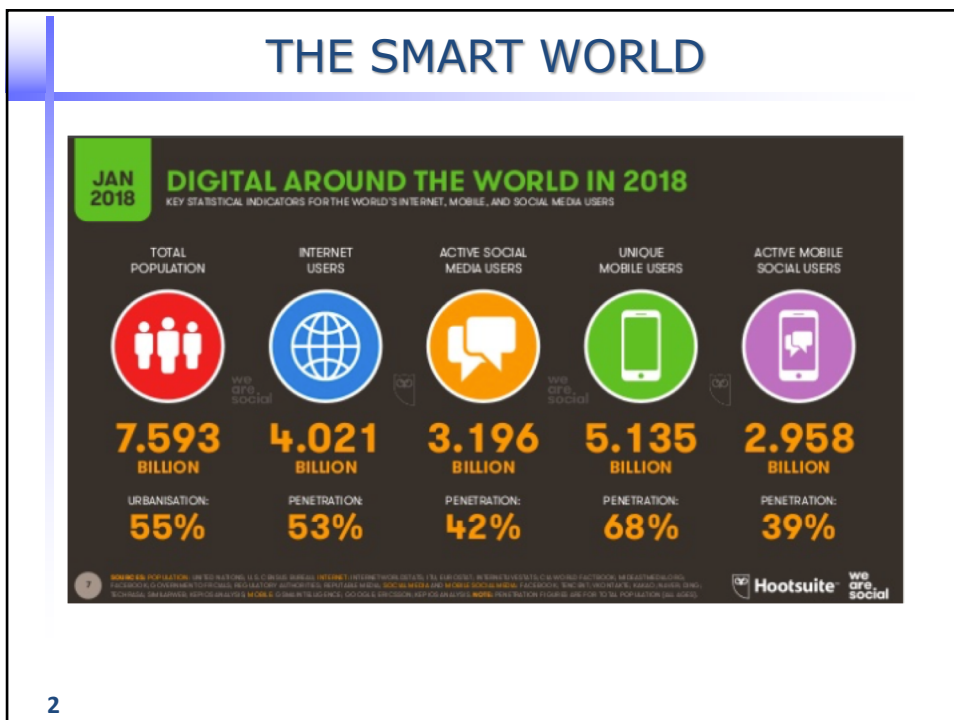


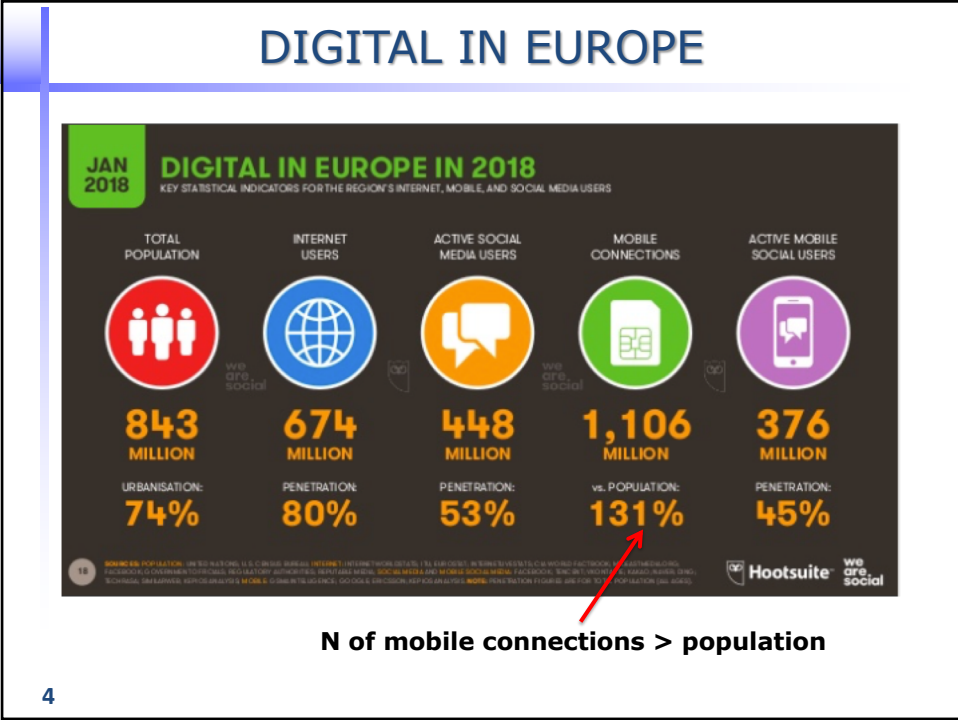
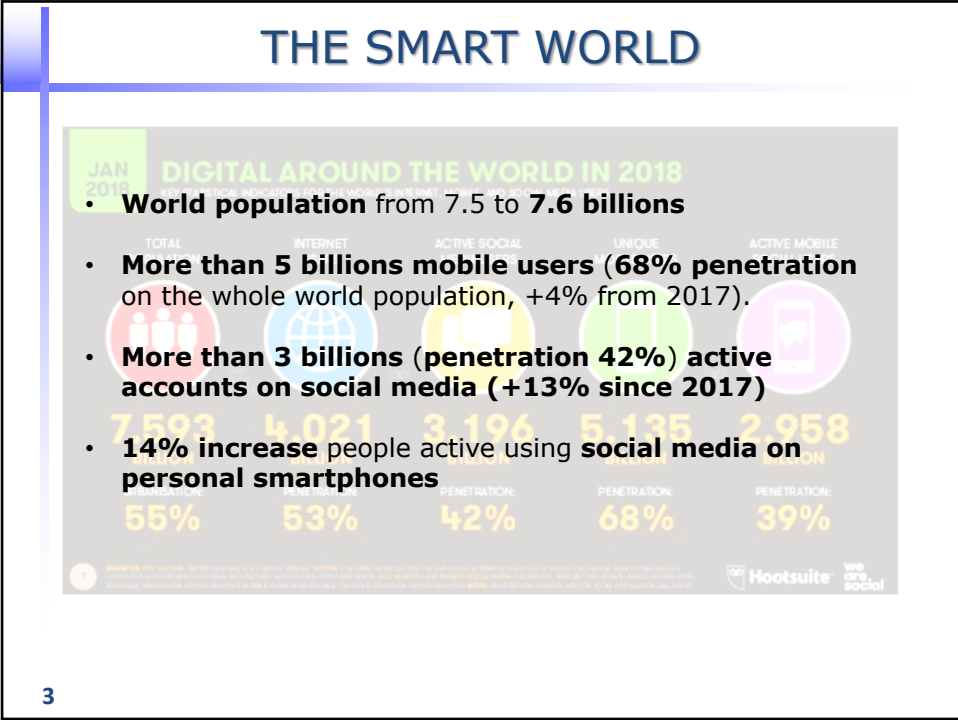
Cooperation activity  
VIII Spring School  
on  
"IoT, economic and management challenges for e-health integration in the enlarged Europe"  
Koper, Slovenia 14<sup>th</sup> - 17<sup>th</sup> May 2018

