Introducing the Digital Medicine Society (DiMe)

NIH Collaboratory Grand Rounds
August 16, 2019

Andy Coravos | CEO, Elektra Labs; Research Collaborator, Harvard-MIT Center for Regulatory Science; Co-founder, Digital Medicine Society

Jen Goldsack | Interim Executive Director, DiMe; Portfolio, Strategy & Ops, HealthMode

It’s an exciting time in the digital era of medicine

In 2014, AliveCor brought the EKG home…

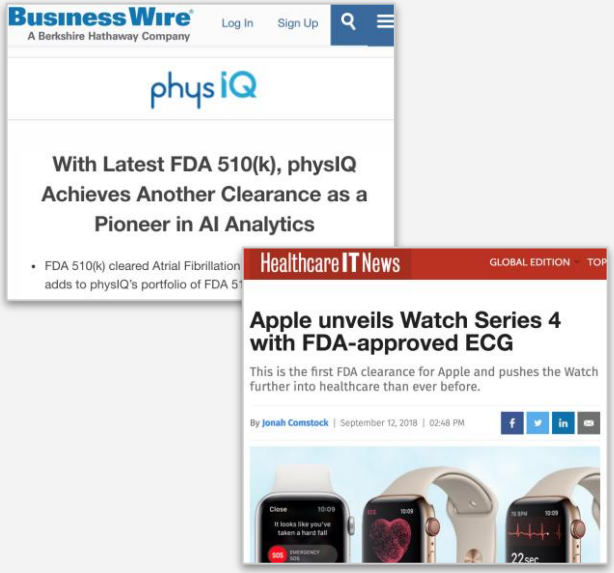
Philips Pagewriter Touch Interpretive EKG Machine: $15k

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

FDA

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

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



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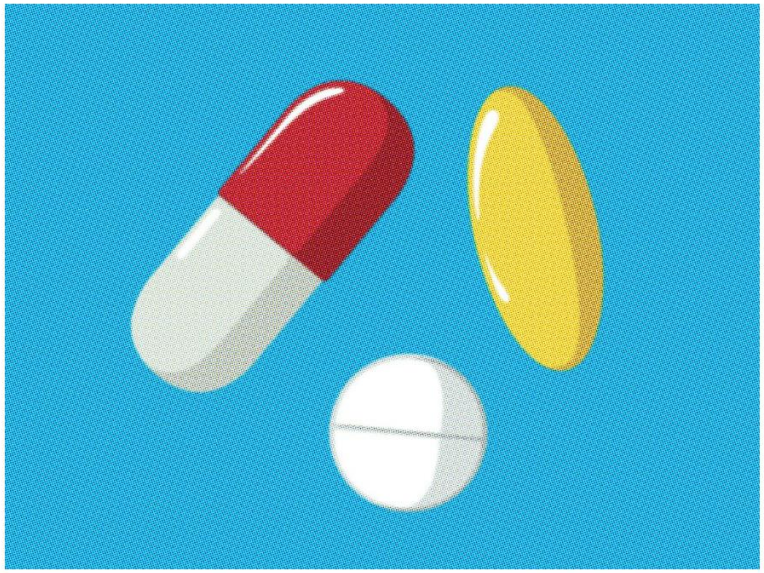
MEGAN MOLTENI SCIENCE 05.22.17 07:00 AM

MEDICINE IS GOING DIGITAL. THE FDA IS RACING TO CATCH UP



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TAGS: Digital H... | FDA | Regulation

Drug/Software Combo Platform Coming Soon To US FDA, Gottlieb Says

24 Oct 2018 | **ANALYSIS**

FDA U.S. FOOD & DRUG ADMINISTRATION

Developing a Software Precertification Program: *A Working Model*

(v0.1- April 2018)

Introduction

The Software Precertification Program is envisioned as a voluntary pathway that embodies a regulatory model more tailored than the current regulatory paradigm to assess the safety and effectiveness of software technologies without inhibiting patient access to these technologies. The program is envisioned to provide a more streamlined and efficient regulatory oversight of software-based medical devices from manufacturers who have demonstrated a robust culture of

fitbit J&J PEAR THERAPEUTICS Roche SAMSUNG

DiME

Are these technologies worthy of the trust we place in them?

