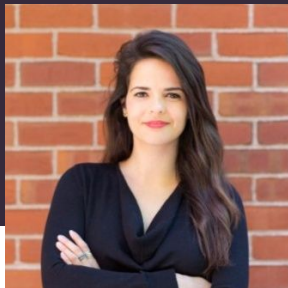# Regulation of AL / ML in the US

6.S897/HST.956: Machine Learning for Healthcare

Andy Coravos

CEO @ Elektra Labs

Research Collaborator @ Harvard-MIT Center for Regulatory Science

Advisor @ Biohacking Village at DEF CON

Formerly

Mark Shervey

Data Engineer @ Institute for Next Generation Healthcare

Icahn School of Medicine at Mount Sinai

@andreacoravos

@markshervey

DISCLAIMERS

The opinions and information in this presentation are our own, and do not necessarily reflect the views of the U.S. government or our affiliated institutions.

Regulations and policies are constantly changing. By the time these views have been presented, the information is already old.

Interact early and often with relevant oversight bodies.

Many definitions and frameworks in the health tech industry are in conflict and/or have not yet been created.

Ask questions!

You can be part of the influencers who defines and envisions the future.

Overview of today's lecture

■ <u>Overview US Regulatory Agencies</u>

A look at the FDA, FTC, FCC and other agencies that have oversight for health-related software and data. With a deeper dive into the newer policies (e.g., software and cybersecurity) coming out of the US FDA.

■ <u>How to submit a public comment</u>

An introduction to how to interact with the US government and influence policy.

■ <u>Institutional Review Board (IRBs)</u>

When to involve the institutional review board (IRB), and how to work with the IRB in digital research.

Before we start, a few examples and use-cases of algorithmically-driven health care products.

Software and algorithms have a wide range of applications

Measure

Diagnose

Treat

With **sensors + algorithms** to create objective measurements

With **advanced algorithms** to support the clinician

With **novel software-based therapies** that may augment or substitute a drug

E.g., Digital biomarkers, clinical decision support

Digital diagnostics

Digital therapeutics

To develop these products, we'll need to build safe and clinically-validated algorithms.

A glossary of terminology and uses of biomarkers and endpoints in biomedical research, medical product development and clinical care

- The BEST framework was created in 2016 by an NIH-FDA Working Group
- Seven types of biomarkers:
  - Diagnostic Biomarker
  - Monitoring Biomarker
  - Pharmacodynamic / Response Biomarker
  - Predictive Biomarker
  - Safety Biomarker
  - Susceptibility / Risk Biomarker

Although not explicitly listed in the BEST framework, a **"digital biomarker"** is a biomarker collected through digital means, often used in a remote (at-home) setting

Source: FDA-NIH BEST Framework, https://www.ncbi.nlm.nih.gov/books/NBK326791/

Modularity of software and sensor products to detect atrial fibrillation through connected technologies

Legend:
- ■ (teal) Software built and maintained by listed manufacturer
- ■ (gray) Software built and maintained by third party
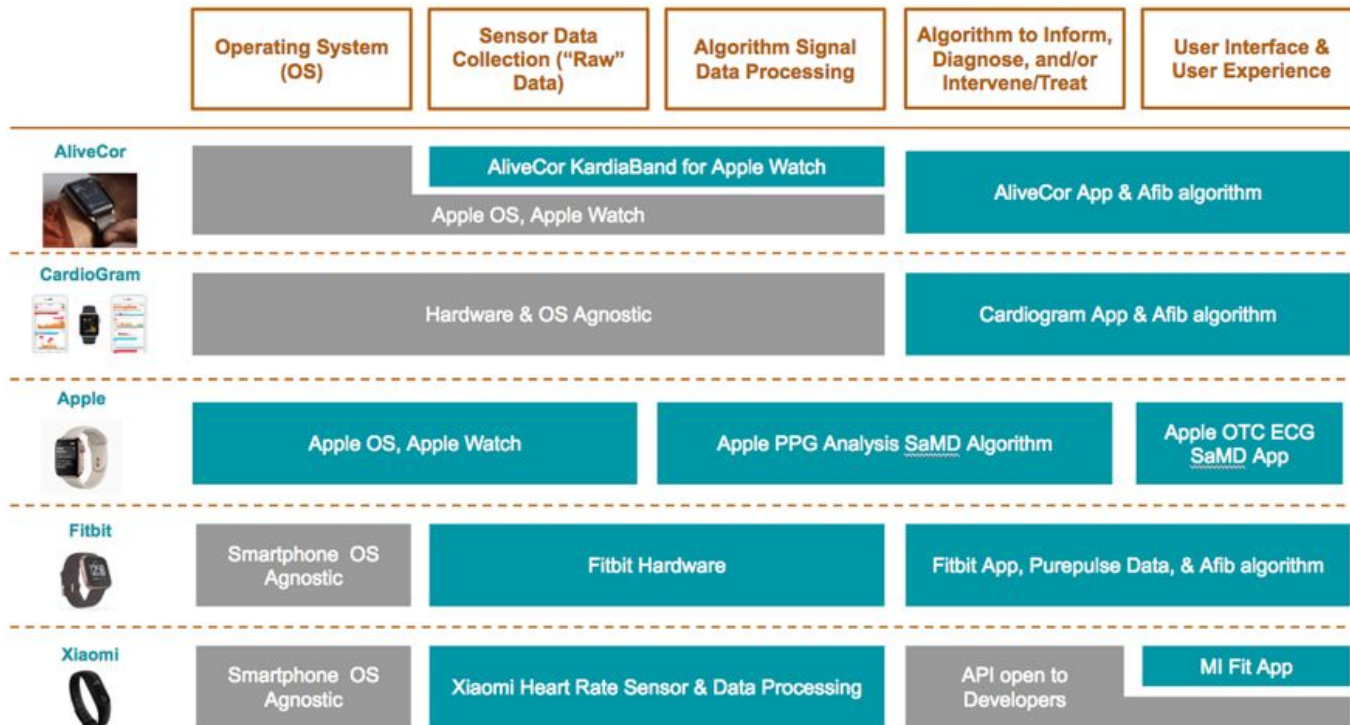
	Operating System (OS)	Sensor Data Collection ("Raw" Data)	Algorithm Signal Data Processing	Algorithm to Inform, Diagnose, and/or Intervene/Treat	User Interface & User Experience
AliveCor	Apple OS, Apple Watch	AliveCor KardiaBand for Apple Watch	Apple OS, Apple Watch	AliveCor App & Afib algorithm	
CardioGram	Hardware & OS Agnostic			Cardiogram App & Afib algorithm	
Apple	Apple OS, Apple Watch		Apple PPG Analysis SaMD Algorithm	Apple OTC ECG SaMD App	
Fitbit	Smartphone OS Agnostic	Fitbit Hardware		Fitbit App, Purepulse Data, & Afib algorithm	
Xiaomi	Smartphone OS Agnostic	Xiaomi Heart Rate Sensor & Data Processing		API open to Developers	MI Fit App

In 2014, AliveCor brought the EKG home…

Take a medical-grade EKG in just 30 seconds. Results are delivered right to your smartphone.

