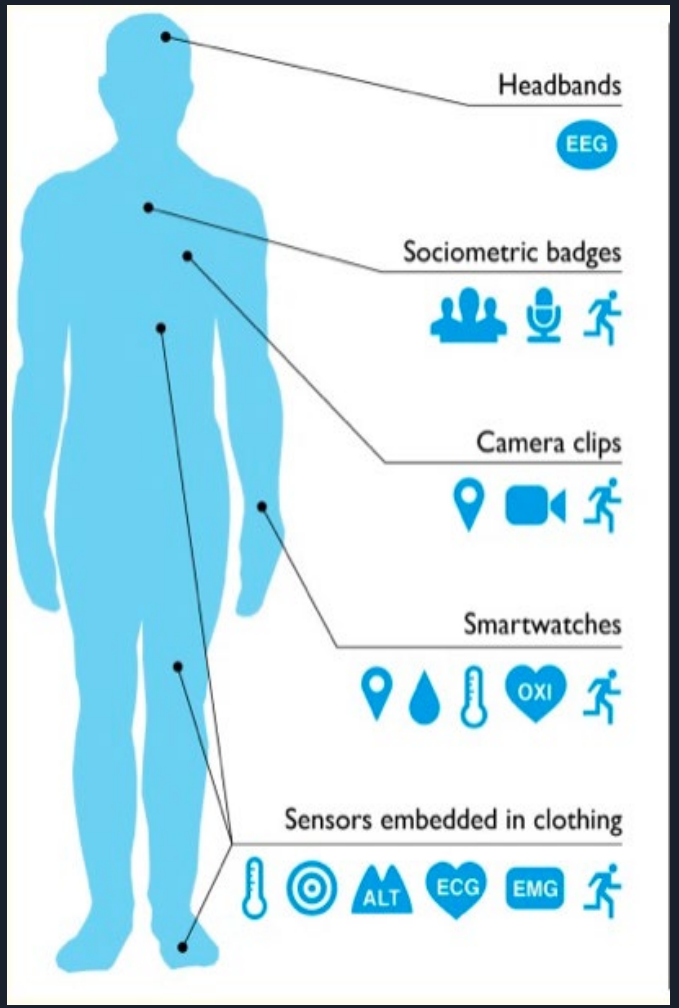
Regulatory Standards for the Safety and Efficacy of Wearable Medical Technologies

Team Never Generic
Thomas Adriaens, Kira Aldrich, Uyen Nguyen, Khang Nong, Mary Zhang

Wearables in the Healthcare Landscape

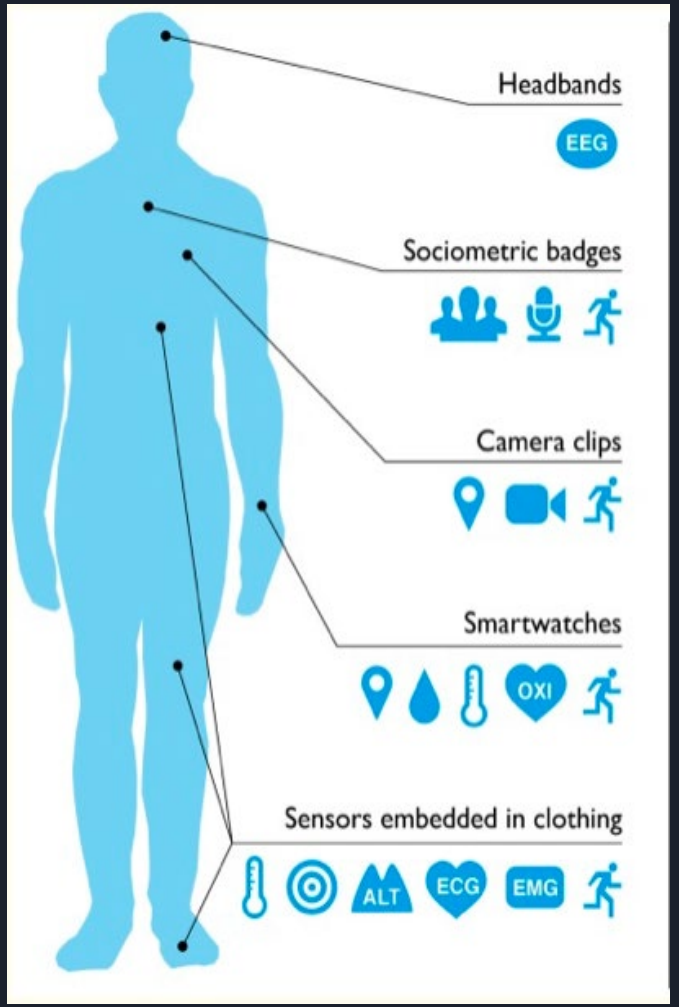
Trend shifting towards patients independently managing their own health using consumer products.