Source: https://www.iamthecavalry.org/

What happens when
bits and bytes
meets
flesh and blood?

Source: https://www.iamthecavalry.org/

JMIR Publications | 20 YEARS

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.

Source: https://www.jmir.org/2019/3/e12568/

I will revere and protect human life, and act always for the benefit of my patients. I recognize that all systems fail; inherent defects and adverse conditions are inevitable. Capabilities meant to improve or save life, may also harm or end life. Where failure impacts patient safety, care delivery must be resilient against both indiscriminate accidents and intentional adversaries. Each of the roles in a diverse care delivery ecosystem shares a common responsibility: As one who seeks to preserve and improve life, I must **first do no harm**.

To that end, I swear to fulfill, to the best of my ability, these principles.

- **Cyber Safety by Design:** I respect domain expertise from those that came before. I will inform design with security lifecycle, adversarial resilience, and secure supply chain practices.
- **Third-Party Collaboration:** I acknowledge that vulnerabilities will persist, despite best efforts. I will invite disclosure of potential safety or security issues, reported in good faith.
- **Evidence Capture:** I foresee unexpected outcomes. I will facilitate evidence capture, preservation, and analysis to learn from safety investigations.
- **Resilience and Containment:** I recognize failures in components and in the environment are inevitable. I will safeguard critical elements of care delivery in adverse conditions, and maintain a safe state with clear indicators when failure is unavoidable.
- **Cyber Safety Updates:** I understand that cyber safety will always change. I will support prompt, agile, and secure updates.

Source: https://www.iamthecavalry.org/domains/medical/oath/

Clinicians have professional societies to support their development (e.g., ASCO)

Where is the **professional home** for those who practice and develop products in the digital era of medicine?

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

The Digital Medicine Society (DiMe) launched three months ago (May 2019)

CISION
PR Newswire

Digital Medicine Society Now Accepting Members

New nonprofit aims to advance digital medicine to optimize human health

DiME DIGITAL MEDICINE SOCIETY

NEWS PROVIDED BY
Digital Medicine Society (DiMe) →
May 14, 2019, 01:53 ET

BOSTON, May 14, 2019 /PRNewswire/ -- The Digital Medicine Society (DiMe), a Massachusetts nonprofit corporation with 501(c)(3) application pending, has launched.

Source: https://www.prnewswire.com/news-releases/digital-medicine-society-now-accepting-members-300848402.html