Philips Pagewriter Touch Interpretive EKG Machine: $15k

Meet Kardia Mobile. Your personal EKG: $99. FDA-Cleared.

… and since then, the FDA has cleared multiple "software-as -a-medical-device" (SaMDs)

BusinessWire
A Berkshire Hathaway Company
Log In   Sign Up

physIQ

With Latest FDA 510(k), physIQ Achieves Another Clearance as a Pioneer in AI Analytics

- FDA 510(k) cleared Atrial Fibrillation adds to physIQ's portfolio of FDA 51...

Healthcare IT News   GLOBAL EDITION   TOP

Apple unveils Watch Series 4 with FDA-approved ECG

This is the first FDA clearance for Apple and pushes the Watch further into healthcare than ever before.

By Jonah Comstock | September 12, 2018 | 02:48 PM

NEURORACER

Press any button to begin

- Developed in a lab at UCSF

- Published in Nature in 2013 and found that video game training enhances cognitive control in older adults

- Technology licensed to Akili Interactive Labs, a start-up, working to commercialize the product

Four Years Later…

☰ FierceBiotech 🔍

MedTech

Akili's video game therapy hits goal in pivotal ADHD trial

by Nick Paul Taylor | Dec 4, 2017 9:10am

➕ f 🐦 in ✉ 🖨
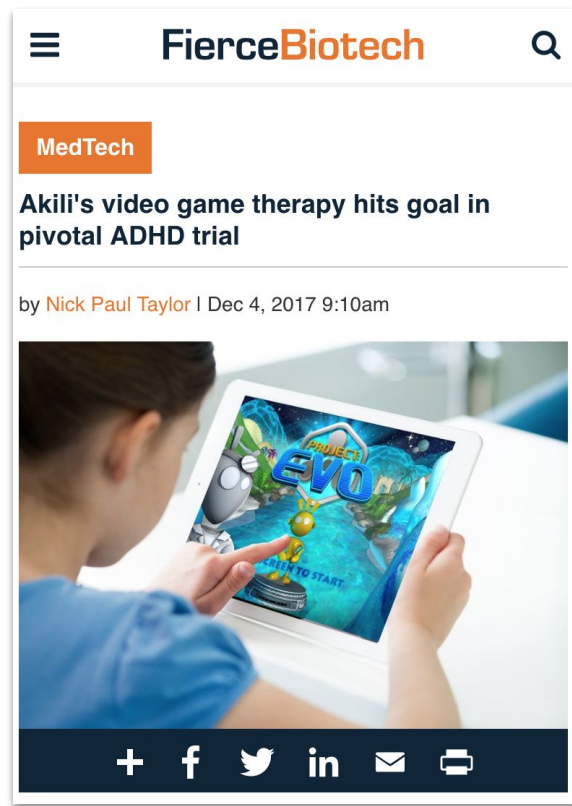
Eric Topol ✔
@EricTopol

Following ⌄

The FDA approvals for #AI in medicine are accelerating.
@US_FDA @aidocmed @ZebraMedVision @baylabsinc @NeuralAnalytics @icometrix @Viz_AI @ArterysInc @maximumqai @AliveCor imagen.ai eyediagnosis.net
now ≥ 1/month; 10/13 scans, 1 eye disease, 1 neuro,1 heart

Company	FDA Approval	Indication
Aidoc	August 2018	CT Brain bleed diagnosis
iCAD	August 2018	Breast density via mammography
Zebra Medical	July 2018	Coronary calcium scoring
Bay Labs	June 2018	Echocardiogram EF determination
Neural Analytics	May 2018	Device for paramedic stroke diagnosis
IDx	April 2018	Diabetic retinopathy diagnosis
Icometrix	April 2018	MRI brain interpretation
Imagen	March 2018	X-ray wrist fracture diagnosis
Viz.ai	February 2018	CT Stroke diagnosis
Arterys	February 2018	Liver and lung cancer (MRI,CT) diagnosis
MaxQ-AI	January 2018	CT Brain bleed diagnosis
Alivecor	November 2017	Atrial fibrillation detection via Apple Watch
Arterys	January 2017	MRI heart interpretation

mobi health news

Roundup: 12 healthcare algorithms cleared by the FDA

As AI cements its role in healthcare, more and more intelligent software offerings are pursuing 510(k) and De Novo approvals.
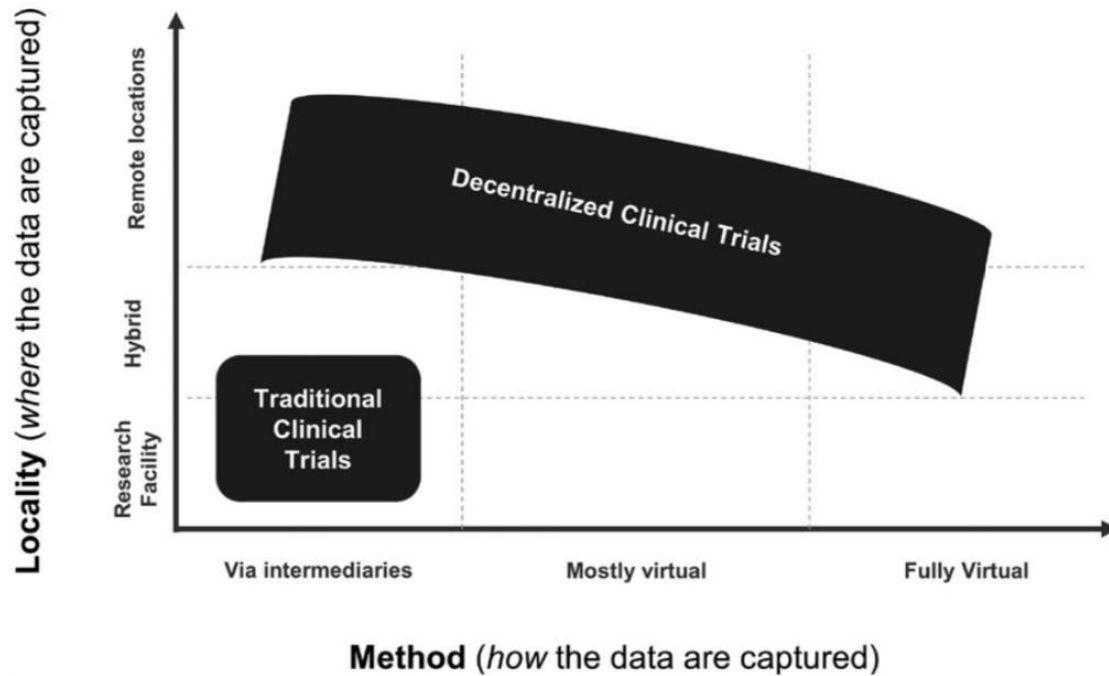
By **Dave Muoio**