# mHealth and Apps for citizens, patients and doctors: promises, caveats, and challenges

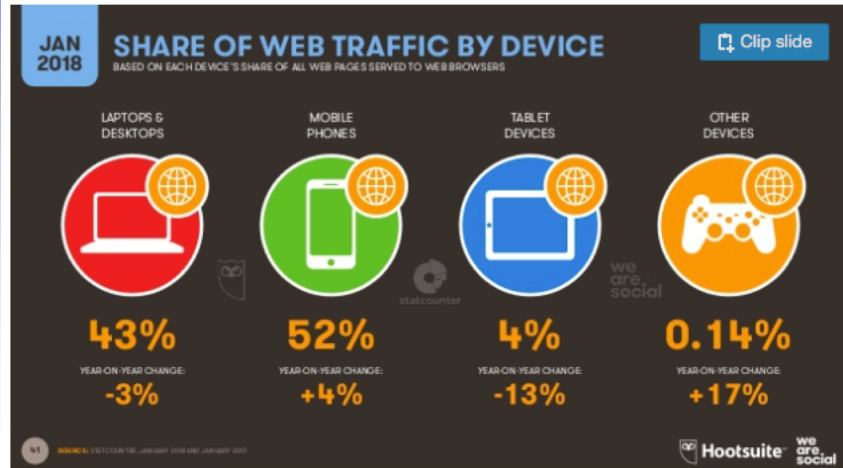
*Sara Marceglia*

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





## WEB TRAFFIC SHARE



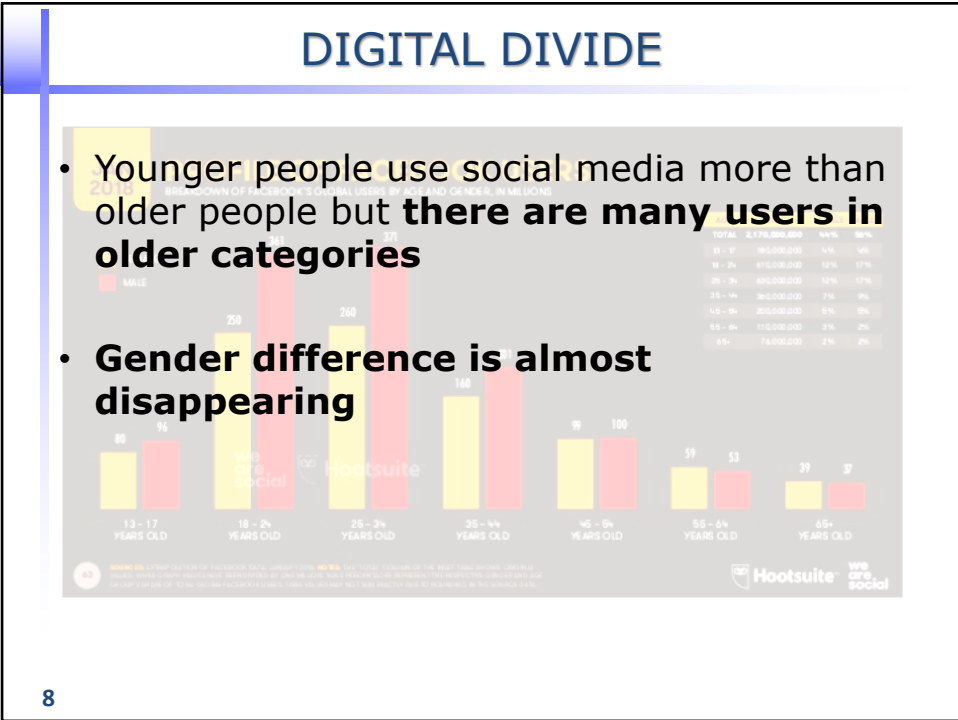
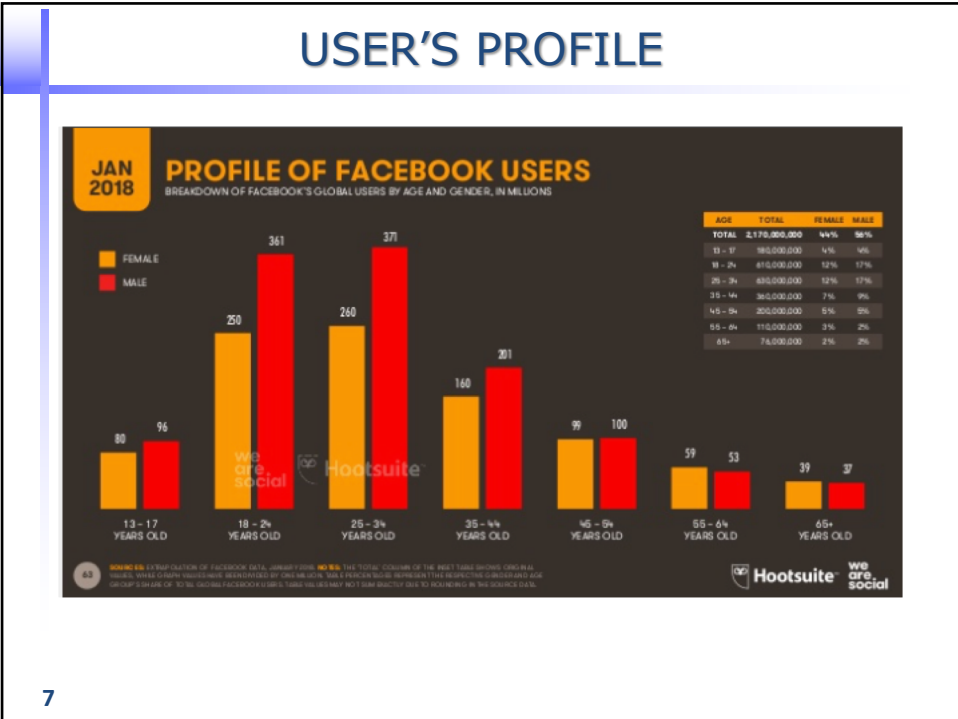
Decrease in Laptop/Desktop users, steady mobile phone users, increase in other devices users

