

mHealth and Internet of Things

Sara Marceglia

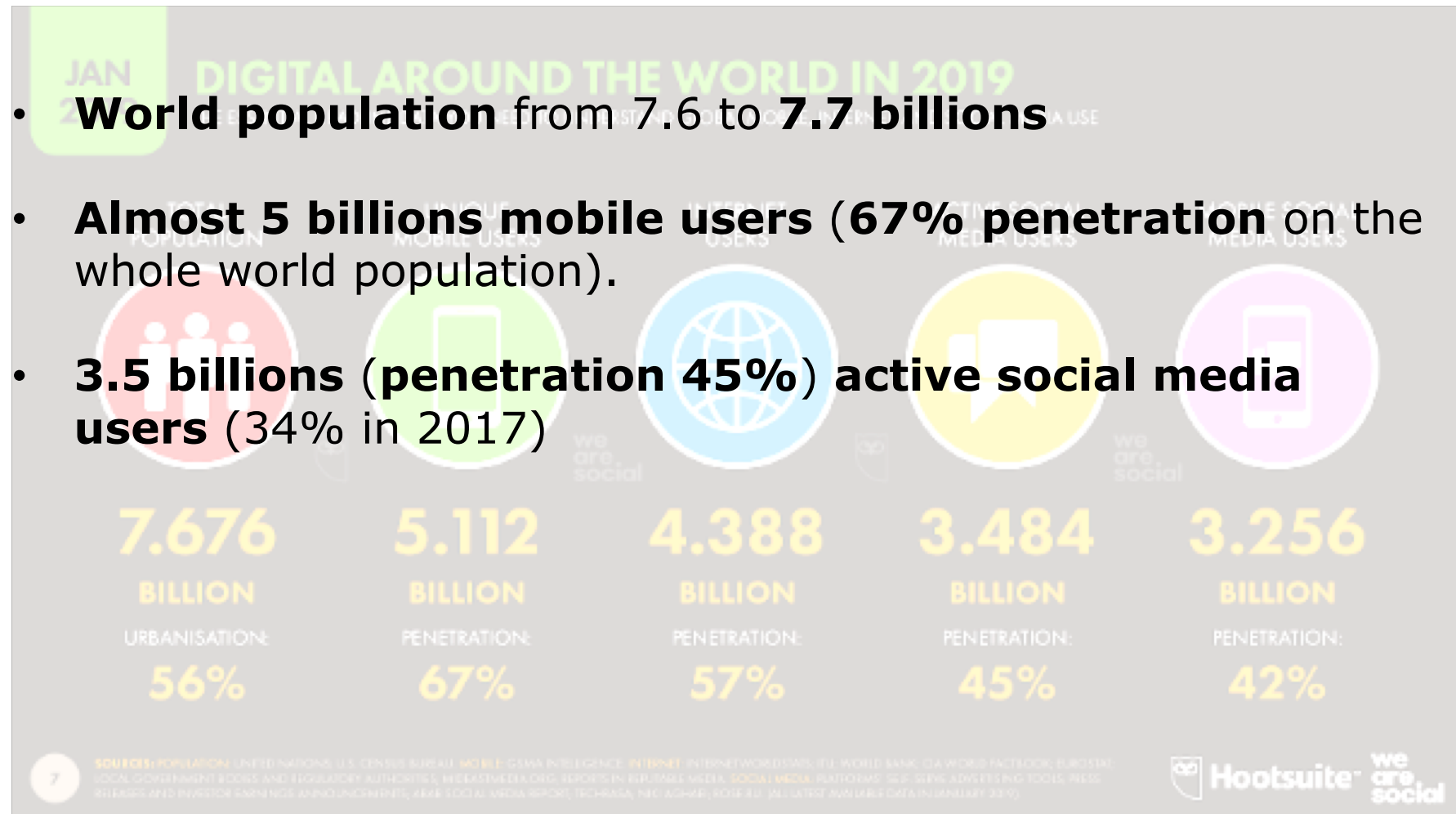


Dipartimento di Ingegneria e Architettura
Università degli Studi di Trieste, Trieste, Italy

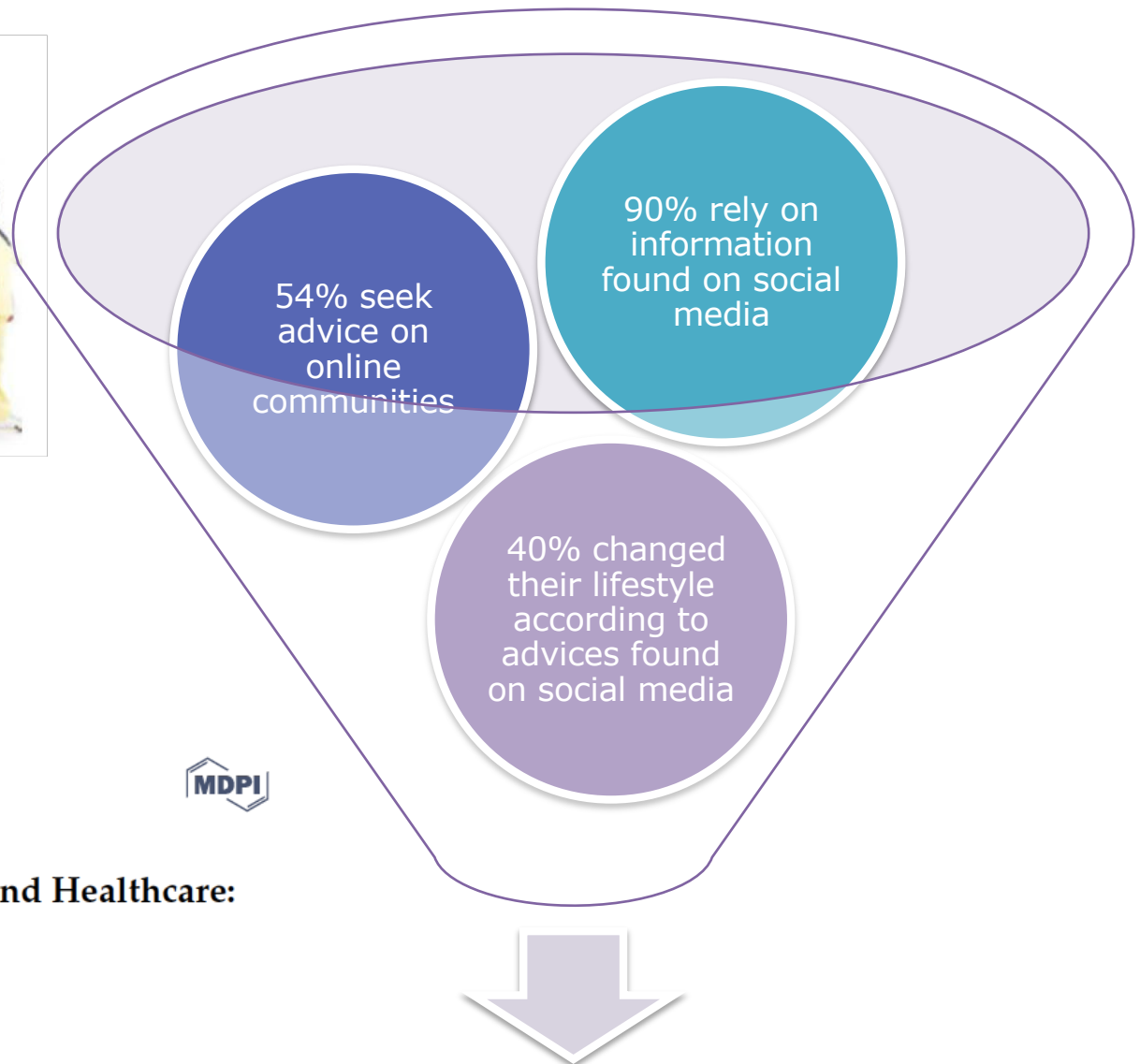
THE SMART WORLD



THE SMART WORLD



HEALTH SOCIAL MEDIA



future internet

Review

**Instagram and WhatsApp in Health and Healthcare:
An Overview**



HEALTH MOBILE APPS

27% of internet users and 20 percent of adults have tracked their weight, diet, exercise routine, symptoms, or another health indicator online.