Wearables in the Healthcare Landscape

Role in patients with chronic conditions

- “Predictive preventative diagnosis”
- User-safety gray area
  - False sense of security
  - Over-reliance & misdiagnosis
- Lack of standardized reliability and validity
  - Stanford HEART Trial (Apple)
  - JAMA Dermatology Review



Science News

from research organizations

Researchers urge caution on wearable health devices

Date: February 3, 2016

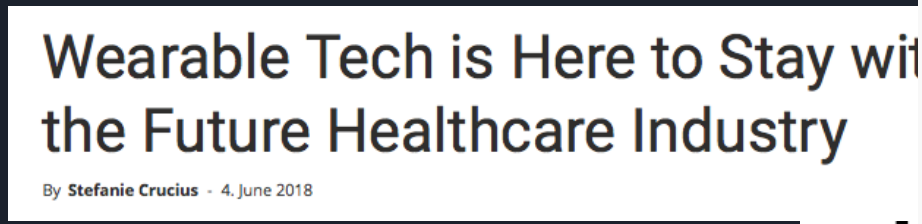
Source: Lancaster University

Summary: Wearable devices to monitor health are not always reliable or secure according to re-

lults expected to
:h next year

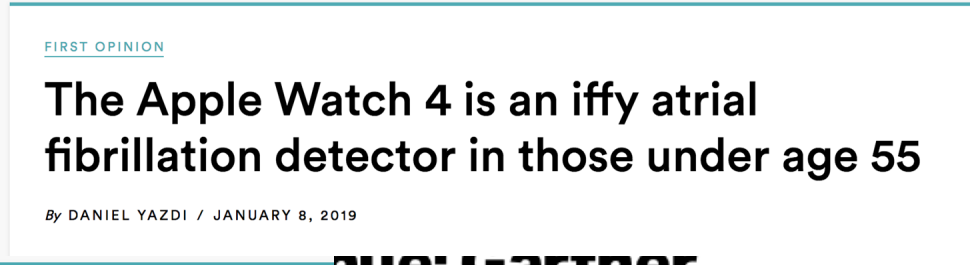
egment growth, thanks to new
s.

BY STEVEN MUSIL | DECEMBER 13, 2018 3:00 AM PST



Wearable Tech is Here to Stay wit
the Future Healthcare Industry

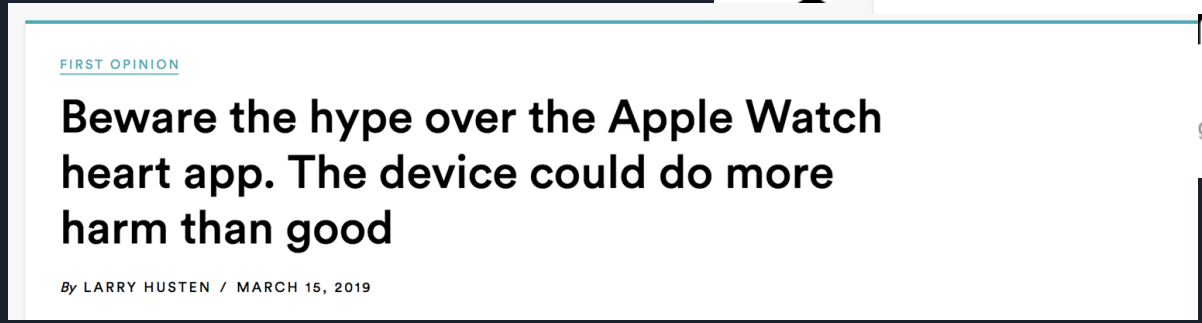
By **Stefanie Crucius** - 4. June 2018



FIRST OPINION

The Apple Watch 4 is an iffy atrial fibrillation detector in those under age 55

By DANIEL YAZDI / JANUARY 8, 2019



FIRST OPINION

Beware the hype over the Apple Watch heart app. The device could do more harm than good

By LARRY HUSTEN / MARCH 15, 2019

nue: Gartner

go

Commer

Definitions

“Wearable medical technologies”

Externally worn and portable devices that operate on software connected to sensor systems intended to measure and track health data.