November 15, 2018

SHARE Share 2886

[1] https://twitter.com/erictopol/status/1028642832171458563?lang=en
[2] https://www.mobihealthnews.com/content/roundup-12-healthcare-algorithms-cleared-fda

Mobile technologies are enabling new clinical investigation designs like **Decentralized Clinical Trials** (DCTs)

Source: Khozin S, Coravos A. Decentralized Trials in the Age of Real-World Evidence and Inclusivity in Clinical Investigations. Clin Pharmacol Ther. 2019;
https://ascpt.onlinelibrary.wiley.com/doi/full/10.1002/cpt.1441

FDA

Q Search

☰ Menu

IN THIS SECTION ⌄

← News & Events

SPEECH

Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making

JANUARY 28, 2019

f Share | 🐦 Tweet | ✉ Email

Speech by

Scott Gottlieb, M.D.
Commissioner of Food and Drugs - Food and Drug Administration

Source:
https://www.fda.gov/news-events/speeches-fda-officials/breaking-down-barriers-between-clinical-trials-and-clinical-care-incorporating-real-world-evidence

Digital tools are not making it easy to adhere to historical distinctions between the intervention and measurement/endpoint collection

Contains Software

Software's Purpose	**Clinical Trial Example** *Trial protocol ...*	*Intervention*	*Endpoint data collected by*	
Collects a measurement	that collects a digital biomarker	Parkinson's Medication	Smartphone-based tapping test	Opportunity for a clinician to send a patient home to behavioral and psychological measures remotely
Alters the treatment / intervention	with a responsive intervention (e.g., variable dosing)	Insulin Pump	Continuous Glucose Monitor (CGM)	An insulin pump with software that responds/doses based on the CGM reading
Is the treatment / intervention	with a digital therapeutic	Akili Interactive Labs Project:EVO for ADHD	The TOVA test (e.g., change in Attention Performance Index)	Rise of digital therapeutics increases available treatment options for physicians

Digital tools are blurring the line between measuring, diagnosing, and intervening

How does the US ensure that the products brought to market are safe and effective?

US Regulatory Agencies

Different but complementary authorities

US Food and Drug Administration (FDA)

- Assure safety and effectiveness of medical products (e.g., drugs, devices)

- Facilitate medical product innovation

- Expedite patient access to high quality medical products

- Promote and adopt consensus standards

Office of the National Coordinator (ONC)

- Adopt standards, administer certification programs for health information technology (HIT)

- Promote electronic health information exchange

- Promote HIT policy

- Coordinate HHS HIT policy with other relevant federal agencies

The Office of the National Coordinator for
Health Information Technology

Federal Communications Commission (FCC)

- Regulate interstate and international communications by radio, television, wire, satellite and cable

- Establish technical regulations, administer authorizations for equipment to minimize interference potential

Federal
Communications
Commission

Federal Trade Commission (FTC)

Mission

- Prevent business practices that are anticompetitive or deceptive or unfair to consumers

- Enhance informed consumer choice

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Source: Mobile Health: Industry Overview and Evolving Regulatory Framework, CERSI, https://cersi.stanford.edu/cersi_mhealth_course

Both the FTC and FDA oversight is focused on consumer protection

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

oversee promotion & advertising

FDA | U.S. FOOD & DRUG
ADMINISTRATION

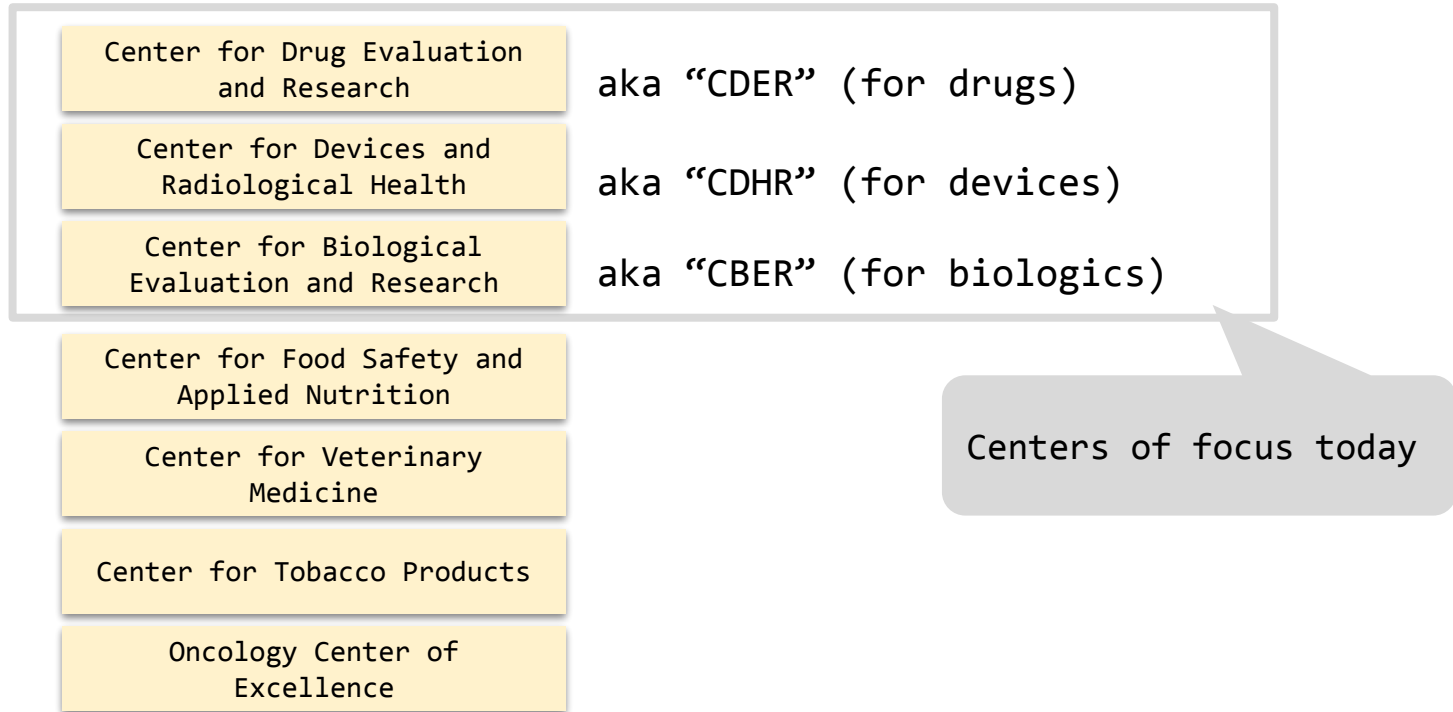oversee promotion & advertising <u>with a public health perspective</u>

What about National Institute of Standards and Technology (NIST)?