5

## MOBILE APPS



6



## INFORMATION SOURCES

**JAN 2018** **THE WORLD'S MOST VISITED WEBSITES**  
RANKINGS OF THE WEBSITES THAT ATTRACT THE GREATEST VOLUME OF WEB TRAFFIC IN THE WORLD

**SIMILARWEB RANKING, BASED ON TOTAL TRAFFIC TO WEBSITE**

#	WEBSITE	CATEGORY	TIME PER VISIT
01	GOOGLE.COM	SEARCH	07:07
02	FACEBOOK.COM	SOCIAL	13:41
03	YOUTUBE.COM	VIDEO	19:56
04	BAIDU.COM	SEARCH	08:49
05	XVIDEOS.COM	ADULT	13:01
06	YIDIANZIKUN.COM	SEARCH	16:12
07	GOOGLE.CO.IN	SEARCH	07:47
08	SOGOU.COM	SEARCH	06:23
09	XNXX.COM	ADULT	13:16
10	YAHOO.COM	NEWS	06:14

**ALEXA RANKING, BASED ON AVERAGE DAILY VISITORS AND PAGE VIEWS**

#	WEBSITE	CATEGORY	TIME PER DAY
01	GOOGLE.COM	SEARCH	07:35
02	YOUTUBE.COM	VIDEO	08:18
03	FACEBOOK.COM	SOCIAL	10:20
04	BAIDU.COM	SEARCH	07:32
05	WIKIPEDIA.ORG	REFERENCE	04:16
06	REDDIT.COM	SOCIAL	16:47
07	YAHOO.COM	NEWS	04:03
08	GOOGLE.CO.IN	SEARCH	07:05
09	QQ.COM	NEWS	04:34
10	AMAZON.COM	SHOPPING	08:29

SOURCES: SIMILARWEB (DATA FOR NOVEMBER 2017); ALEXA (DATA FOR SEPTEMBER 6 - JANUARY 2008); TRAFFIC: HOURS AND SECONDS.

Hootsuite we are social

9

## MOBILE AND INFORMATION SOURCES

**JAN 2016** **THE WORLD'S MOST VISITED WEBSITES**  
RANKINGS OF THE WEBSITES THAT ATTRACT THE GREATEST VOLUME OF WEB TRAFFIC IN THE WORLD