Devices in Development

Examples:

Apple Watch APIs

FitBit

Smartwatch SmartMonitor

Samsung Galaxy Gear Watch

Device Classifications

Class	Definition	Examples
1	No to mild risk to patient	Thermometers, bedpans, stethoscopes
2	Moderate to high risk to patient	Powered wheelchairs, Apple Watch Series 4, pregnancy test kits
3	High risk to patient	Pacemakers, breast implants

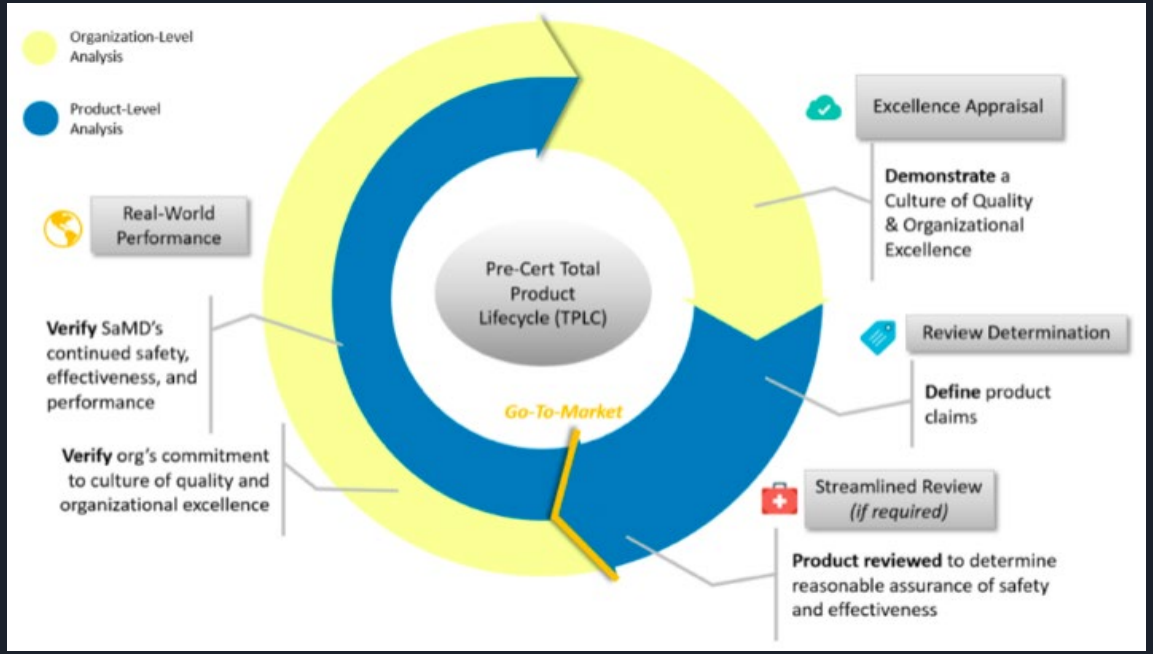
De Novo and 510(K)

De Novo - Classification process for new medical devices to get approved using risk based strategy.

510(K) Pathway- Approval process for medical devices that are substantially equivalent to an approved device already on the market.

The “Pre -Cert” Program

- Digital Health Software Pre-certification Program (“Pre-Cert”)



- SaMD - “Software intended to be used for medical purposes that perform these purposes without being part of a hardware medical device”

Our Proposal

A recommendation and proposal for guidelines addressing the emergence of health-based technologies regarding issues surrounding safety and efficacy

Recommendation 1

After De Novo is granted, an FDA verification mark shall be given to a Class 2 medical device provided it meets high-quality clinical standards based on sufficient clinical trial data demonstrating accuracy and precision in results.

- Patient assurance
- Company incentive
- Digital Health Software Precertification Program

Recommendation 2

False positives and negatives from class II wearable devices with diagnostic and monitoring implications shall be reported to the Manufacturer and User Facility Device Experience (MAUDE) database by patients, healthcare providers, or the manufacturer.