- Non-regulatory federal agency

- Mission: promote innovation & industrial competitiveness

- Involvement in the form of standards for mobile products and software

The FDA has multiple Centers, and three are the most relevant to our discussion today

Center for Drug Evaluation and Research

aka "CDER" (for drugs)

Center for Devices and Radiological Health

aka "CDHR" (for devices)

Center for Biological Evaluation and Research

aka "CBER" (for biologics)

Center for Food Safety and Applied Nutrition

Center for Veterinary Medicine

Center for Tobacco Products

Oncology Center of Excellence

Centers of focus today

Source: https://www.fda.gov/about-fda/fda-organization-charts/fda-organization-overview

And then came the 21st Century Cures Act, which spurred and authorized FDA innovation around software regulation

- The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016

- Designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

- Changed definitions and regulations around what is considered to be a "device"

[1] https://www.federalregister.gov/documents/2018/11/20/2018-25206/prescription-drug-use-related-software-establishment-of-a-public-docket-request-for-comments
[2] https://pink.pharmaintelligence.informa.com/PS124134/DrugSoftware-Combo-Platform-Coming-Soon-To-US-FDA-Gottlieb-Says
[3] https://www.wired.com/2017/05/medicine-going-digital-fda-racing-catch/

But, what is a medical device?

The FDA defines a medical device as

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

- **intended for use** in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Source: https://www.fda.gov/industry/regulated-products/medical-device-overview#What%20is%20a%20medical%20device

Work items > Software as a Medical Device (SaMD)

Software as a Medical Device (SaMD)

A- A+ 🖨

This work item is now complete. This page has been retained for historical reference.

The charter of the Working Group (WG) is to develop guidance that supports innovation and timely access to safe and effective Software as a Medical Device (SaMD) globally. The work is intended to identify commonalities, establish a common vocabulary and develop approaches for appropriate regulatory controls that promote prospective convergence in areas of advanced and innovative technologies in this topic area.

Source: http://www.imdrf.org/workitems/wi-samd.asp

Source: http://www.imdrf.org/workitems/wi-samd.asp
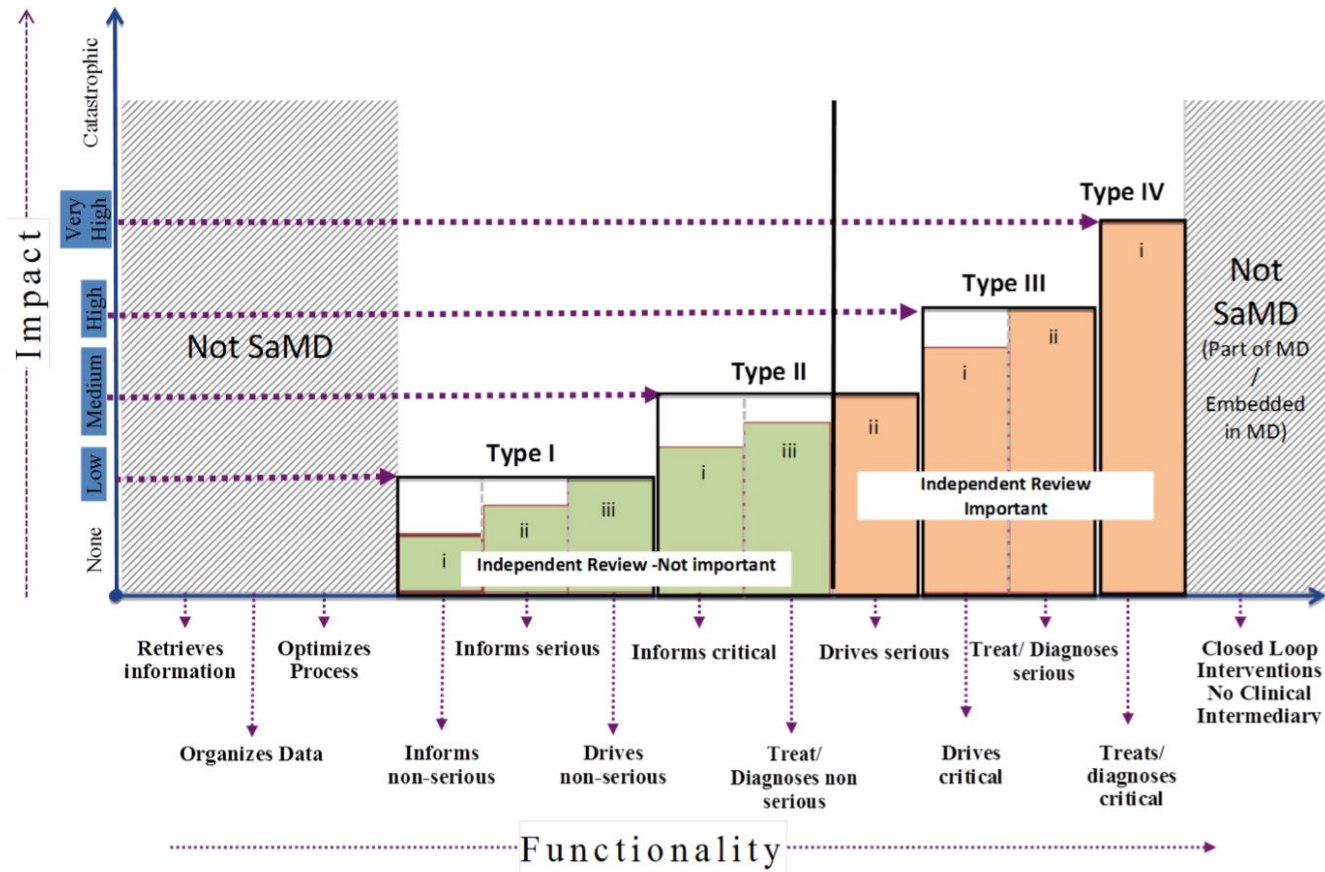
A "device" is a <u>Term of Art</u> at the FDA

(Try to minimize using the term "device"
unless the product is actually a device.)