15000+
Apps
Health&
Fitness

29%
prefers
remote
visits

60%
activity
monitor

33%
Use
health
apps

36%
symptom
checker

**“I don’t know, but I
can try to find out” is
the default setting
for people with
health questions.**

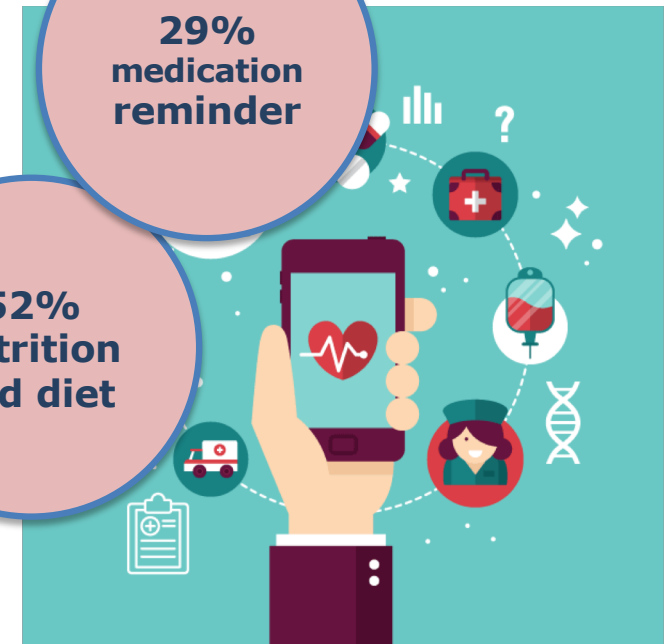
29%
medication
reminder

30%
pathology
monitor

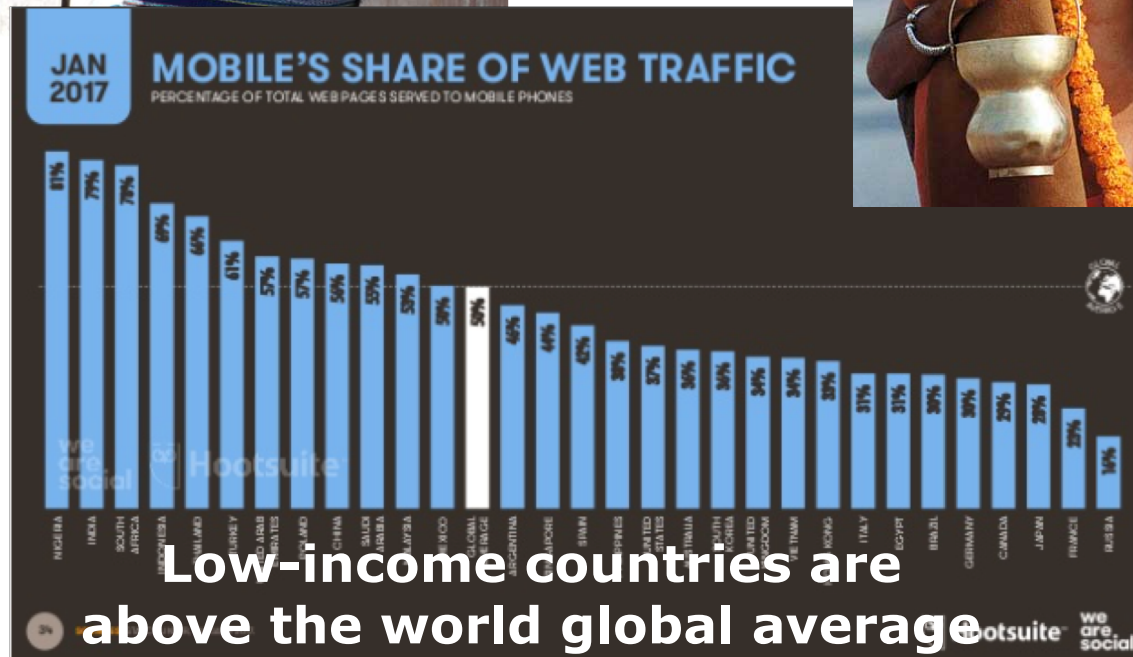
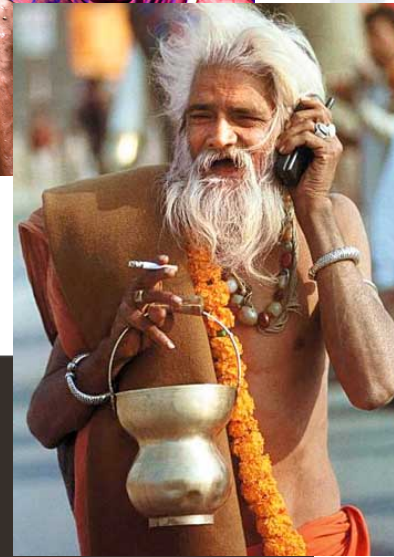
52%
nutrition
and diet

40%
data
exchange
with
physician

90%
would
like to
exchange
data
with
physician



HEALTHCARE INCLUSION



- Digital inclusion also of developing countries
- Distributing healthcare benefits across society (equity)

REAL-TIME COMMUNICATION

INTERACTIVE JOURNAL OF MEDICAL RESEARCH

Giordano et al

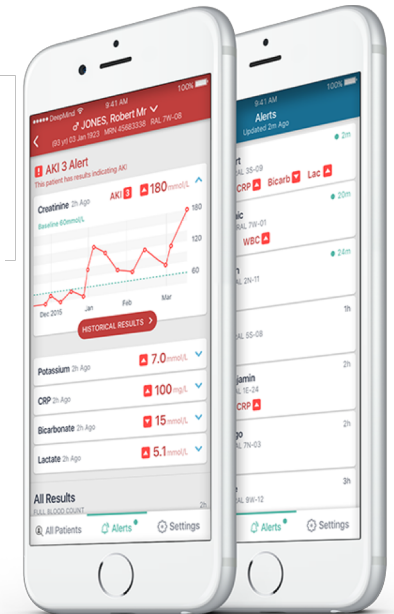
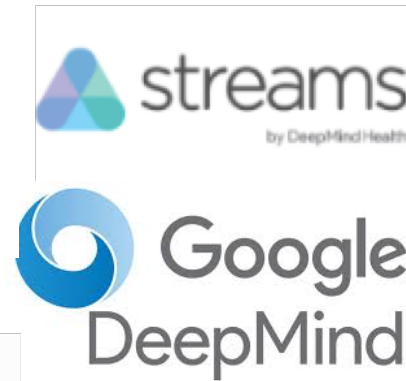
Original Paper

WhatsApp Messenger as an Adjunctive Tool for Telemedicine: An Overview

The mobile app Orchestra connects patients with their doctors for more continuous care, while researchers have access to useful data



eClinicalWorks adds telehealth feature to mobile app
By [Heather Mack](#)



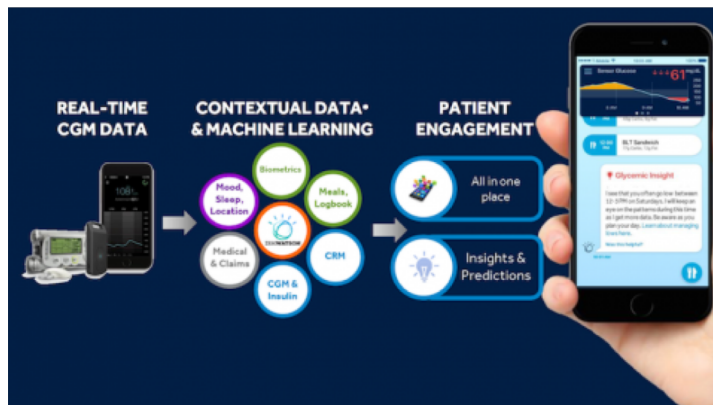
The app helps doctors get information about their acute kidney failure patients to enable faster diagnostics where time is of the



'breaking news' alerts doctors' attention is patients who need it the moment.