- Manufacturer improvement
- FDA investigation for false-negatives and malfunctions causing significant patient harm.

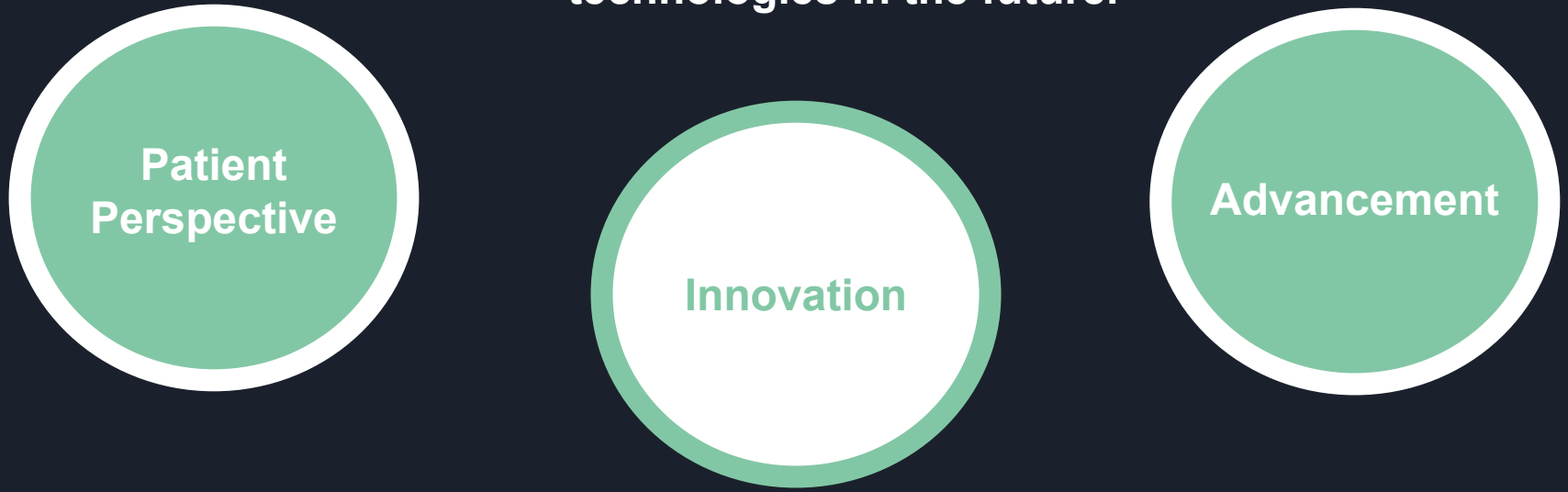
Recommendation 3

Alongside a formally written privacy statement, it is recommended that the medical device manufacturer should have a user-friendly informed consent tutorial to be included in the interface of the medical device or another supported device

- The FDA can incentivize it by using the verification mark per Recommendation 1.

Closing Remarks

With these recommendations, we hope that the FDA can be prepared for the imminent release of many wearable medical technologies in the future.



Thank You!

- **Dr. James Polli**
- **Dr. Marisa Cruz**
- **Ms. Roxane Modares**
- **CERSI and the FDA**

Questions?

References

- Reeder, B., & David, A. (2016). Health at hand: a systematic review of smart watch uses for health and wellness. Journal of biomedical informatics, 63, 269-276.
- Piwek, L., Ellis, D. A., Andrews, S., & Joinson, A. (2016). The rise of consumer health wearables: promises and barriers. PLoS Medicine, 13(2), e1001953.
- US Food and Drug Administration. (2019, February). Digital Health Software Precertification (Pre-Cert) Program. Retrieved from https://www.fda.gov/medicaldevices/digitalhealth/digitalhealthprecertprogram/default.htm
- US Food and Drug Administration. (2017, October). De Novo Classification Process (Evaluation of Automatic Class III Designation). Retrieved from https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080197.pdf
- US Food and Drug Administration. (2014, July). The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]. Retrieved from https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf
- US Food and Drug Administration. (2016, November). Medical Device Reporting for Manufacturers. Retrieved from https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf
- US Food and Drug Administration. Digital Health Action Plan. Retrieved from https://www.fda.gov/downloads/medicaldevices/digitalhealth/ucm568735.pdf