Is my product a "device"?

Talk with your regulator and lawyer!

The next example is metaphorical rather than factual.

Device?   Not a device?

Device?   Not a device?

Trick question.

It's all about what the manufacturer claims the product can do.

The exact same product can be developed and marketed either as a "device" (and thus, regulated) or not as a "device" (and unregulated) **simply through a change of words, and no change in hardware or code.**

Asking "is my digital product a medical device?" is not the most useful question.

A better question would: "what is the **intended use** of the product?"

(i.e. is the organization making a **medical device claim**?)
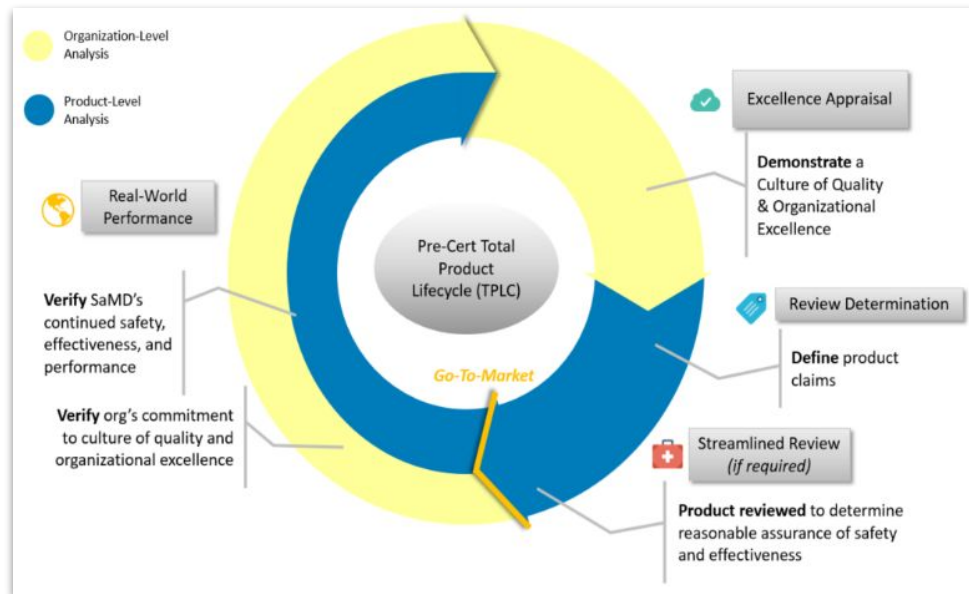
U.S. FOOD & DRUG ADMINISTRATION

Search FDA

‹ back to Digital Health

Digital Health Software Precertification (Pre-Cert) Program

f SHARE 🐦 TWEET + ✉ EMAIL

The Software Precertification Pilot Program (Pre-Cert)'s version 1.0 working model explains how the FDA has reimagined its way of regulating digital health products and details the proposed key components of the Pre-Cert pilot program.

Organization-Level Analysis

Product-Level Analysis

Pre-Cert Total Product Lifecycle (TPLC)

Excellence Appraisal
Demonstrate a Culture of Quality & Organizational Excellence

Review Determination
Define product claims

Real-World Performance

Verify SaMD's continued safety, effectiveness, and performance

Verify org's commitment to culture of quality and organizational excellence

Go-To-Market

Streamlined Review *(if required)*
Product reviewed to determine reasonable assurance of safety and effectiveness

Hot off the presses: The most recent version of FDA's Pre-Cert program launched in January 2019. **This program is in the planning phase (pilot).**

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback

This past month the FDA's Digital Health Unit issued a draft discussion paper on modifications for AI/ML-based SaMDs

Source: https://www.regulations.gov/document?D=FDA-2019-N-1185-0001

FDA-Cleared
!=
FDA-Approved

Regulatory Pathways for Device Development

Regulatory Pathway	510k	De Novo	Premarket Approval
Product risk levels	Class I and II	Class I and II	Class III
FDA decision type	Cleared	Granted	Approved
Requires a predicate	Yes	No	No
Decision criteria	Product demonstrates 'substantial equivalence' to a predicate (e.g., no independent assessment of the product required)	Probable benefits of the product outweigh probable risks	Requires independent assessment of the product's safety and effectiveness

Source: Karger Digital Biomarkers, "Digital Medicine: A Primer on Measurement" (May 2019)

Ok, so the tools are safe and effective -- but what about the information collected from the tools?

The 'Internet of Bodies' Is Here. Are Courts and Regulators Ready?

A network of smart devices attached to or implanted in bodies raises a host of legal and policy questions

By Andrea M. Matwyshyn

Nov. 12, 2018 11:19 a.m. ET

We've all heard of the Internet of Things, a network of products ranging from refrigerators to cars to industrial control systems that are connected to the internet.

Now comes the Internet of Bodies—a network of smart devices that are attached to or inside our bodies. But using the human body as a technology platform raises a host of challenging legal and policy questions that regulators and

Our healthcare system has strong protections for patients' biospecimens, like blood or genomic data, but what about our **digital specimens**?

Sources
[1] https://www.wsj.com/articles/the-internet-of-bodies-is-here-are-courts-and-regulators-ready-1542039566
[2] https://www.thelancet.com/journals/landig/article/PIIS2589-7500(19)30001-9/fulltext

GPS

Fitness tracking app Strava gives away location of secret US army bases

Data about exercise routes shared online by soldiers can be used to pinpoint overseas facilities

● Latest: Strava suggests military users 'opt out' of heatmap as row deepens

This Thermometer Tells Your Temperature, Then Tells Firms Where to Advertise

REGULATION

There's No Such Thing as Anonymous Data

by Scott Berinato

FEBRUARY 09, 2015

HEALTH INSURANCE HUSTLE

Your Medical Devices Are Not Keeping Your Health Data to Themselves

CPAP units, heart monitors, blood glucose meters and lifestyle apps generate information that can be used in ways patients don't necessarily expect. It can be sold for advertising or even shared with insurers, who may use it to deny reimbursement.

