Guiding Principles on Ethics in Digital Health Produced During a Seminar at Stanford Libraries

Cala Health, Inc. and more than 30 representatives from technology, pharmaceutical, healthcare, public policy, law and bioethics convene at Stanford to address the responsibility around management of personal data.

February 21, 2019 —Stanford, Calif.— Stanford Libraries and its partners today unveiled Guiding Principles on Ethics in Digital Health resulting from a multiday seminar that brought together industry, academic and nonprofit leaders to address the growing concern about management and use of personal health data by digital health organizations.

The statement begins to define 10 principles for digital health entities to ensure the ethical use of their products and services and the information they collect and generate. These principles aim to help digital health organizations navigate potential conflicts between individuals' need for privacy and society's need for protecting public health.

"Libraries have long served as staunch advocates of protecting personal data," said Michael A. Keller, Stanford's university librarian and vice provost for teaching and learning. "An academic library's online and offline environments are designed to pique conversation and debate, and given the exponential rate of developments occurring in the digital health space, we offered to initiate the conversation and report out on results of the seminar."

In July and November 2018 participants discussed and deliberated what consumers should expect from a digital health organization and what obligations that organization has to consumers and to society. The resulting Guiding Principles represent the shared views of over 30 participants:

1. The products of digital health companies should always work in patients' interests.
2. Sharing digital health information should always be to improve a patient's outcomes and those of others.
3. "Do no harm" should apply to the use and sharing of all digital health information.
4. Patients should never be forced to use digital health products against their wishes.
5. Patients should be able to decide whether their information is shared, and to know how a digital health company uses information to generate revenues.
6. Digital health information should be accurate.
7. Digital health information should be protected with strong security tools.
8. Security violations should be reported promptly along with what is being done to fix them.
9. Digital health products should allow patients to be more connected to their care givers.
10. Patients should be actively engaged in the community that is shaping digital health products.

Additional details for each of the 10 principles are available online for download and broader sharing.

"The range of senior level participants in the meetings and the quality of contributions give me confidence that a set of leaders are emerging who take ethical considerations associated with management of personal data very seriously," said Keller, who convened the Digital Health Ethics Seminar and is planning to launch an entire series of conversations with leaders from various industries to discuss ethical implications in their respective verticals. Future seminars under consideration are ethics in communications, transportation, and agriculture and food supply.

"The Guiding Principles on Ethics in Digital Health is a positive step towards ensuring organizations take seriously their duty to care for personal data" said Kate Rosebluth, CEO, Cala Health. She continued, "At Cala Health we partner with patients on all aspects of our wearable neuro-modulation therapies, from product development to real-world user design ensuring that we deliver on the patient's interest in their chronic disease data."

Stanford Libraries have been at the forefront of development of digital technologies, tools and information services. The Guiding Principles for Ethics in Digital Health and all forthcoming documentation from the other seminars in the series will eventually be deposited into the Stanford Digital Repository and become part of the university's discovery environment. "Our intent is to not just make these principles as accessible as possible, but to preserve them as a snapshot in time for researchers and industry leaders invested in this topic," said Keller.

"This is only a first step at addressing the ethical questions looming in digital health. We must start somewhere, so let these principles serve as the conversation starter," said Keller. "We want this first set of ten statements to spur conversations in board rooms, classrooms and community centers around the country and ultimately be refined and adopted widely."

To download the Guiding Principles, learn more about the participants and the seminar visit https://library.stanford.edu/digitalhealthethics.

ABOUT STANFORD LIBRARIES

Stanford Libraries is considered a leading institution for the development of digital technologies, tools and services impacting libraries and archives worldwide. With notable developments in digital technology and its use to increase speed-to-knowledge, Stanford Libraries has become a destination for many of the world's leaders of knowledge curation. With a collection of over 12 million items, Stanford Libraries has created a dynamic discovery environment that powers research, teaching and learning at Stanford and beyond. https://library.stanford.edu | @StanfordLibs

About Cala Health

Cala Health is a bioelectronic medicine company transforming the standard of care for chronic disease. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation. The first indication for Cala

Health's wearable therapy is Essential Tremor, a disease experienced by more than seven million people and characterized by severe hand tremors. New therapies are under development in neurology, cardiology and psychiatry. The company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology. For more information, visit www.calahealth.com.

PARTICIPATING MEMBERS IN DRAFTING GUIDING PRINCIPLES:

Regina Benjamin, M.D.	Gulf States Health Policy Center, UAB	18th Surgeon General of the United States
Samuel Brown, M.D.	Intermountain	Associate Professor, Critical Care & Medical Ethics
Caricia Catalania	IDEO	Head of Healthcare
William Carson, M.D.	Otsuka Pharmaceutical	President of Clinical Development
Jennie Chin Hansen	Independent consultant	Former President of American Geriatrics Society
Sheila Colclasure	Acxiom	Senior Vice, President Global Data Ethics
Stan Crosley	Indiana University	Director of Center for Law, Ethics & Applied Research
Robert Epstein, M.D.	Epstein Health	Chief Executive Officer
Ken Favaro	Act2	Managing Partner
Frank Fischer	Neuropace	Chief Executive Officer
Amy Gutierrez, Pharm D.	Kaiser Permanente	Chief Pharmacy Officer
Jodi Halpern, M.D. Ph.D.	UC Berkeley	Professor of Bioethics and Medical Humanities
Michael A. Keller	Stanford University	Vice Provost for Libraries and University Press and Vice Provost for Teaching and Learning
Alan Levy	Chrono Therapeutics	Founder, Board member, former CEO
David Magnus, M.D.	Stanford University	Professor of Medicine and Biomedical Ethics
Praveen Raja	PATH	Vice President, Technology Development
Kate Rosenbluth	Cala Health	Chief Executive Officer
Paul Saffo	Stanford University	Consulting Professor of Engineering
George Savage, M.D.	Proteus Digital Health	Chief Medical Officer
Mona Sobhani, Ph.D.	University of Southern California	Director of Research and Operations, Center for Body Computing
Joseph R. Swedish	Anthem, Inc	Senior Advisor, former Chairman and CEO
Jon Symonds	HSBC	Vice Chairman of HSBC Holdings
Andrew Thompson	Proteus Digital Health	Chief Executive Officer
Conrad Vial, M.D.	Sutter Health	Chief Physician Executive
Benjamin Wanamaker	Aetna CVS	Vice President, Consumer Technology and Services
Andrew Wright	Otsuka Pharmaceuticals	Vice President of Digital Medicines
Meng Zhang	Tencent	General Manager, Tencent Medical Information Center

And others who prefer to remain anonymous.

###

Contacts:
Gabrielle Karampelas, Stanford Libraries
M: 650-492-9855
T: 650-497-4414
Gkaram@stanford.edu

Terri Clevenger, Cala Health
T: 203-856-4326
Terri.clevenger@icrinc.com