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FIRST OPINION

DiMe: Calling all who serve in digital medicine

By JEN GOLDSACK, BEAU WOODS, *and* ERIC PERAKSLIS / JUNE 5, 2019

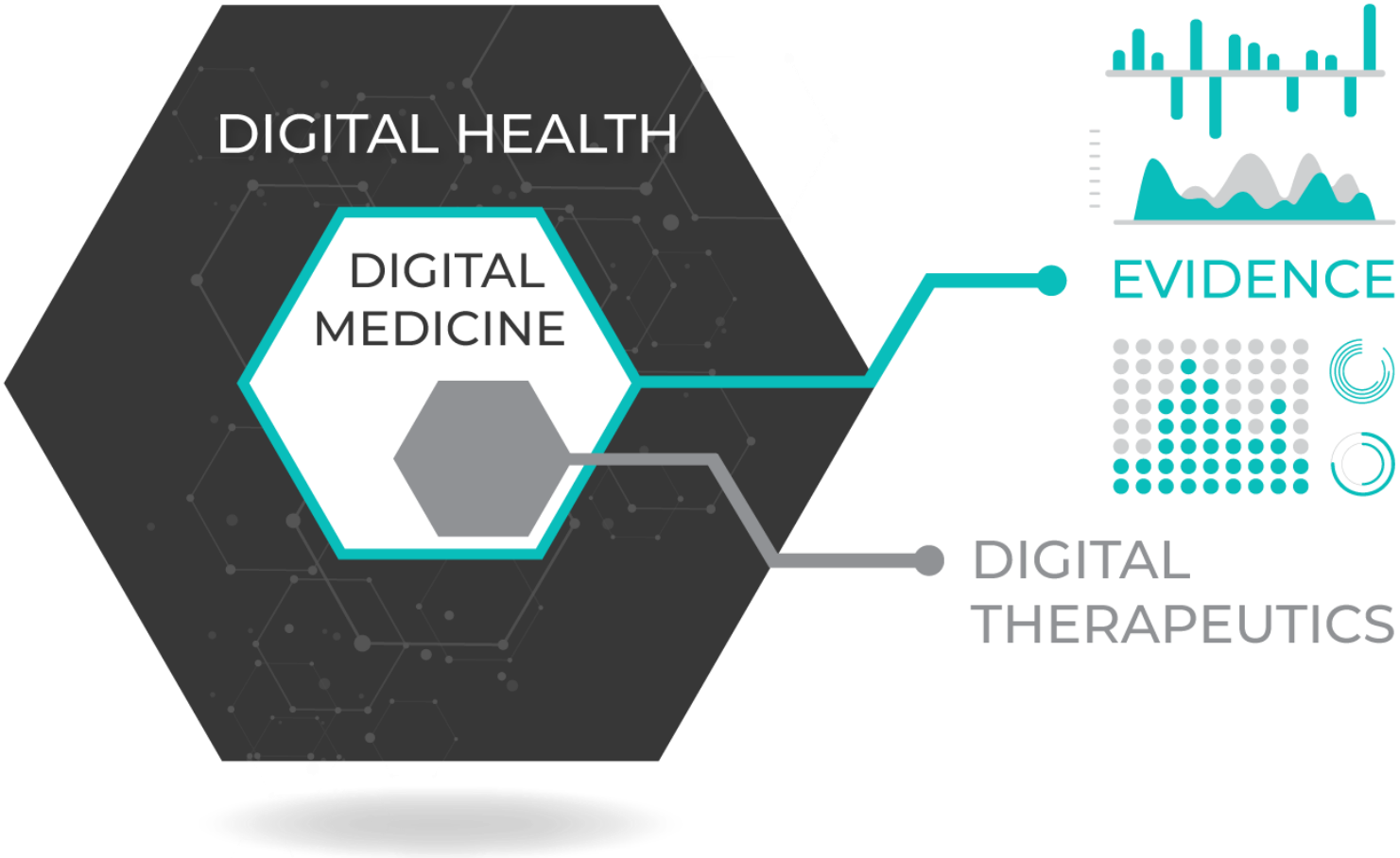
ADOBE

From smart pacemakers to diagnostic algorithms and digital therapeutics, medicine is becoming more digitized every year. Digital medicine tools offer the possibility of improved health outcomes, lower costs, and better access to

Source: https://www.statnews.com/2019/06/05/new-digital-medicine-society/

DiMe sits at the intersection of two communities

What is Digital Medicine?



Source: https://medium.com/digital-medicine-society-dime/laying-the-foundation-defining-digital-medicine-49ab7b6ab6ef