Justin Volz, special to ProPublica

HEALTH INSURANCE HUSTLE

You Snooze, You Lose: Insurers Make The Old Adage Literally True

[1]
https://www.theguardian.com/world/2018/jan/28/fitness-tracking-app-gives-away-location-of-secret-us-army-bases
[2] https://www.nytimes.com/2018/10/23/business/media/fever-advertisements-medicine-clorox.html
[3] https://www.propublica.com/article/your-medical-devices-are-not-keeping-your-health-data-to-themselves
[4] https://hbr.com/2015/02/theres-no-such-thing-as-anonymous-data

There are many agencies that may oversee health tech products, and there are also many gaps in the current regulatory system.

**U.S. FOOD & DRUG ADMINISTRATION** — Oversees human subjects testing, though many healthy-lifestyle devices fall out of agency's purview (not a "device")

FEDERAL TRADE COMMISSION — PROTECTING AMERICA'S CONSUMERS — Police unfair and deceptive practices; main enforcement for security and privacy - small agency

Federal Communications Commission — Oversees connectivity and net neutrality (e.g., regulating access to the internet)
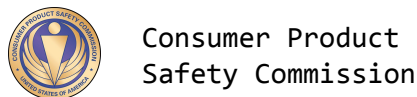
Consumer Product Safety Commission — Only recently started proposed rulemaking for Internet of things

cfpb — Consumer Financial Protection Bureau — Oversees information that's used in background testing and other social evaluations

Examples of how government agencies have interacted with members of the public to inform guidance on new technologies.

FDA and Duke are collaborating in a public-private partnership with member organizations of the Clinical Trial Transformation Initiative (CTTI)

Novel Endpoints, Launched June 2017

Mobile Technologies, Launched July 2018

[1] https://www.ctti-clinicaltrials.org/projects/novel-endpoints
[2] https://www.ctti-clinicaltrials.org/projects/mobile-technologies
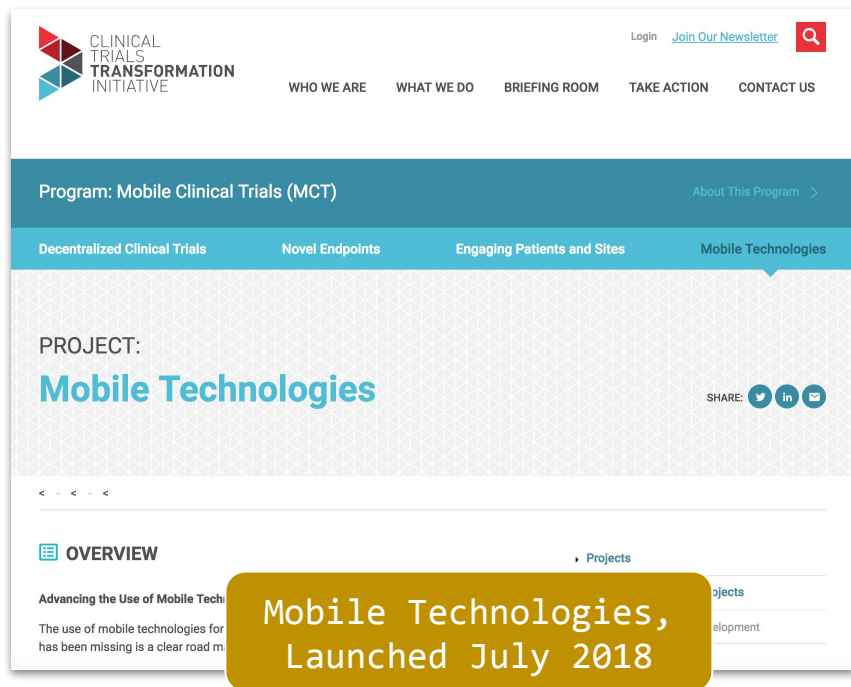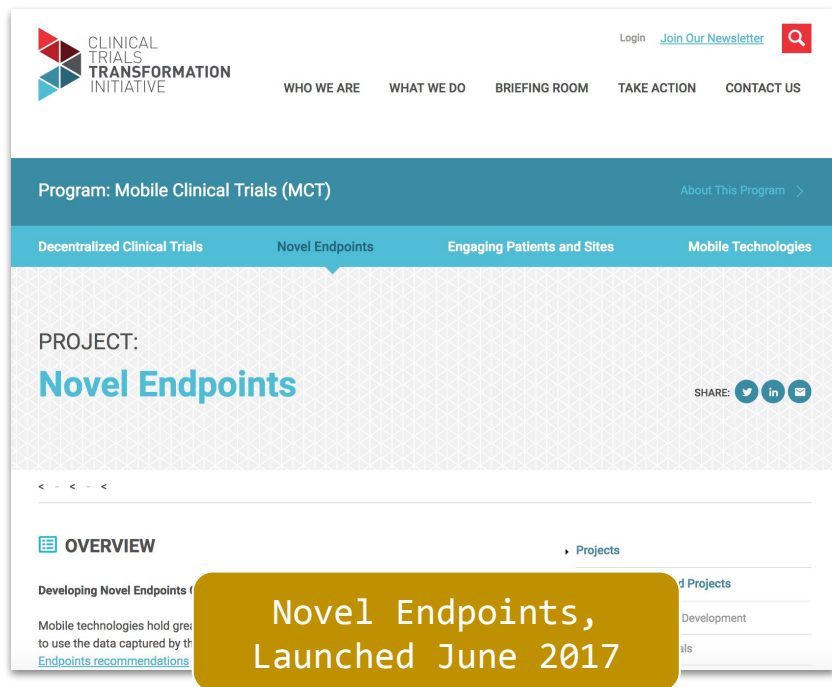
U.S. FOOD & DRUG ADMINISTRATION

Search FDA

‹ back to Workshops & Conferences (Medical Devices)

Public Workshop - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices January 29-30, 2019

f SHARE   🐦 TWEET   +   ✉ EMAIL

The Food and Drug Administration (FDA) is announcing a public Workshop entitled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The purpose of the workshop is to discuss the newly released draft guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. FDA seeks to bring together diverse stakeholders to discuss, in-depth, the draft guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and the sub-topic of the draft guidance regarding a Cybersecurity Bill of Materials (CBOM), which can be a critical element in identifying assets, threats, and vulnerabilities.

Scott Gottlieb, M.D. ✔ @SGottliebFDA · Jan 29, 2019

Replying to @SGottliebFDA

Workshops like this are one part of our ongoing efforts to bring together all stakeholders in the cybersecurity ecosystem to carry out a "whole of community" approach in which we're all doing our part to ensure devices are secure and patients are protected.

Scott Gottlieb, M.D. ✔ @SGottliebFDA

At future events – like @Defcon – we encourage manufacturers to increase engagement with the cyber research community through device demos and our #wehearthackers event. This demonstrates a company's commitment to cyber principles: Trustworthiness. Transparency. Resilience.

