Introducing the Digital Medicine Society (DiMe)

NIH Collaboratory Grand Rounds
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It’s an exciting time in the digital era of medicine

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


... and since then, the FDA has cleared multiple “software-as-a-medical-device” (SaMDs)
MEDICINE IS GOING DIGITAL. THE FDA IS RACING TO CATCH UP

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

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 through a practical, evidence-based, risk-based methodology.

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/
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.

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.jmir.org/2019/3/e12568/](https://www.jmir.org/2019/3/e12568/)
Source: [https://www.iamthecavalry.org/domains/medical/oath/](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)


Digital Medicine Society Now Accepting Members

New nonprofit aims to advance digital medicine to optimize human health

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

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 care.

Source: https://www.statnews.com/2019/06/05/new-digital-medicine-society/
DiMe sits at the intersection of two communities
What is Digital Medicine?

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

- Generates evidence
- Facilitates collaborations
- Promotes education
Crowdsourced library of digital endpoints

Digital endpoints in industry sponsored studies of:
- new medical products
- new applications of existing medical products

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](https://drive.google.com/file/d/1nAXc4YcP1NoxEwevXo3Fa9PreIqbQXm2/view?usp=sharing)
Public Workshop - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices January 29-30, 2019

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 revised guidance on the content of Premarket Submissions. This effort is part of a broader initiative to work with the industry to ensure medical devices are secure and patients are protected.

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.

Learn more about the FDA-led initiative at WeHeartHackers.org
DiMe at DEF CON 27: What We Can Learn from the Security Research Community

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

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

Patient Engagement Advisory Committee Meeting
Cybersecurity in Medical Devices

Tuesday, September 10, 2019 • Gaithersburg, MD

How can you help? Share details with other clinicians and patients.
Join the DiMe community

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

Machine Learning for Healthcare Professionals
Tuesday, September 3 at 11am ET

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

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

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

**Moderator:** Andy Coravos, MBA | CEO, Elektra Labs; Fellow, Harvard-MIT Center for Regulatory Science
Want to continue the conversation?

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www.dimesociety.org