DiMe is advancing digital medicine to optimize human health

RESEARCH

Solving for
Lack of Evidence

COMMUNICATION & EDUCATION

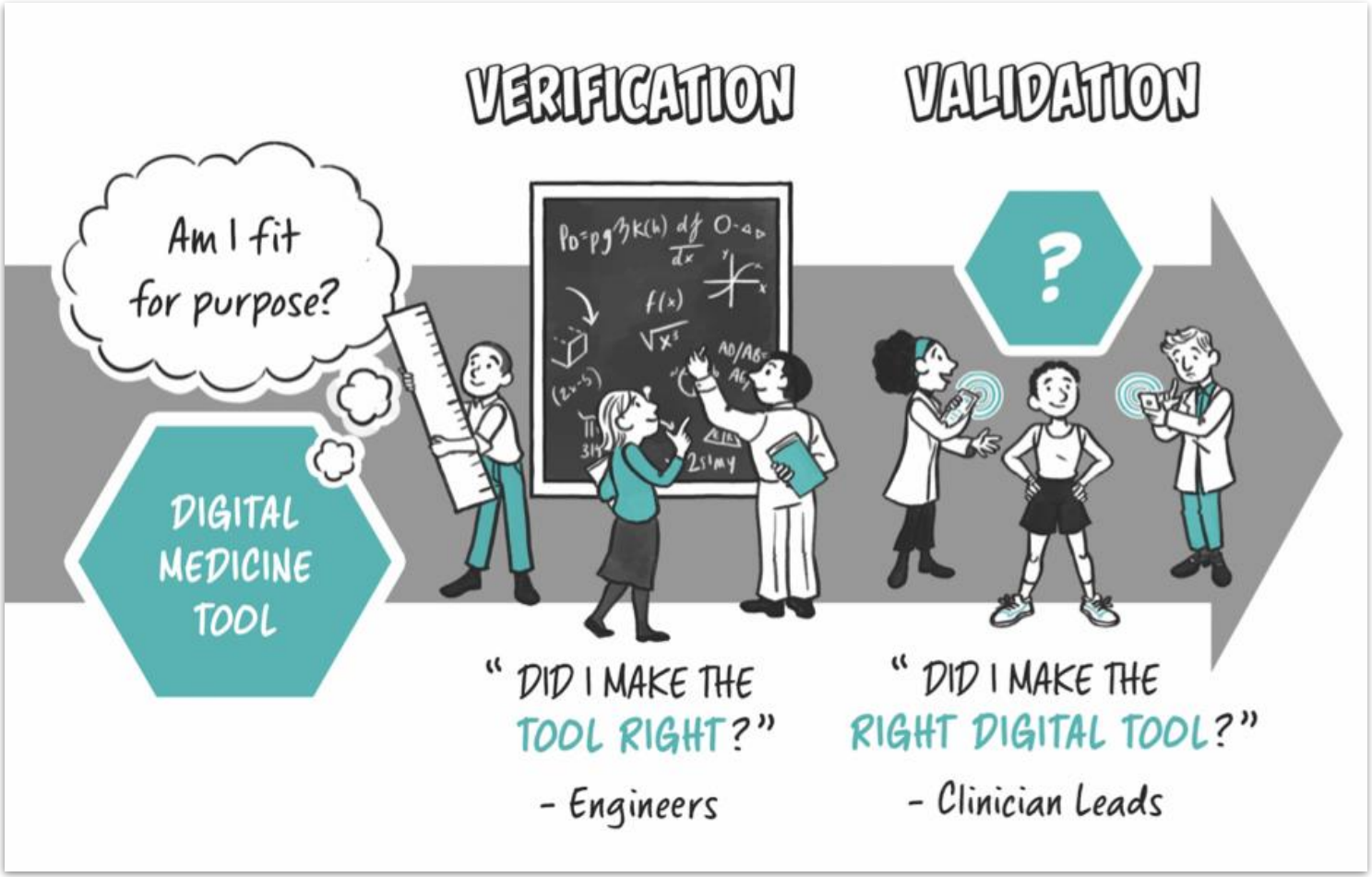
Solving for
Fragmentation & Lack of Alignment