♡ 31   11:06 AM - Jan 29, 2019

Medtronic	BD	PHILIPS	Abbott	Thermo Fisher SCIENTIFIC	elektralabs	MAYO CLINIC	SIEMENS Healthineers
Medtronic	Becton Dickinson	Philips Health	Abbott	Thermofisher Scientific	Elektra Labs	Mayo Clinic	Siemens Healthineers

Learn more about the FDA-led initiative at **WeHeartHackers.org**

[1] https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-content-premarket-submissions-management-cybersecurity-medical-devices-january-29-30
[2] WeHeartHackers.org

The Case for a Hippocratic Oath for Connected Medical Devices: Viewpoint

Beau Woods; Andrea Coravos; Joshua David Corman

ABSTRACT

Prior to graduating from medical school, soon-to-be physicians take the Hippocratic Oath, a symbolic declaration to provide care in the best interest of patients. As the medical community increasingly deploys connected devices to deliver patient care, a critical question emerges: should the manufacturers and adopters of these connected technologies be governed by the symbolic spirit of the Hippocratic Oath? In 2016, I Am The Cavalry, a grassroots initiative from the cybersecurity research community, published the first Hippocratic Oath for Connected Medical Devices (HOCMD). Over the past three years, the HOCMD has gained broad support and influenced regulatory policy. We introduce five case studies of the HOCMD in practice, leading to a safer and more effective adoption of connected medical technologies.

[1] https://www.jmir.org/2019/3/e12568/
[2] DiMeSociety.org

Clinicians have professional societies to support their development, e.g., the Society for Neuro-Oncology (SNO).

What exists for those who practice and develop digital medicine products?

Members from government agencies have teamed up with software engineers, security researchers and more to launch...

Learn more about the 501(c)3 Digital Medicine (DiME) Society at **DiMeSociety.org**.

How can YOU participate in the US rulemaking process?

Serve a "Tour of Duty"

Source: https://rockhealth.com/create-meaningful-change-in-healthcare-serve-a-tour-of-duty-in-government/
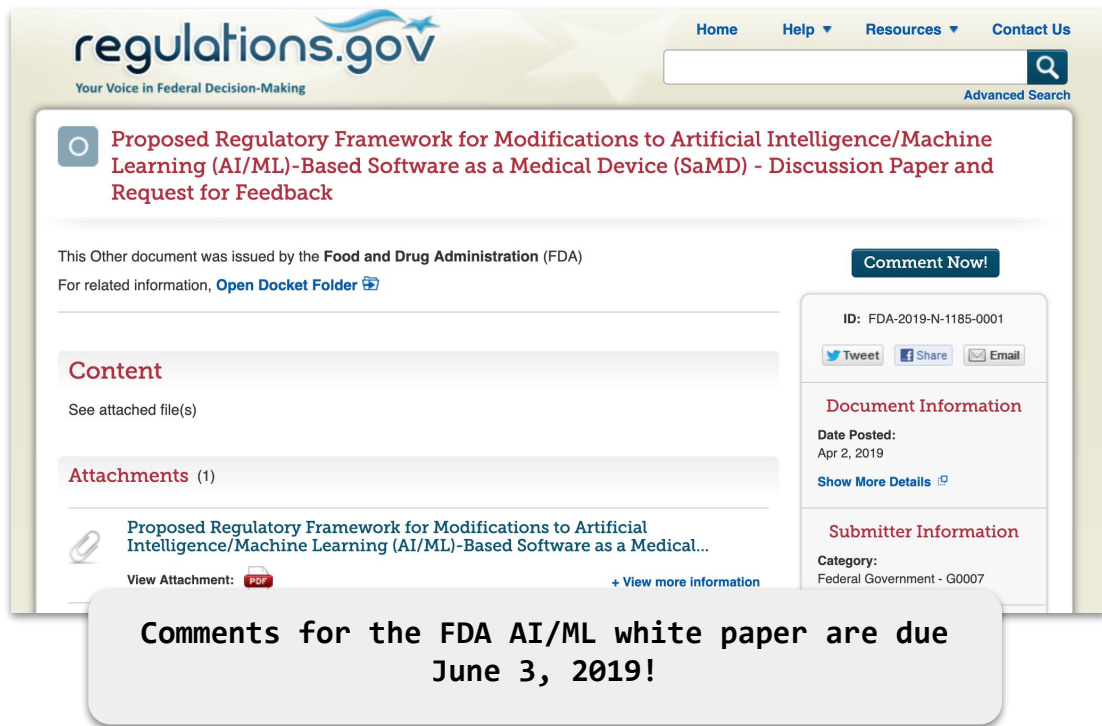
Submit a comment to the public docket

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Your Voice in Federal Decision-Making

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Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback

This Other document was issued by the **Food and Drug Administration** (FDA)
For related information, **Open Docket Folder** 📁

Comment Now!

ID: FDA-2019-N-1185-0001

🐦 Tweet   f Share   ✉ Email

Content

See attached file(s)

Attachments (1)

📎 Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical...

View Attachment: 📄 PDF   + View more information

Document Information

Date Posted:
Apr 2, 2019

Show More Details 🗗

Submitter Information

Category:
Federal Government - G0007

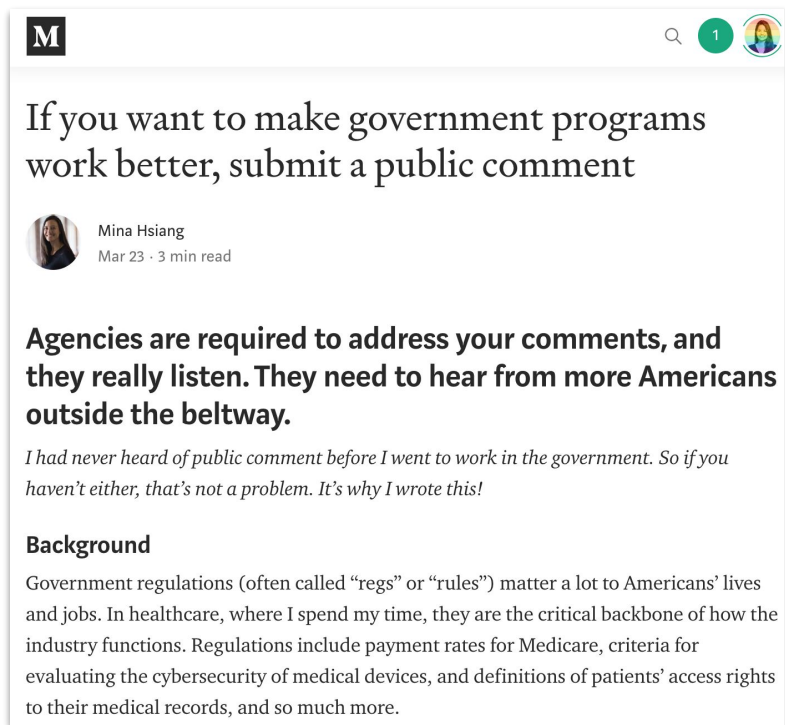**Comments for the FDA AI/ML white paper are due June 3, 2019!**

Whenever an agency is proposing either brand-new regulations or changes to existing ones, they must do it in two phases.