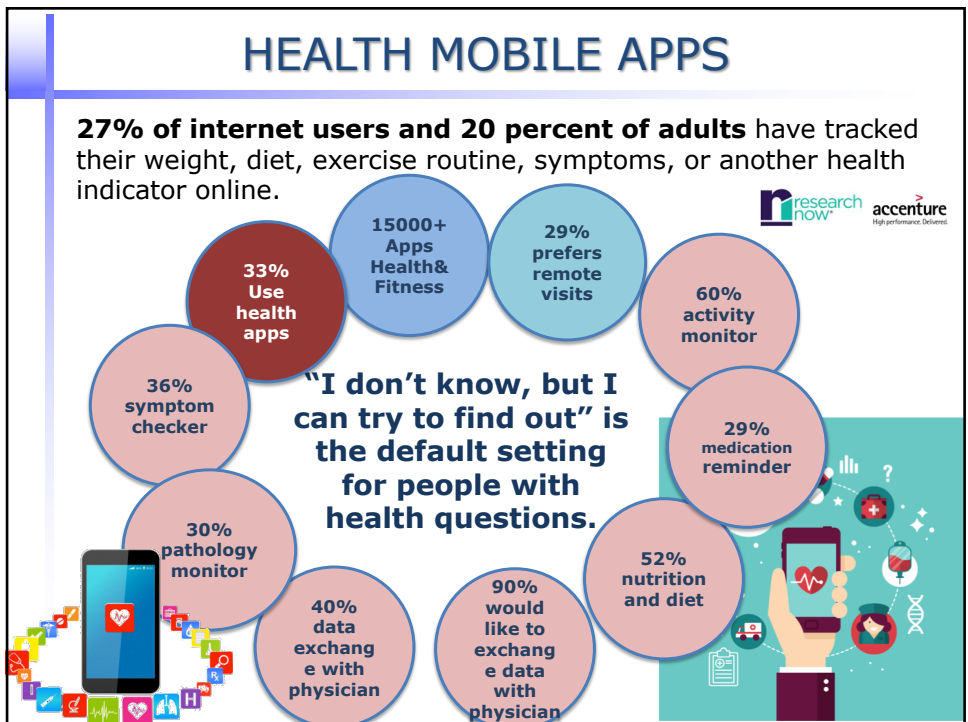
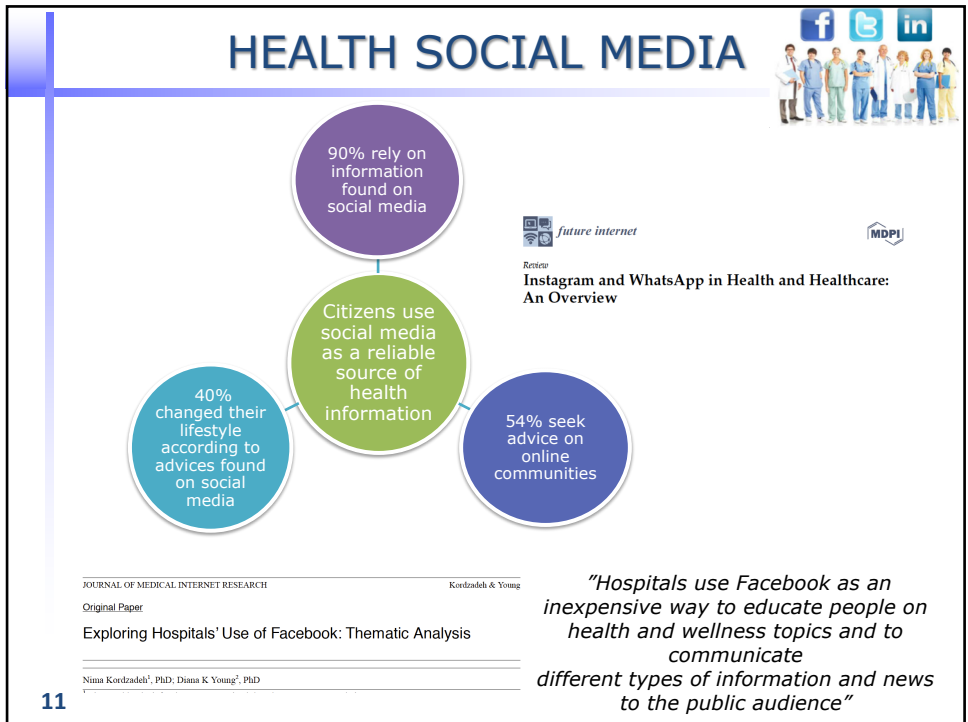
- Internet search engines like **Google** are the **3rd source of information** (51,4%)
- Facebook** is the **fifth** (43,7%).
- Among **younger people**:
  - First: Facebook (71,1%)**
  - Second: Google (68,7%)**
  - Fourth: YouTube (53,6%)**

#	WEBSITE	CATEGORY	TIME PER VISIT
01	GOOGLE.COM	SEARCH	07:07
02	FACEBOOK.COM	SOCIAL	13:41
03	YOUTUBE.COM	VIDEO	19:56
04	BAIDU.COM	SEARCH	08:49
05	XVIDEOS.COM	ADULT	13:01
06	YIDIANZIKUN.COM	SEARCH	16:12
07	GOOGLE.CO.IN	SEARCH	07:47
08	SOGOU.COM	SEARCH	06:23
09	XNXX.COM	ADULT	13:16
10	YAHOO.COM	NEWS	06:14

SOURCES: SIMILARWEB (DATA FOR NOVEMBER 2015); ALEXA (DATA FOR SEPTEMBER 6 - JANUARY 2008); TRAFFIC: HOURS AND SECONDS.

Censis 2016 Hootsuite we are social

10



## WEARABLES



Fitbit Charge HR salva la vita ad un malato di cuore!

The number of devices connected to the Internet was 12.5 billion in 2010, making the number of connected devices per person >1 (1.84) for the first time in history. Now they are 25 billions



O'Ve: lo smartwatch che monitora i raggi UV e ci protegge dalle malattie della pelle!



SOWATCH: lo smartwatch che previene l'ictus

You can be 100 percent identified, as an individual, by your Fitbit data.