PATIENT-CENTERED MEDICINE

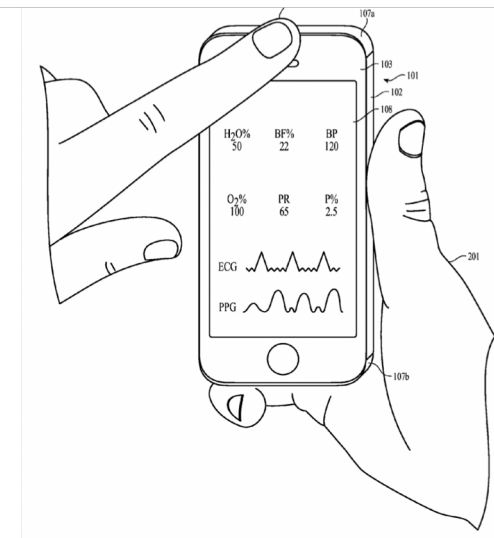
- Patient inclusion in healthcare delivery
- Increased education capability
- Services for non-patients (wellness, healthy lifestyle)
- Moving some health responsibilities to patients



Cochlear Limited launches FDA-cleared, Apple-compatible cochlear implant
By [Jeff Lagasse](#)



Newly granted Apple patent shows ways to turn an iPhone into a health sensor



MEDICAL PRACTICE



Carrier 5:44 PM 100%

Jennifer Harrison

Chart ID: GLKA000001 Gender: Female Age: 25 DoB: 02/15/1986

Chief Complaint: unspecified pain or illness

Temperature Pulse Blood Pressure Respiratory Rate Oxygen Saturation

Height Weight

Clinical Checklist

Diagram 1

General WNL

ON

General Comments

HEENT WNL

Yes

Speech to text in progress

0:00:06

Tap to end

Speech to Text

dr chrono

Lock New eRx eRx Refills Chat Help

VisualDx
mobile

S

Q

A

B

C

D

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M

N

O

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W


X


Y


Z


 **Sarcoidosis**


 **Scabies**

 **Scabies (Pediatric)**

 **Scabies, Crusted**

 **Scar, Anogenital**

 **Scarlet Fever**



COLLECTING DATA FOR RESEARCH

Crowdsourcing for research



A Wandering Mind Is an Unhappy Mind

Matthew A. Killian and David T. Gilbert

We solved this problem by developing a Web application for the iPhone (Apple Incorporated, Cupertino, California), which we used to create an unusually large database of real-time reports of thoughts, feelings, and actions of a broad range of people as they went about their daily activities. The application contacts participants through

To Your Health

Large DNA study using 23andMe data finds 15 sites linked to depression

Collect digital data for advanced analytics

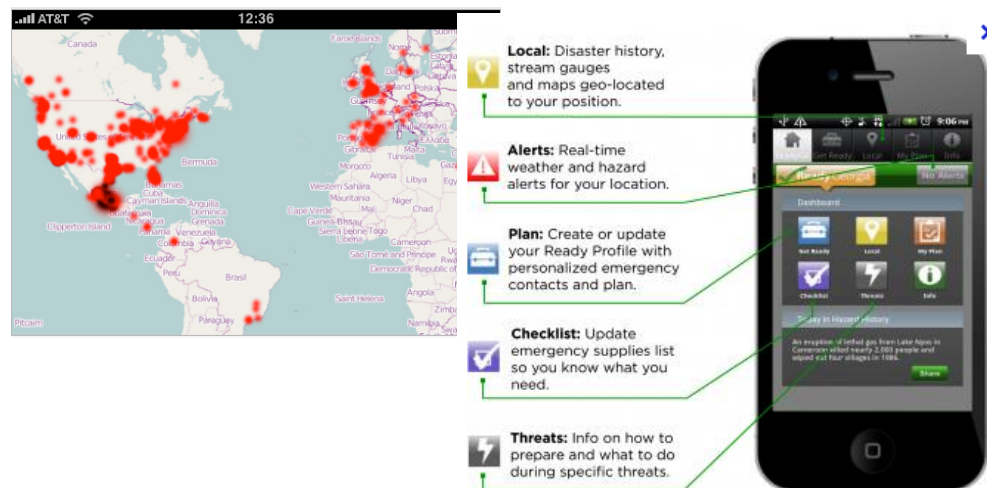


About Research Partnership News Careers Contact

Novel Data and Analytics

Evidation Health's technology platform and services enable healthcare companies to partner with patients and consumers who are engaged in understanding and improving health outcomes.

Mapping diseases with GPS



Sanofi and Evidation Health to work together to understand, treat disease

By Jeff Lagasse | August 1, 2017

Medicines aren't the only tools that biopharma companies like Sanofi are using to help patients. Information technology has become a key tool in every part of Sanofi's business, and among the most important digital tools are data and analytics; they enable the company to apply insights gained from real world evidence to the discovery, development and delivery of new medicines. To advance that...

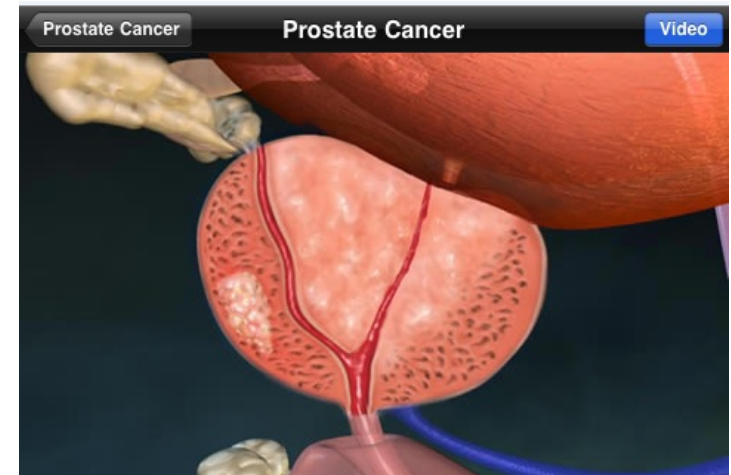
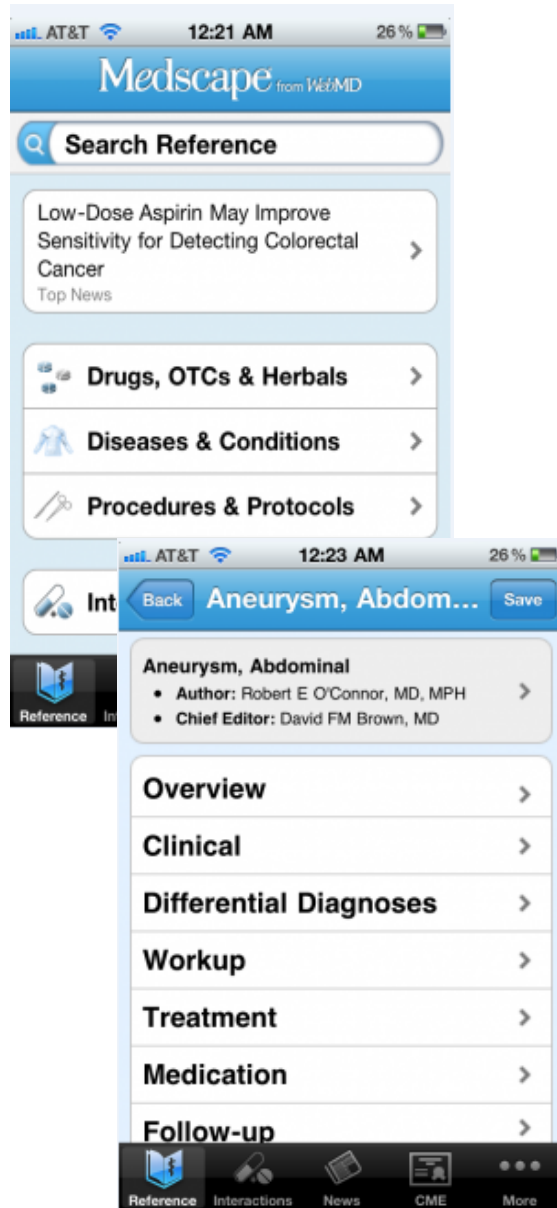


