American Recovery and Reinvestment Act of 2009 (ARRA)

Share:

Entrepreneurial Finance for Biomedical Innovators

Overview

The National Institutes of Health (NIH) supports the development and commercialization of biomedical technologies through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. With the goal of bringing life-saving innovations to market, NIH SBIR/STTR funding provides early-stage seed capital to US-owned small businesses. While the commercialization of biomedical technologies can require a significant amount of both time and money, rigorous financial planning can help navigate and mitigate risks for small businesses and can enhance chances of success along the pathway to market. For biomedical innovators considering funding through the NIH SBIR/STTR programs (https://sbir.nih.gov), it is imperative to evaluate the use of federal grant funding within the context of a broader financial plan.

Course Objectives

The purpose of this course is to present biomedical entrepreneurs with a detailed framework for building a step-wise, validated financial plan. Moving beyond the short-term perspective of immediate financing needs to a comprehensive, long-term financial plan will increase the probability of success for your venture. The primary learning objectives for this course are as follows:

- Understand the importance of financial planning for your small business
- Gain perspective on SBIR/STTR funding within the broader context of your financial plan
- Learn practical approaches to developing a long-term financial plan
- Evaluate the various sources of funding
- Examine the use of comparables in validating your financial plan

Course Materials

The course is presented in a series of five sequential videos. The video modules and course details can be found below.

+ **Module 1: Introduction to Financial Planning**
+ **Module 2: Assumptions and Personal Needs**
+ **Module 3: Building the Financial Plan**
+ **Module 4: Sources of Capital**
+ **Module 5: Exploring Comparables**

https://www.nibib.nih.gov/entrepreneurial-finance-course

HEAL Initiative: At a glance

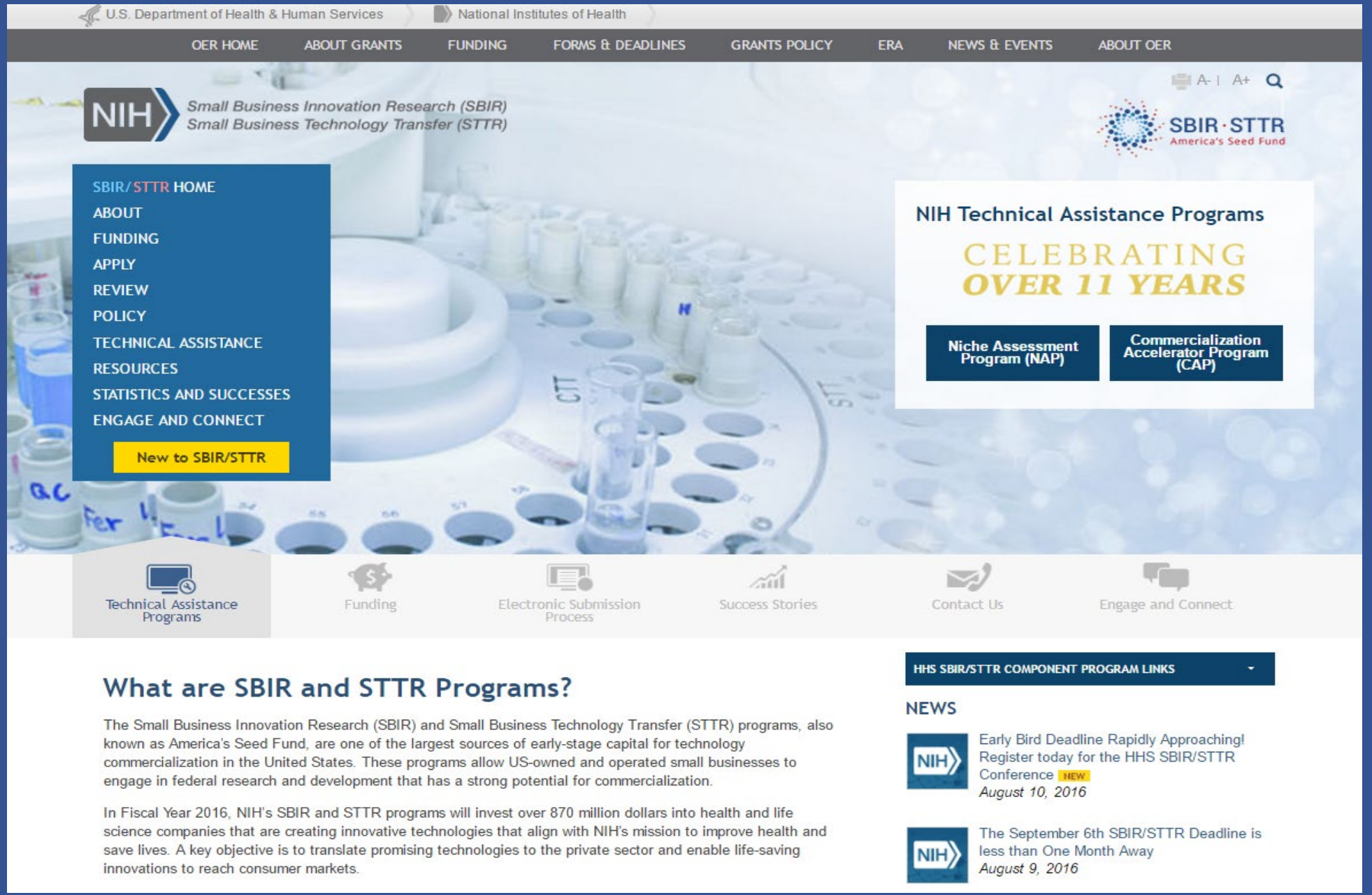
- **$500M/year Trans - NIH effort**
  - Over $850M to be obligated in FY2019
- **12 NIH Institute and Centers leading 26 HEAL research projects**
  - Over 20 collaborating Institutes, Centers and Offices
  - From prevention research, basic and translational research, clinical trials, to implementation science
  - Multiple projects integrating research into new settings
    - e.g. health care, criminal justice, Medicare populations etc.
- **Released 40+ funding announcements for FY2019**