THIM, il primo wearable al mondo "migliora-sonno" | Video



Hodei Technology helps hospitals use Google Glass for surgical collaboration: rural telemedicine



13 Dignity Health using Google Glass to improve clinical efficiency



## IO(h)T

### 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.

14

## 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**

15

## WEARABLE HEALTH DEVICES

### Hollywog launches smartphone-controlled pain management wearable

By Dave Muolo | October 09, 2017

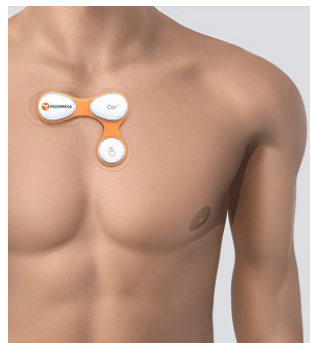
SHARE



### Peerbridge's wireless multi-channel ECG cleared by FDA

By Dave Muolo | October 06, 2017

SHARE 373



16



## 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

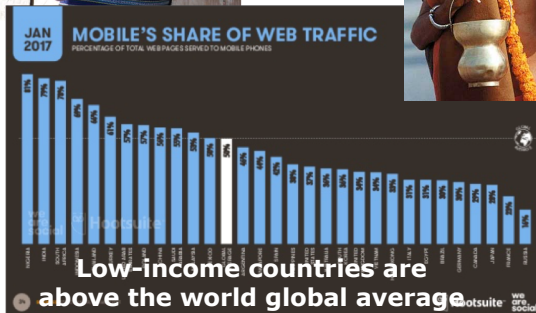
For those who have been aware of Proteus for a long time, the importance of this latest regulatory win might not be obvious. It's far from the first FDA nod for the startup, which saw its patch first cleared in 2010 and its pill first cleared in 2012. Proteus has also been using its technology in small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

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.



17

## HEALTHCARE INCLUSION



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

18

## 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

19



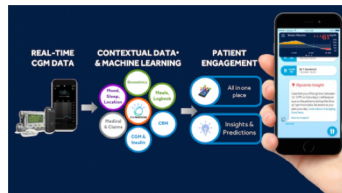
The app helps doctors get information about their acute kidney failure patients to enable faster diagnostics where time is of the



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

## PATIENT-CENTERED MEDICINE

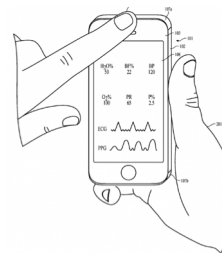
- Patient inclusion in healthcare delivery
- Increased education capability
- Services for non-patients (wellness, healthy lifestyle)
- Moving some health responsibilities to patients



Cochlear Limited launches FDA-cleared, Apple-compatible cochlear implant  
By Jeff Lagasse

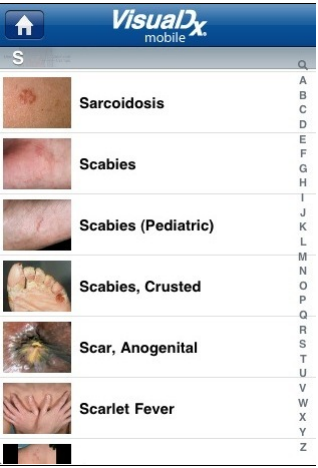


Newly granted Apple patent shows ways to turn an iPhone into a health sensor



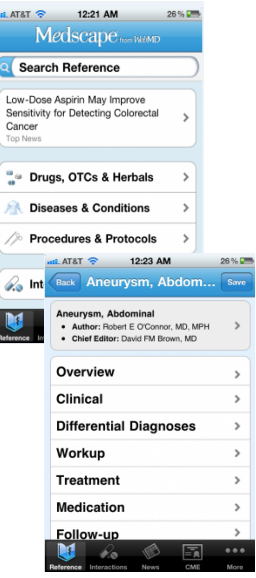
## MEDICAL PRACTICE


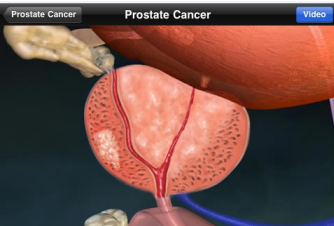
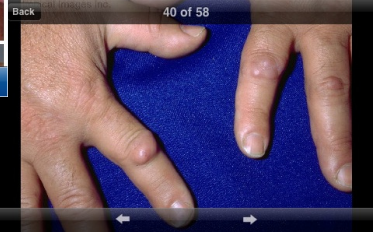