1) First the agency will post a draft and ask the public to comment on it

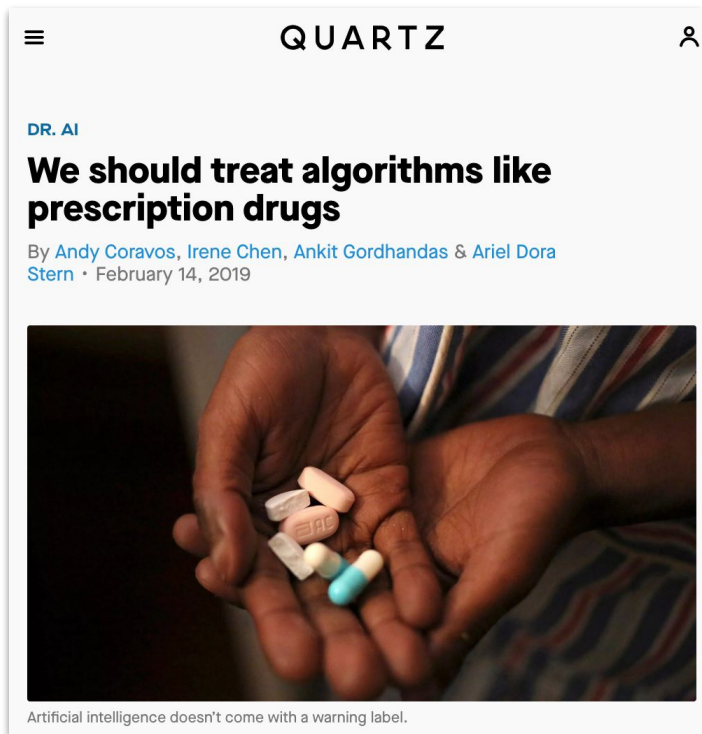2) Then, they read and digest the comments and draft a final version

Source: https://www.regulations.gov/document?D=FDA-2019-N-1185-0001

Reasons to submit a public comment

If you want to make government programs work better, submit a public comment

Mina Hsiang
Mar 23 · 3 min read

Agencies are required to address your comments, and they really listen. They need to hear from more Americans outside the beltway.

I had never heard of public comment before I went to work in the government. So if you haven't either, that's not a problem. It's why I wrote this!

Background

Government regulations (often called "regs" or "rules") matter a lot to Americans' lives and jobs. In healthcare, where I spend my time, they are the critical backbone of how the industry functions. Regulations include payment rates for Medicare, criteria for evaluating the cybersecurity of medical devices, and definitions of patients' access rights to their medical records, and so much more.

- **Anyone can comment.** experts in the field, startups, corporations, lobbying groups, concerned citizens.

- **You will be heard.** Legally, the agency is required to address all comments in the final rule

- **Be a voice from the people.** Major industry players and trade groups almost always submit comments. Meanwhile, there are unfortunately lots of groups who rarely do, like startups, individual doctors, engineers, product managers, security experts, user researchers, and people from families who struggle with the exact scenarios being discussed.

Source: https://medium.com/@mina.h/if-you-have-feedback-on-how-government-programs-can-work-better-you-should-submit-public-comments-22378a934896

Kick around ideas with colleagues to improve the regulatory paradigm. Our society needs new models.

QUARTZ

DR. AI

We should treat algorithms like prescription drugs

By Andy Coravos, Irene Chen, Ankit Gordhandas & Ariel Dora Stern • February 14, 2019

Artificial intelligence doesn't come with a warning label.

For example, co-authored this op-ed with Irene Chen.

Using **'clinical trials'** frameworks to teach us about AI and algorithm development:

- Designing the **testing protocols** depending on the understanding of the **mechanism of action**

- **Inclusion and exclusion** criteria

- Identifying the "**sponsor**" of the trial

- **Public reporting** of results (e.g., ClinicalTrials.gov)

- Using and adapting existing tools like **informed consent**

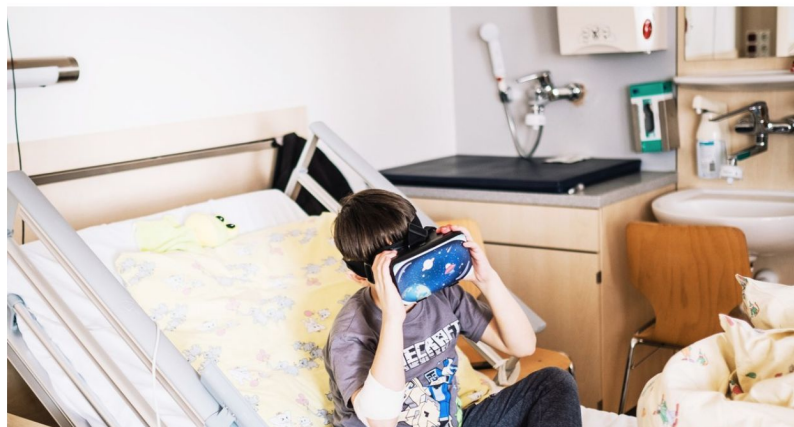Source: https://qz.com/1540594/treating-algorithms-like-prescription-drugs-could-reduce-ai-bias/

While it's possible you will have to interact with government agencies, it's even more like you'll interact with… your IRB.

APPENDIX

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ANDY CORAVOS SCIENCE 11.20.18 09:00 AM

THE DOCTOR PRESCRIBES VIDEO GAMES AND VIRTUAL REALITY REHAB

In Nov 2018, WIRED published an op-ed based on the digital medicine framework.

Contained a landscape analysis of software and algorithms that:

- **Measure** health

- **Diagnose**

- **Treat** diseases

... and a perspective on how to bring these products to market safely, effectively and ethically.

Source: WIRED November 2018, https://www.wired.com/story/prescription-video-games-and-vr-rehab/