Brigham and Women's partners with Evidation Health to research impact of digital tools in clinical trials

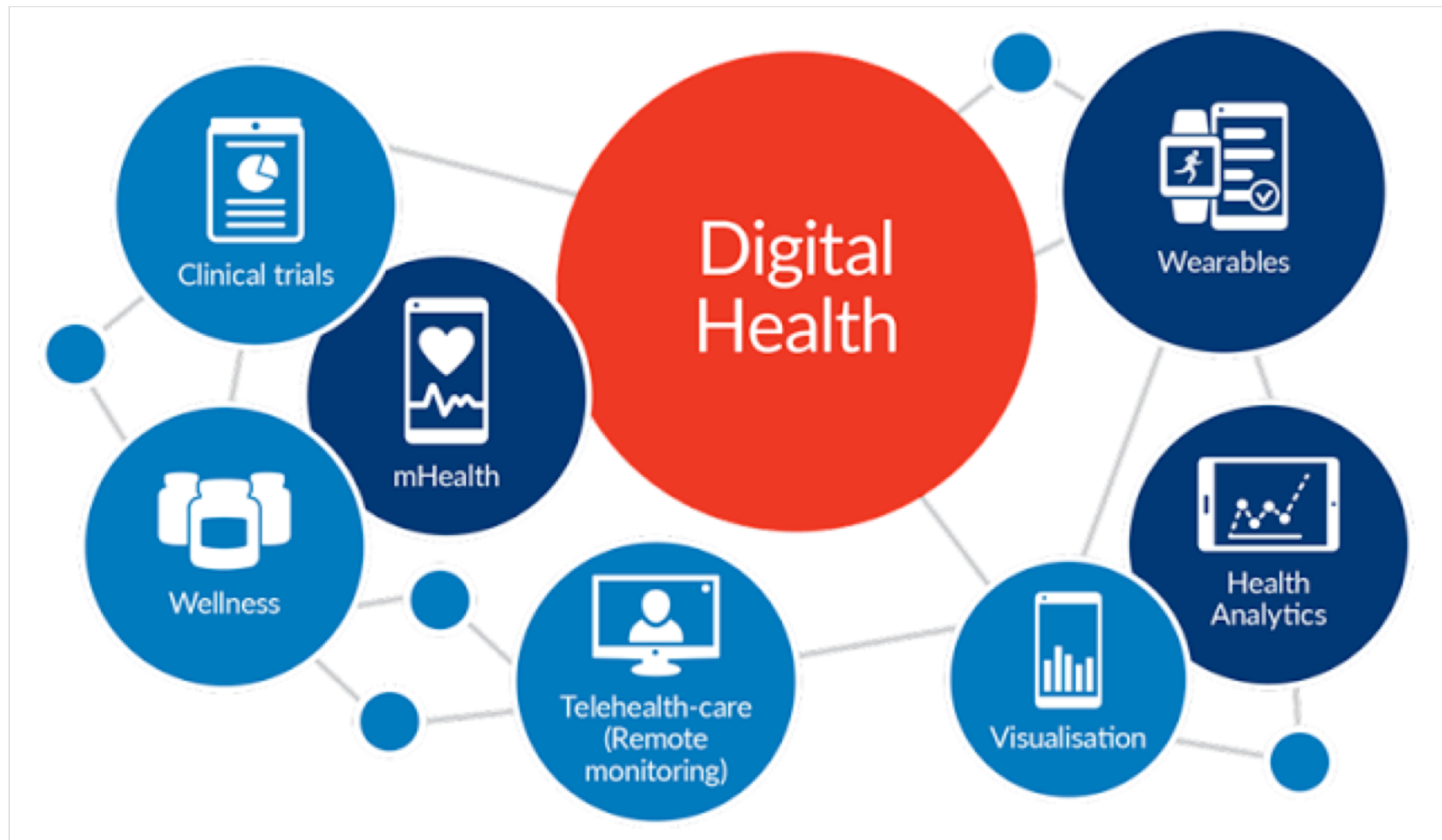
By Heather Mack | October 21, 2016

The innovation arm of Brigham and Women's Hospital has partnered with efficacy-focused digital health company Evidation Health to collaborate on a project measuring the real life impact of digital health solutions on clinical and financial outcomes. The idea is to combine forces to develop methods of creating direct-to-patient trials of digital health solutions, leveraging the research...

MEDICAL EDUCATION



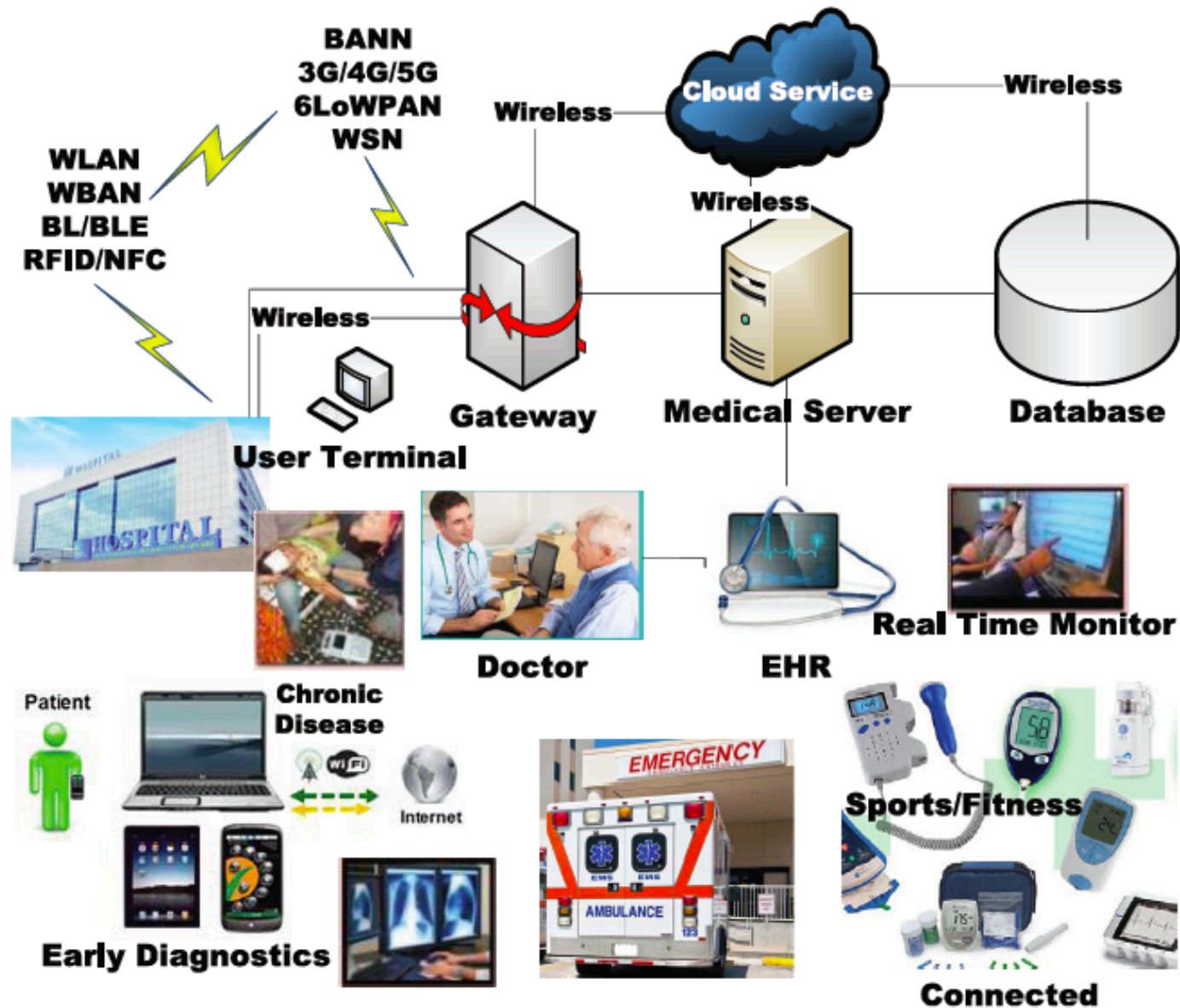
mHEALTH AND IoT



IoT

*"Interconnection of sensing and actuating **devices** providing the ability to **share information** across platforms through a unified framework, developing a common operating picture for **enabling innovative applications**. This is achieved by seamless **ubiquitous sensing, data analytics and information representation with Cloud computing** as the unifying framework."*