Small Businesses and the HEAL Initiative: Enhancing Pain Management

SBIR · STTR
America's Seed Fund

NIH invites small businesses to submit research proposals on Enhancing Pain Management

- **HEAL includes set-aside funds for Small Business (SBIR/STTR) programs**
- **SBIR and STTR Omnibus/Parent Grant Solicitations**
  - **NOT-NS-19-014:** HEAL Initiative: Notice of Interest in Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Applications Directed at Enhanced Pain Management and Improved Treatments for Opioid Misuse and Addiction
- **HEAL Enhancing Pain Management RFAs**
  - **RFA-NS-19-020:** HEAL Initiative: Optimization of Non-addictive Therapies [Small Molecules and Biologics] to Treat Pain - (U44 Clinical Trial Not Allowed)
  - **RFA-NS-19-017:** HEAL Initiative: Translational Devices to Treat Pain (U44 Clinical Trial Optional)



http://sbir.nih.gov

Email:

sbir@od.nih.gov

@NIHsbir

Public-private Partnerships

Partnering with the International Trade Association

Murat Muftari, Senior International Trade Specialist, Department of Commerce, International Trade Administration

MedHealth

Our Mission

U.S. COMMERCIAL SERVICE

United States of America
Department of Commerce

Grow U.S. exports to **increase** U.S. jobs.


We have global **relationships** and **expertise** in **every** major industry **sector**.

Leverage the strength of the U.S. government

- Market access problems
- Unfair contract competition
- Meetings with the right partners
- Getting paid

Country Commercial Guides
Your Starting Point for Global Success

TopMarkets
A Market Assessment Tool for U.S. Exporters

DEC
EAST MICHIGAN
DISTRICT EXPORT COUNCIL
Working for America's Exporters

EXPORTING BASICS
Episode 09: Sales Channels

Market Diversification Tool

You can also access self-help resources on www.export.gov


Your **local** trade specialist can **counsel** you and
connect you to resources across the **globe**.