COMMUNITY BUILDING

Solving for
Isolated Silos of Progress

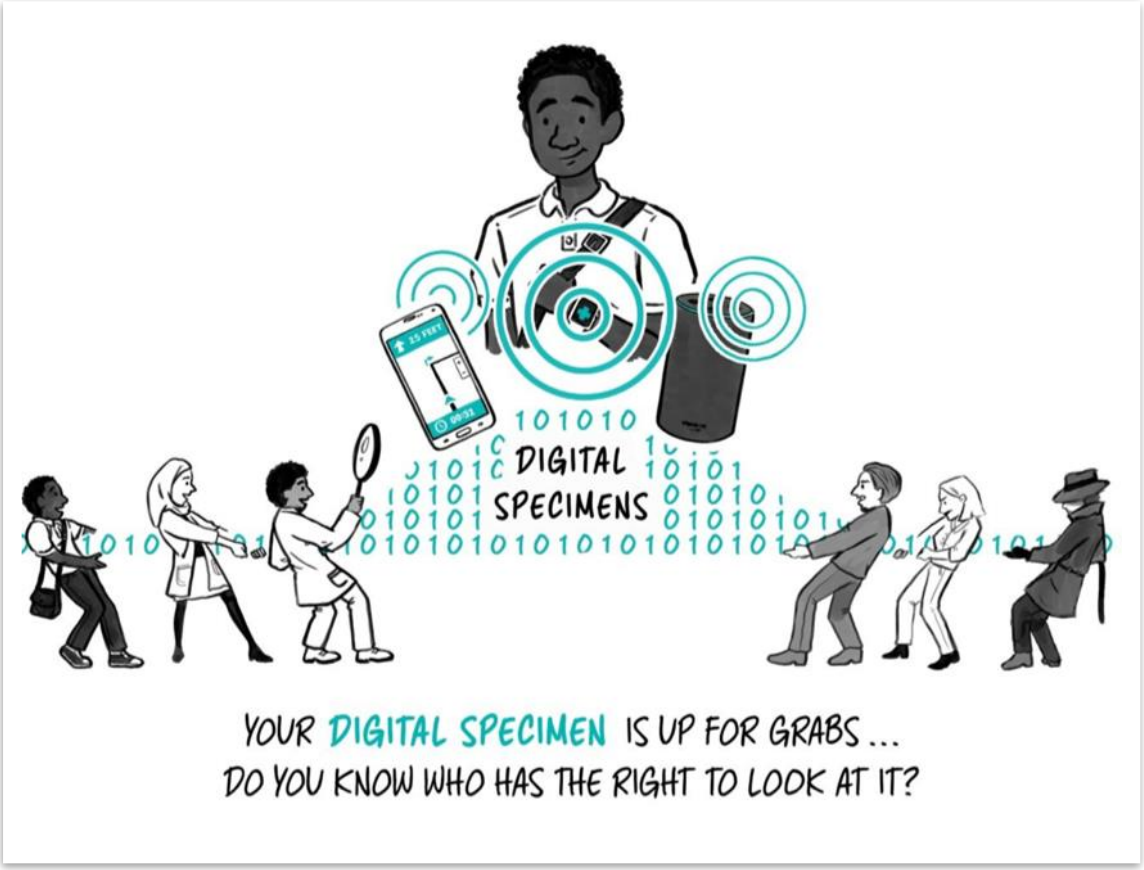
Myth-Busting!

It’s hard to evaluate whether a digital tool is fit for purpose



Digital Medicine: A Primer on Measurement

Coravos A, Goldsack JC, Karlin DR, Nebeker C, Perakslis E, Zimmerman N, and Erb MK.



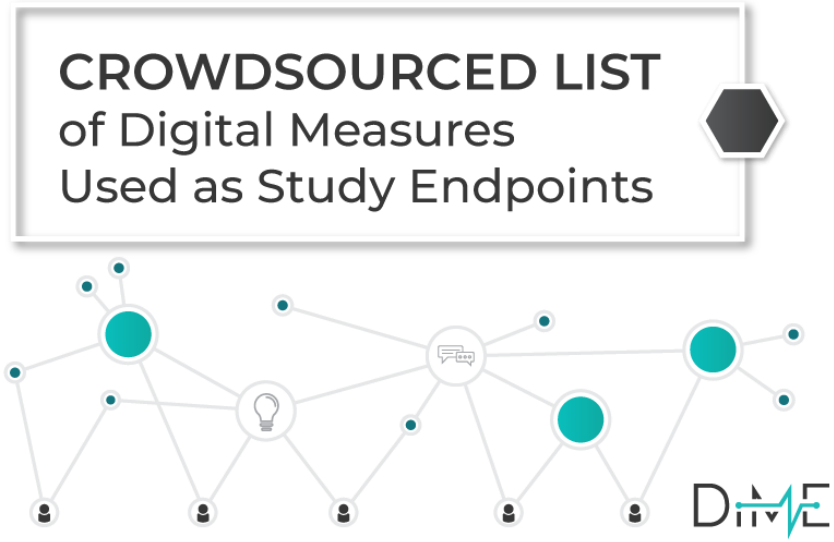
Source: https://www.karger.com/Article/FullText/500413

The era of “Move Fast and Break Things” is over

Crowdsourced library of digital endpoints

Digital endpoints in industry sponsored studies of:

- new medical products
- new applications of existing medical products



Learn more: www.dimesociety.org/index.php/knowledge-center/library-of-digital-endpoints

WSJ

JOURNAL REPORTS: TECHNOLOGY

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**?