Internet of (health) Things



Apple Watch adds gym equipment integration, built-in Bluetooth



"Apple Watch is designed to help you live a healthier life," CEO Tim Cook said, "and people are absolutely loving the fitness capabilities, the health capabilities, the quick access to information, and even the ability to swim with it."

The biggest update to the Apple Watch health and fitness suite was an integration between the watch and fitness equipment at the gym. Brands like LifeFitness, Matrix, TechnoGym, Star Trac, Cybex, Schwinn, and StairMaster, which sell 80 percent of the country's fitness equipment, will start to roll out Apple Watch-integrated equipment this fall.

IO(h)T

- Intellis system for treating chronic pain by delivering neurostimulation at the spinal cord.
- Using a Samsung Galaxy Tab S2, the patient's caregiver can adjust the neurostimulation according to a workflow designed by Medtronic called Evolve.



Medtronic gets FDA clearance for pain management implant that interfaces with Samsung tablet

WEREABLE HEALTH

Hollywog launches smartphone-controlled pain management wearable

By Dave Muoio | October 09, 2017

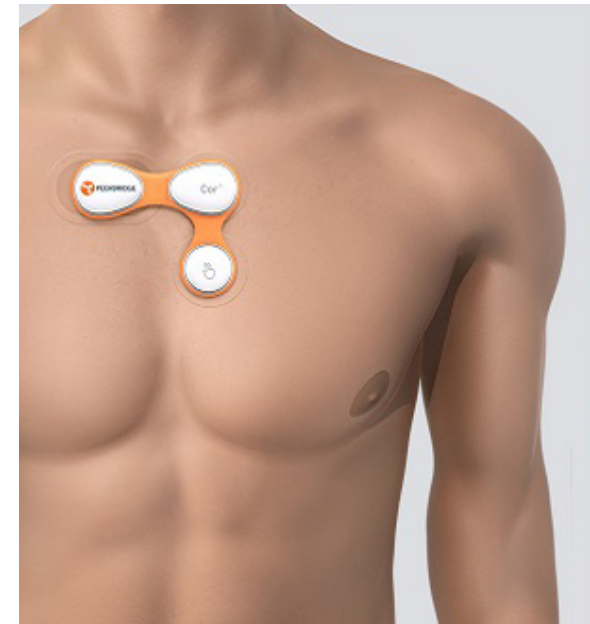
SHARE < 55



Peerbridge's wireless multi-channel ECG cleared by FDA

By Dave Muoio | October 06, 2017

SHARE < 573



Hearable: hearing aids with Bluetooth capability and connection to smartphones

SENSORS AND DRUGS

In-Depth: How digital sensors could change the face of pharma

By **Jonah Comstock** | November 17, 2017

Earlier this week, Proteus Digital Health and Otsuka Pharmaceuticals announced that Abilify MyCite, a new, sensor-enabled version of Otsuka's drug for schizophrenia, **had received FDA approval** for mental health conditions including schizophrenia and bipolar disorder.

The Proteus digital medicine platform is a medication management and adherence system that includes sensor-enabled pills, a peel-and-stick biometric sensor patch worn on the body, and a companion smartphone app. The patch records when a pill is ingested and can also track other things like sleep patterns and physical activity levels.

A historic clearance

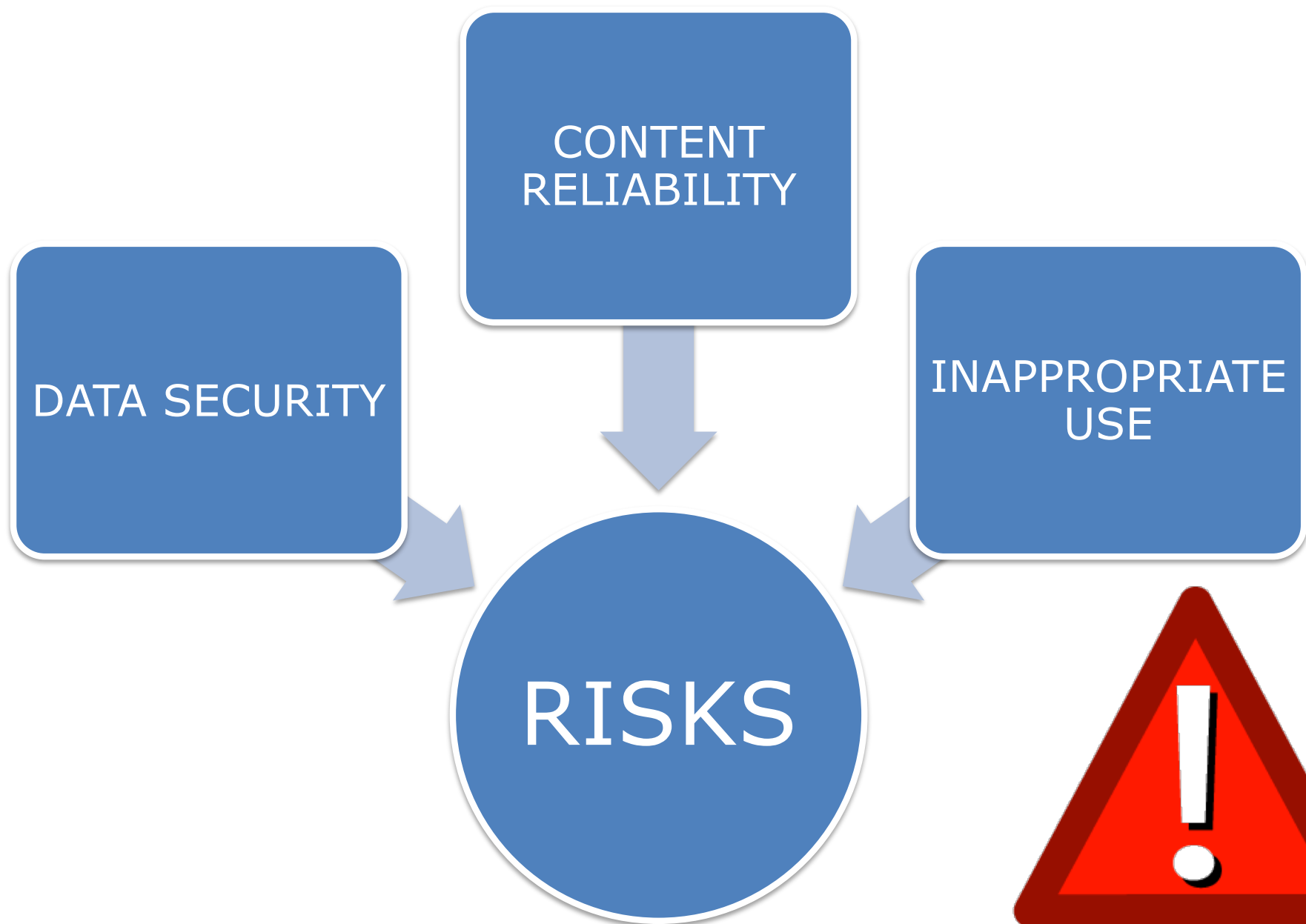
For those who have been aware of Proteus for a long time, the importance of this latest regulatory win might not be obvious. It's far from the first FDA nod for the startup, which saw its patch first cleared in 2010 and its pill first cleared in 2012. Proteus has also been using its technology in small hospital deployments for some time.




mobihealthnews


Nonetheless, this is something new and potentially game changing. For one thing, previous clearances went through the FDA's medical device pathway and didn't allow the system to be prescribed the way the Abilify's clearance eventually will.