Supporting your export **growth** every step of the way.

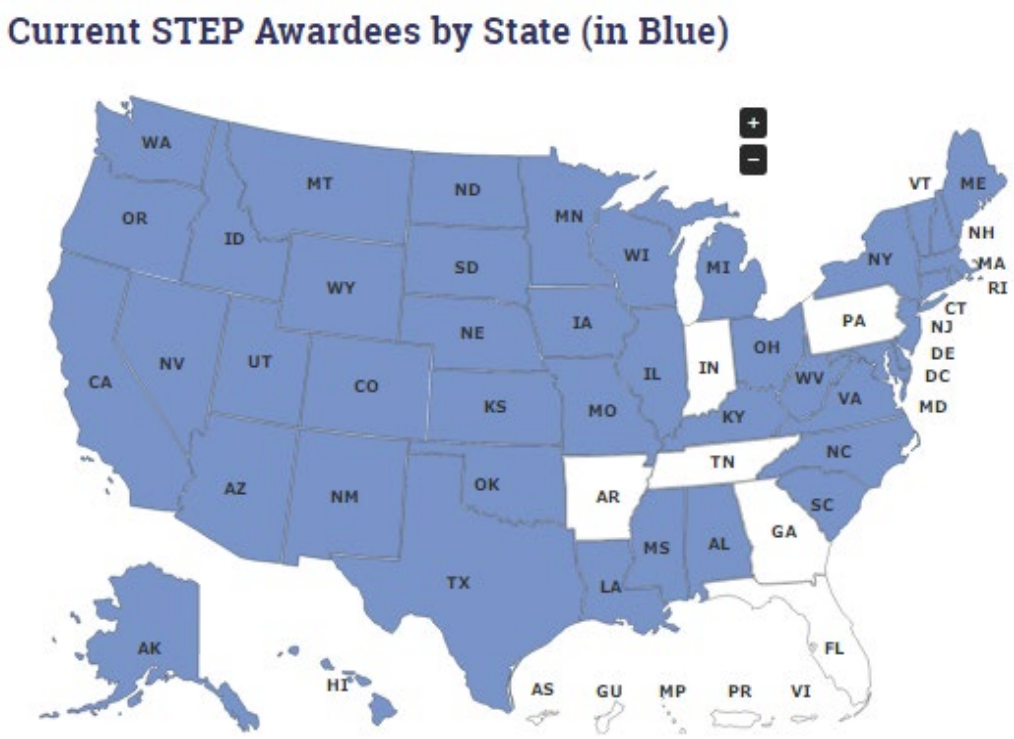
Service highlight: In-country **business matchmaking** to connect you with the right **partners**.

- Customized market and industry briefings
- Post-meeting and follow-up strategies
- Help with travel & interpreter service
- Appointments with prospective partners

STEP Program

STEP awards federal dollars to states and territories to fund eligible small business export development activities

FY 2016 Awards by State



STEP-supported export activities

- Participation in foreign trade missions, market sales trips, and trade shows
- Obtaining services to support foreign market entry (DOC)
- Website development to attract foreign buyers
- Design of international marketing products and campaigns

For Information:

http://www.sba.gov/STEP

U.S. COMMERCIAL SERVICE
United States of America
Department of Commerce

CONTACT US

Murat Muftari
Senior International Trade Specialist
(248) 296-2620
Murat.Muftari@trade.gov
www.export.gov

Public-private Partnerships

Partnering with VentureWell

Heath Naquin, Senior Global and Government Liaison Officer

MedHealth

Public-private Partnerships

Partnering with the Michigan Economic Development Corporation

Nadia Abunasser, Federal and Development Projects Director

MedHealth

Break and Transition

All attendees must exit the Garage to accommodate room transition to Bay One and Bay Two for breakout sessions.

MedHealth
STARTUP DAY
with the U.S. Department of Health and Human Services