Source: https://drive.google.com/file/d/1nAXc4YcP1NoxEwevXo3Fa9PreIqbQXm2/view?usp=sharing


DEF CON

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

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 r
Submis

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
Medtronic

BD
Becton Dickinson

PHILIPS
Philips Health

Abbott
Abbott

ThermoFisher SCIENTIFIC
Thermofisher Scientific

elektralabs
Elektra Labs

MAYO CLINIC
Mayo Clinic

SIEMENS Healthineers
Siemens Healthineers

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

DiME

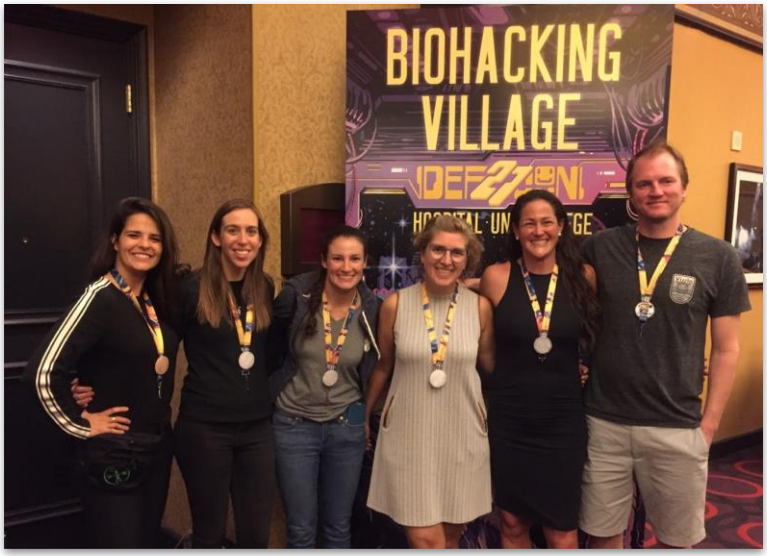
DiMe at DEF CON 27: What We Can Learn from the Security Research Community