## MEDICAL EDUCATION



# COLLECTING DATA FOR RESEARCH

## Crowdsourcing for research

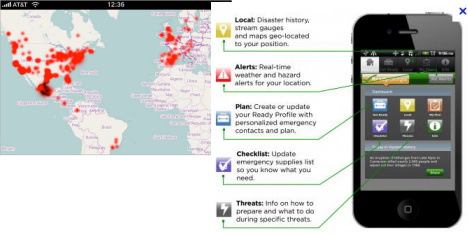
### A Wandering Mind Is an Unhappy Mind

**Science**  
AAAS

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

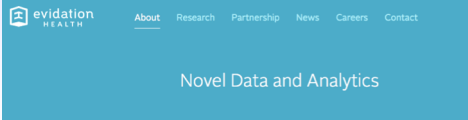
**To Your Health**  
**Large DNA study using 23andMe data finds 15 sites linked to depression**

## Mapping diseases with GPS



- Local:** Disaster history, stream gauges, and maps geo-located to your position.
- Alerts:** Real-time weather and hazard alerts for your location.
- Plan:** Create or update your Ready Profile with personalized emergency contacts and plan.
- Checklist:** Update emergency supplies list to you know what you need.
- Threats:** Info on how to prepare and what to do during specific threats.

## Collect digital data for advanced 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.

### 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

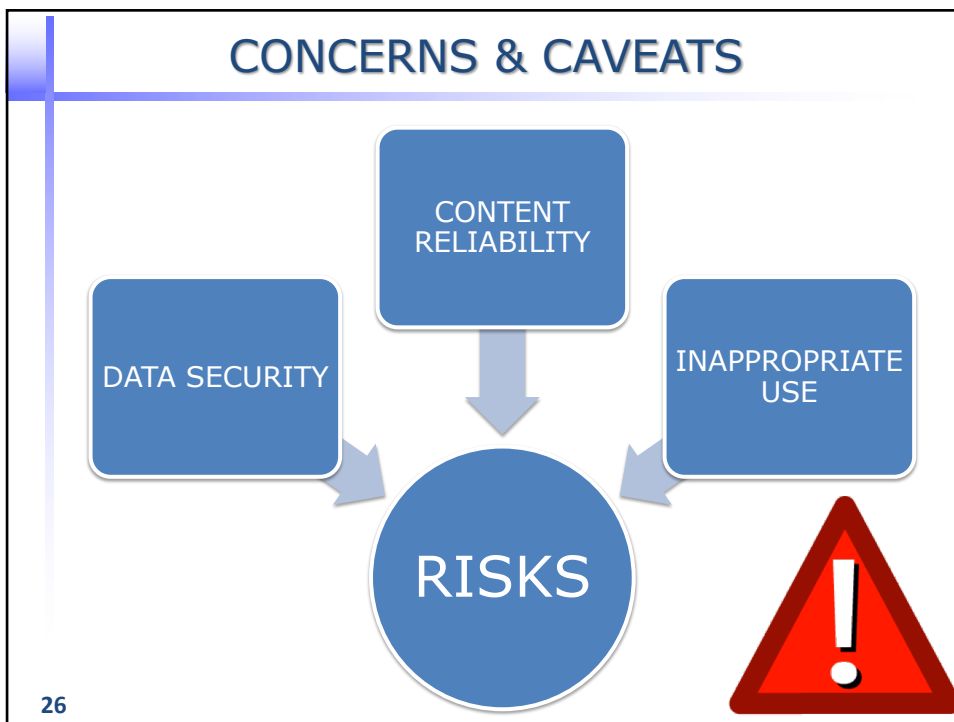
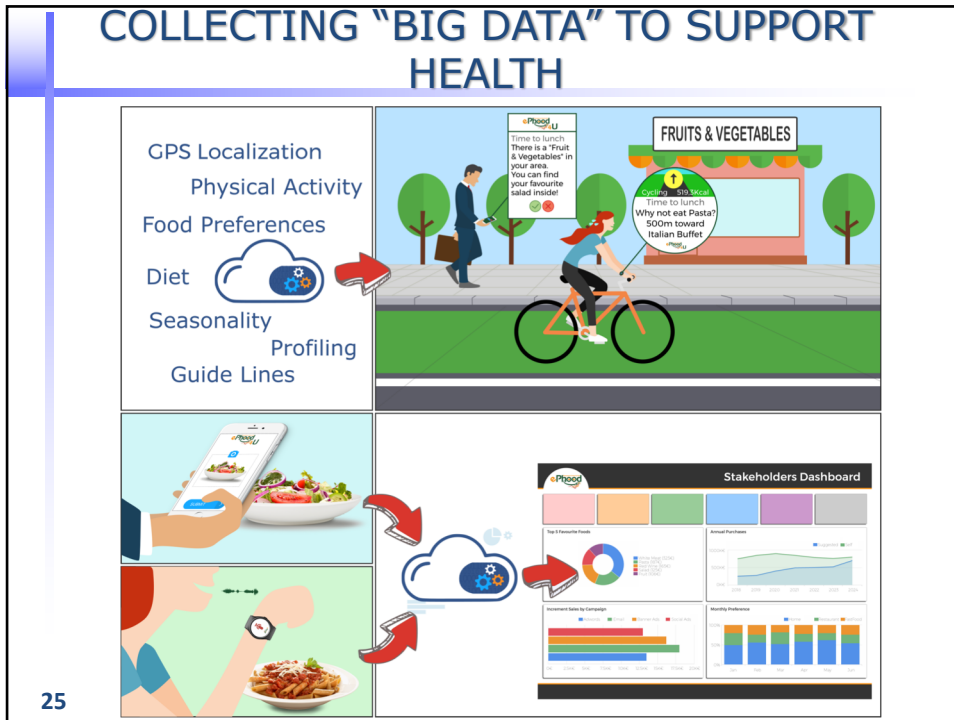
The innovation arm of Brigham and Women's Hospital has partnered with efficacy-focused digital health company Evidation Health to collaborate on a project measuring the real life impact of digital health solutions on clinical and financial outcomes. The idea is to combine forces to develop methods of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