CONCERNS & CAVEATS




QUALITY, RELIABILITY, AND USEFULNESS

NIH U.S. National Library of Medicine

 **MedlinePlus**
Trusted Health Information for You

Search MedlinePlus

About

 **HealthDay**

Is Web-Based Test for Prediabetes Faulty?

Assessment finds 8 in 10 Americans over 60 at risk, a conclusion questioned by several experts

Monday, October 3, 2016

JAMA | Original Investigation

Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss The IDEA Randomized Clinical Trial

John M. Jakicic, PhD; Kelliann K. Davis, PhD; Renee J. Rogers, PhD; Wendy C. King, PhD; Marsha D. Marcus, PhD; Diane Helsel, PhD, RD; Amy D. Rickman, PhD, RD, LDN; Abdus S. Wahed, PhD; Steven H. Belle, PhD

September 20, 2016

Activity Trackers Are Ineffective at Sustaining Weight Loss

Newly released Pitt study, published today in JAMA, finds commercially available wearable devices for gauging physical activity are not useful tools for weight loss

STUDY

Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection

Joel A. Wolf, BA; Jacqueline F. Moreau, BA; Oleg Akilov, MD; Timothy Patton, DO; Joseph C. English III, MD; Jonhan Ho, MD; Laura K. Ferris, MD, PhD

Medical apps for smartphones: lack of evidence undermines quality and safety

Arthur Willem Gerard Buijink,¹ Benjamin Jelle Visser,² Louise Marshall³

BMJ

BMJ 2013;346:f1811 doi: 10.1136/bmj.f1811 (Published 20 March 2013)

Page 1 of 2

How do we know whether medical apps work?

Smartphone apps have the potential to transform the way the public manage their health and interact with health services, says **Margaret McCartney**, but regulation of medical apps has only just started

Margaret McCartney *general practitioner, Glasgow*

OPEN ACCESS Freely available online

PLOS ONE

mHealth: A Strategic Field without a Solid Scientific Soul. A Systematic Review of Pain-Related Apps

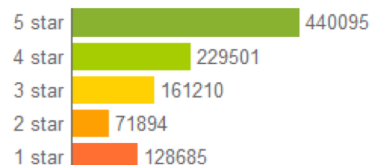
Rocío de la Vega, Jordi Miró*

Unit for the Study and Treatment of Pain - ALGOS, Research Center for Behavior Assessment, Department of Psychology and Institut d'Investigació Sanitària Pere Virgili, Universitat Rovira i Virgili, Tarragona, Spain



PATIENT'S QUALITY EVALUATION

User Reviews



Average rating:

3.8



1,028,105

WIRED APPS

LE MIGLIORI APP PER MOBILE PER SALUTE

Categoria: **salute**

Benessere e salute: le applicazioni che non possono mancare sul tuo smartphone se vuoi avere cura di te stesso.

marie claire



PROFUMI
Eterno Chanel N°5

TENDENZE
Vestiamo alla
marinara



MODA | SFILATE | BELLEZZA | BENESSERE | NEWS E PERSONE | LIFESTYLE | MAGAZINE | MAISON | CU



Le 10 migliori app per la salute per iPhone 6



Like

21

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Codici sconto | Donne vere | Digital School | Mondadori per te

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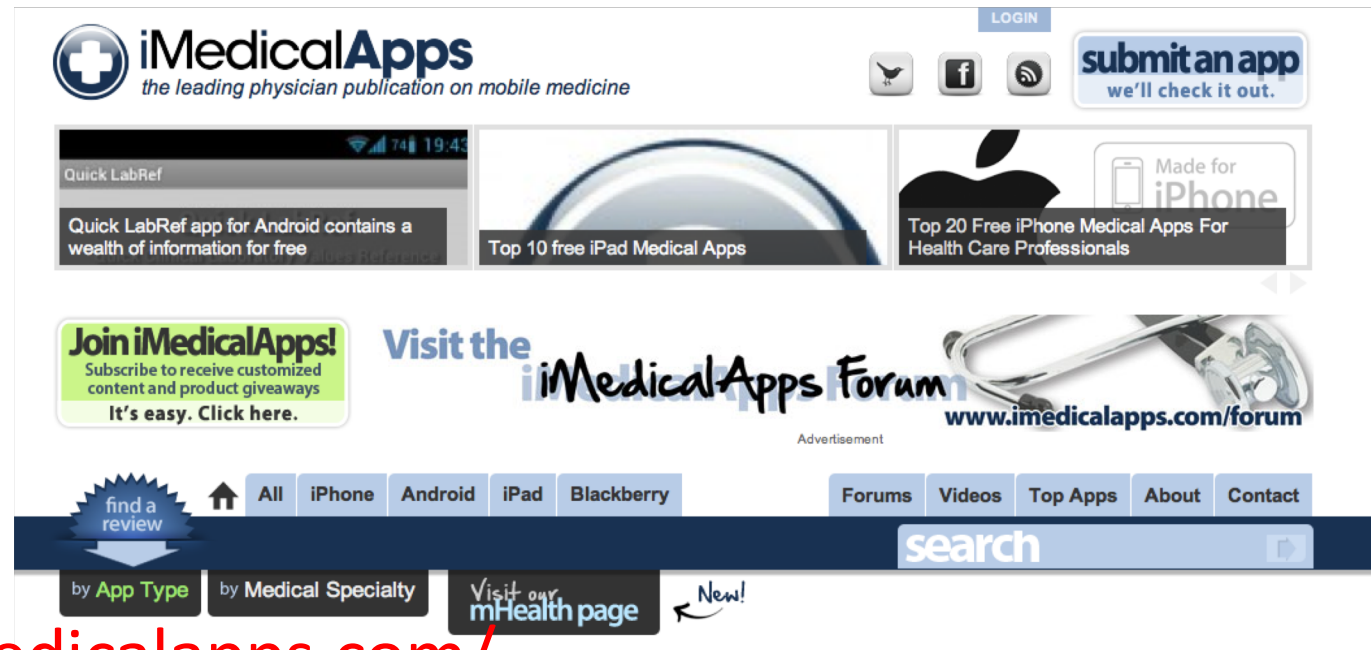
Mi piace 53

Home | News | Bellezza | Moda | Sfilate | Cucina | Ricette | Mamme | Salute | Casa | Fai da te

Le app per la nostra salute

Come monitorare il proprio stato di salute direttamente dallo smartphone? Ecco una raccolta delle migliori app gratuite disponibili per iPhone:

SPECIALIZED REVIEW SITES



<http://www.imedicalapps.com/>

Curated Health Apps & Devices

With a Focus on Clinical Relevance, Safety, and Efficacy

Reviews by Clinicians, Researchers, & Patients.

Led by Experts From Top Ranked Teaching Hospitals & Universities.