Jennifer Goldsack Following
Aug 14 · 3 min read

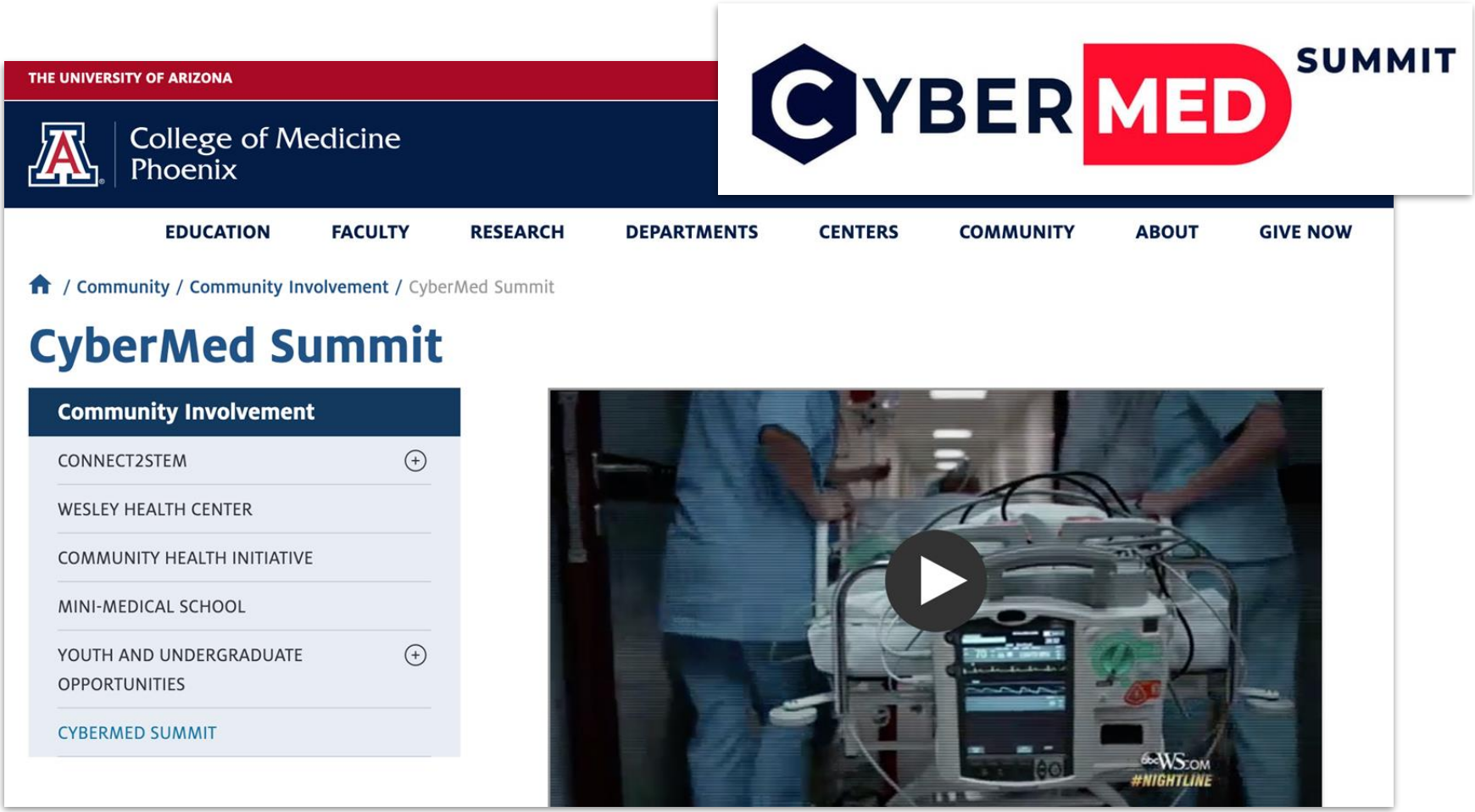
At the BioHacking Village at DEF CON this weekend, the Digital Medicine Society (DiMe) won the Research Competition after pitching our vision for the future of digital medicine to a panel of judges from several industry companies: Abbott, BD, EY, Siemens, and Thermo Fisher. Fellow award winners included Ember.Bio for their work developing RXN wristbands and Mindseye Biomedical.

This award symbolizes much more than DiMe's growing impact in the field of digital medicine. It reflects the security research community's dedication to collaborating with the medical device industry and ensuring the safety of new health technologies — themes reinforced by the event talks, labs, and attendees.

The Medical Device Industry is Embracing Security Researchers



Source: https://medium.com/digital-medicine-society-dime/dime-at-def-con-27-what-we-can-learn-from-the-security-research-community-9558fb4113d1



Join us at CyberMed Summit November 14-15 in San Diego, CA. **RSVP**.

Join us and the FDA at the upcoming PEAC meeting on September 10

How can you help? Share details with other clinicians and patients.

More here: http://bit.ly/2YV5nbj

Join the DiMe community

Could the Digital Medicine Society (DiMe) be your professional home?

Join us. **bit.ly/join-dime**

slack

Machine Learning for Healthcare Professionals

Tuesday, September 3 at 11am ET

Presenter:
Ben Birnbaum, PhD | Machine Learning Lead, Flatiron Health

Presenter: Irene Chen, MS | PhD Candidate at MIT Computer Science & Artificial Intelligence Lab

Presenter: Luca Foschini, PhD | Co-Founder and Chief Data Scientist, Evidation Health

Moderator: Andy Coravos, MBA, | CEO, Elektra Labs; Fellow, Harvard-MIT Center for Regulatory Science

Want to continue the conversation?

@_DiMeSociety

Jennifer@dimesociety.org

@AndreaCoravos

www.dimesociety.org