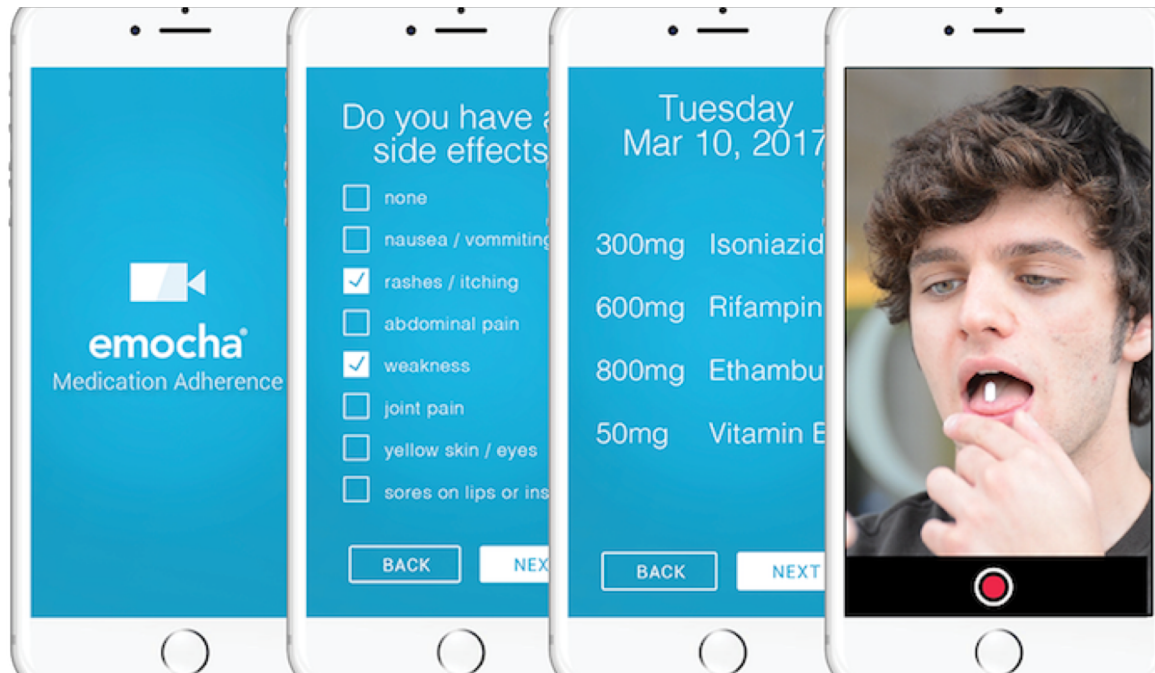
Hacking Medicine's consumer health review site launches

By [Jonah Comstock](#) | May 03, 2016

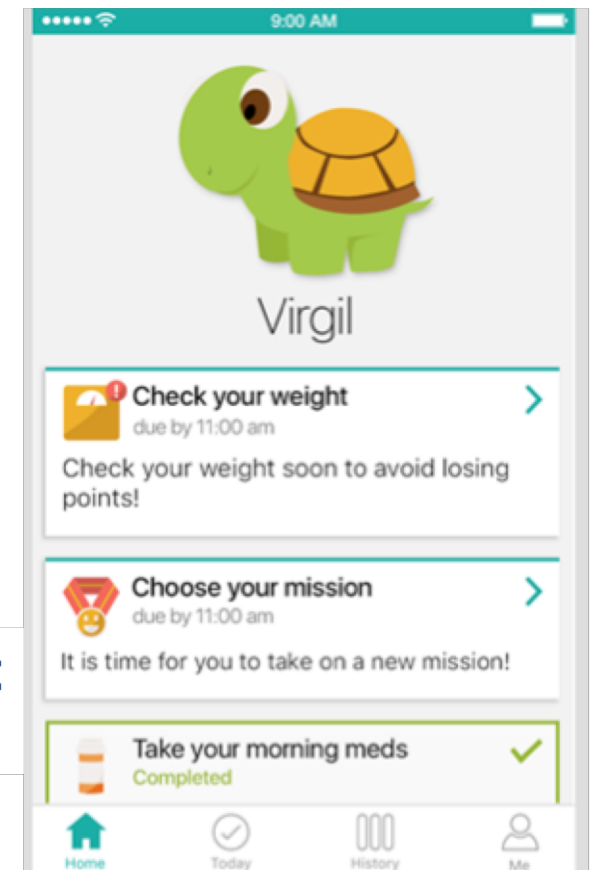
<http://www.rankedhealth.com>

COMPANIES MOVING FORWARD

With \$1.7M NIDA grant, emocha will evaluate its app for treating opioid addiction



Duke to study two mobile apps in 8,000-patient quality improvement trial



CLINICAL STUDIES

Akili preparing FDA bid following strong results of adolescent ADHD trial

By **Dave Muoio** | December 04, 2017

Boston-based **Akili Interactive Labs** has announced positive results from the largest clinical trial of its video game-based pediatric ADHD treatment yet. In light of these data, the company announced that it now plans to file AKL-T01, also known as Project: Evo ADHD Treatment, for FDA clearance as a novel treatment for children and adolescents with ADHD



Study: Smartphone photos found 83 percent accurate for pediatric dermatology diagnoses

By **Laura Lovett** | December 04, 2017

SHARE

FDA APPROVAL

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** |

Healthcare IT News sister site MobiHealthNews was half right when it **predicted in February of this year** that an algorithm for detecting atrial fibrillation could be the Apple's first FDA-cleared product. The company did receive clearance for such an algorithm, likely using data from the **recently-concluded Apple Heart Study to submit the application.**






https://www.healthcareitnews.com/news/apple-unveils-watch-series-4-fda-approved-ecg?mkt_tok=eyJpIjoiWXpFeE5EQTFaalJrTjJSayIsInQiOiJ4bDRrb2M5ckZYK1V2SlJwbkxvaXUwak9WbDdRUEJ0VjIjXNDI5VTBVdmNtTTJpWnRwenRuSmNkaGUyU0lVWW15TFJXajU3TUI3UjU0NE5KQ013TERESVRHREhVNVdcL2cwVjV2c2J6TkdrRVhDV2FtMEVmVEMrXC9Fcm5FbDFzUTFHIn0%3D

PRESCRIBING APPS

Mount Sinai launches RxUniverse, a system-wide platform to prescribe medical apps

By **Heather Mack** (/content/heather-mack) | November 03, 2016





Have you prescribed an app today?

Please choose your organization

Mount Sinai

[Forgot Password?](#)

Log in

[New User? Register Here](#)

GUIDELINES



Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff

Document issued on February 9, 2015.

This document supersedes "Mobile Medical Applications: Guidance for Food and Drug Administration Staff" issued on September 25, 2013.

This document was updated to be consistent with the guidance document "Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" issued on February 9, 2015.

For questions about this document regarding CDRH-regulated devices, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-7800.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

The new Regulations on medical devices

May 2017

On 5 April 2017, 2 new Regulations on medical devices were adopted. These replace the existing Directives.

Reclassification of mobile medical apps for smartphones and other mobile devices → **generally risk class IIa, but under certain conditions can be risk class IIb or III.** (Rule 11 in Annex VIII MDR)

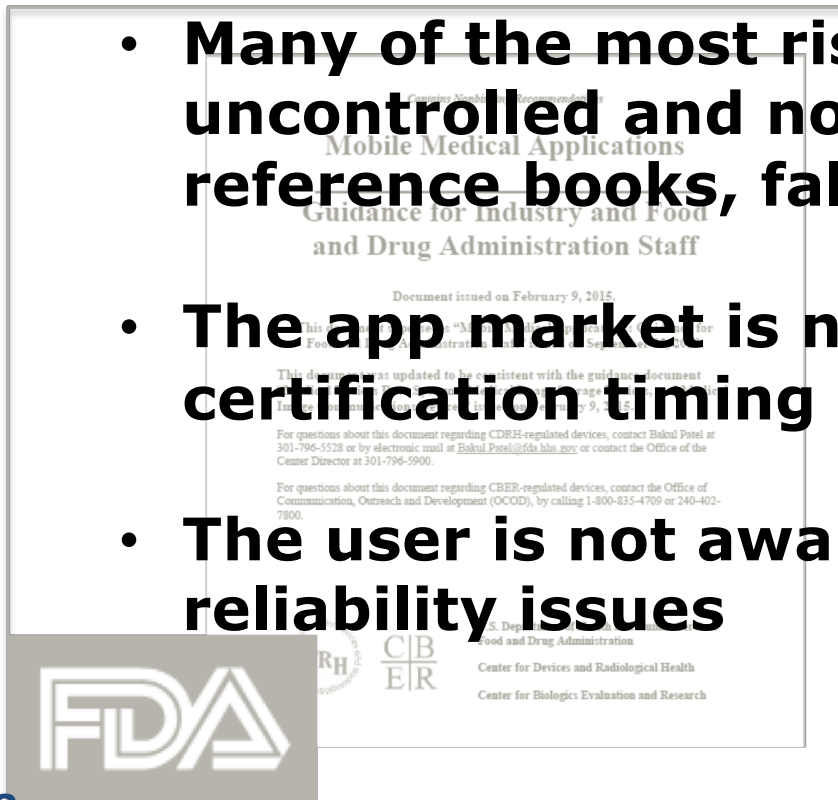
mHealth assessment guidelines working group



GUIDELINES

HOWEVER...

- There is a grey zone of Apps that are not medical devices and fall outside the regulation
- Many of the most risky Apps, such as uncontrolled and not expert-reviewed reference books, fall outside the regulation
- The app market is not compatible with certification timing
- The user is not aware of quality and reliability issues



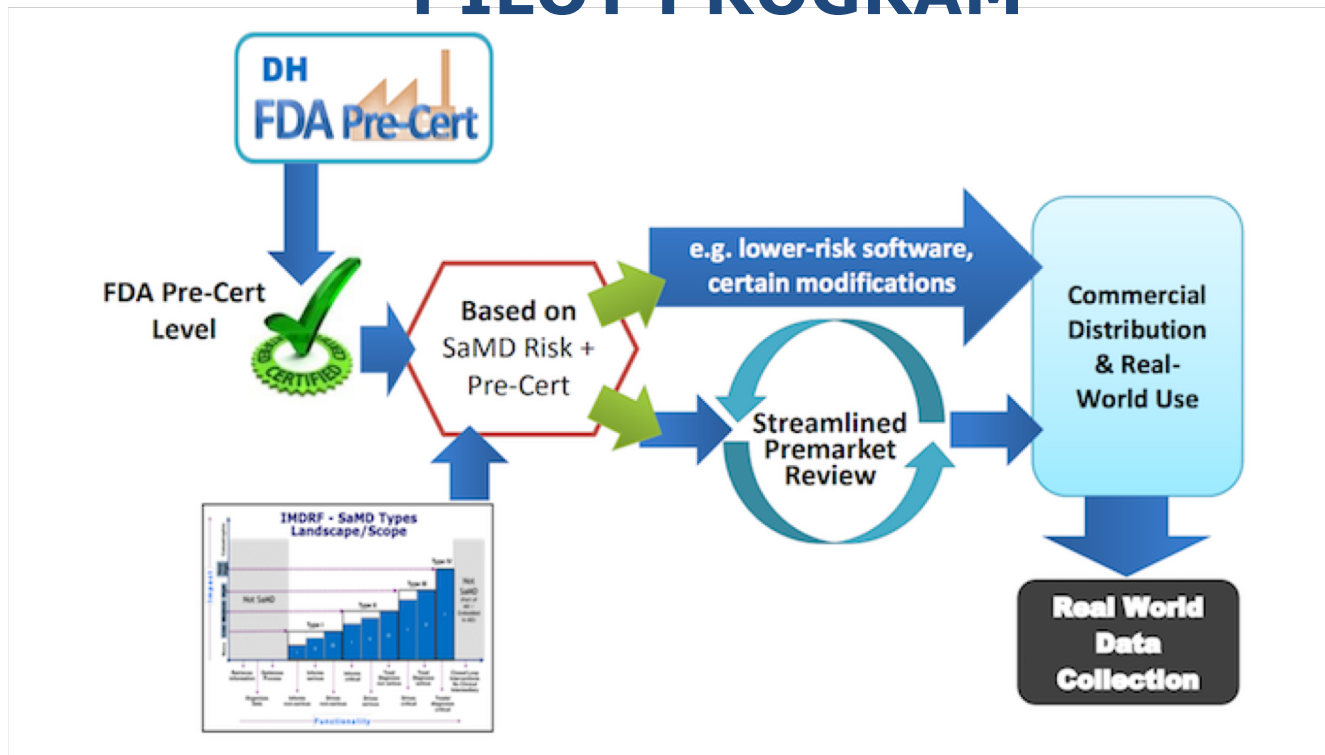
EU REGULATION

Sotware e app mediche sono “dispositivi medici” e dovranno avere il marchio CE. La sentenza della Corte di Giustizia Europea

La Corte ha stabilito che “un software è di per sé un dispositivo medico quando è specificamente destinato dal fabbricante ad essere impiegato per una o più delle finalità mediche stabilite nella definizione di dispositivo medico” e partendo da tale assunto hanno dichiarato che il software può essere dispositivi medico anche senza impiego “sull'uomo”. [LA SENTENZA](#)

RESPONSE FROM THE FDA

THE FDA PRE-CERTIFICATION PILOT PROGRAM



- The basic goal of the Pre-Cert program is that it will **focus not on particular products but on firms and developers.**
- If the FDA is satisfied that the firm is responsible and safe in its development, **then it won't need to regulate each product from that firm.**

RISKS FOR USERS

Cyberpsychology, Behavior, and Social Networking, VOL. 19, NO. 11 | Original Articles

normal

The Facebook Experiment: Quitting Facebook Leads to Higher Levels of Well-Being

Tromholt Morten ✉

Published Online: 1 Nov 2016 | <https://doi.org/10.1089/cyber.2016.0259>

DISOTERTED MEMORIES

"If we direct all of our attention toward capturing the best shots for our social media followers to admire, less will be available to enjoy other aspects of the experience in real time,"

SLEEP

Getting worked up with anxiety or envy from what we see on social media keeps the brain on high alert, preventing us from falling asleep

Gen Z is quitting social media in droves because it makes them unhappy, study finds

March 09, 2018 by Oliver McAteer, Campaign

It's the most socially savvy generation, but many are leaving multiple platforms and marketers need to know why.

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN®

Guidance for the Clinician in
Rendering Pediatric Care

Clinical Report—The Impact of Social Media on
Children, Adolescents, and Families

SECURITY AND PRIVACY



- Individuals may have **a limited or incorrect understanding of when data about their health is protected by law, and when it is not** → some health-related information are stored in places that usually treat non-health information (e.g., Twitter, Facebook, etc) → HIPAA rule does not apply
- Health information collected in **different places without consistent security standards** may pose a cybersecurity threat (of which individuals may be unaware)
- Medical device manufacturers may not be covered entities or business associates under HIPAA. This leaves a **health care provider using a medical device with potentially greater responsibility for assuring privacy and security protections** for health information created and shared by the device



DATA COLLECTION

- Through mHealth apps and wearables terabytes of personal health data are collected daily →
 - Who owns the data?
 - Will the makers of the fitness bands sell personal information?
 - Will it be anonymous and aggregated or associated with us by name?
 - What if we want to contribute our data—to a doctor? To a research study?
 - How are they collected?
 - Who can use/analyze these data

IOT AND ENLARGED NETWORKS



ICS-CERT

INDUSTRIAL CONTROL SYSTEMS CYBER EMERGENCY RESPONSE TEAM

Advisory (ICSMA-17-250-02)

Smiths Medical Medfusion 4000 Wireless Syringe Infusion Pump Vulnerabilities

Original release date: September 07, 2017

- Challenge of Io(h)T → Securing health care data and medical devices (consumer and clinical) to protect patients and provide the highest level of care.
- Io(h)T often uses non-regulated devices that may affect privacy, safety, and patient care.
- Who is in charge?
 - FDA
 - HIPAA
 - HHS
 - Government
- Too many regulations that apply to different devices/systems that are now connected → need to harmonize existing and future laws and regulations that affect healthcare industry cybersecurity.

CHALLENGES: INTEGRATION