# COLLECTING "BIG DATA" TO SUPPORT HEALTH



www.ibm.com

24



# QUALITY, RELIABILITY, AND USEFULNESS

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; Robert K. Davis, PhD; Bruce J. Rogers, PhD; Wendy C. King, PhD; Barbara D. Marcus, PhD; Daniel H. Hadji, PhD; Amy D. Robinson, PhD; RD; Loni N. Hodas, S. Weibull, PhD; Steven H. Belle, PhD

September 20, 2016

**Activity Trackers Are Ineffective at Sustaining Weight Loss**

Newly released PIR 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. Morcos, BA; Oleg Abilev, MD; Timothy Patton, DO; Joseph C. English III, MD; Jonathan Ho, MD; Laura K. Ferris, MD, PhD

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

Arthur Willem Gerard Buijink,<sup>1</sup> Benjamin Jelle Visser,<sup>2</sup> Louise Marshall<sup>3</sup>

**BMJ**

BMJ 2015;349:f1811 doi: 10.1136/bmj.f1811 (Published 20 March 2015) 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

**PLOS ONE**

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

Rocio 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

27

# COMPANIES MOVING FORWARD

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

**emocha**  
Medication Adherence

Do you have side effects?

- none
- nausea / vomiting
- rashes / itching
- abdominal pain
- weakness
- joint pain
- yellow skin / eyes
- sores on lips or inside

300mg Isoniazid  
600mg Rifampin  
800mg Ethambu  
50mg Vitamin E

Tuesday Mar 10, 2017

BACK NEXT

**Virgil**

Check your weight due by 11:00 am

Check your weight soon to avoid losing points!

Choose your mission due by 11:00 am

It is time for you to take on a new mission!

Take your morning meds Completed

Home Today History Me

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

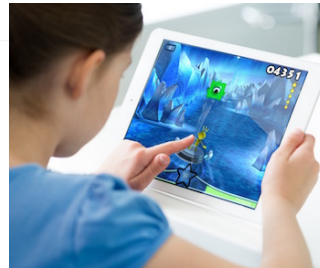
28

## COMPANIES MOVING FORWARD

### 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

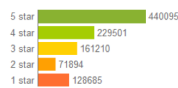
By **Laura Lovett** | December 04, 2017

SHARE

29

## 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 Eternio Chanel N°5 TENDENZE Vestiamo alla moda

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



Le 10 migliori app per la salute per iPhone 6



30

**DONNA MODERNA** Codici sconto | Donne vere | Digital School | Mondadori per te

Newsletter | Concorsi | Abbonati

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



The screenshot shows the iMedicalApps website interface. At the top, there's a navigation bar with 'iMedicalApps' logo and 'submit an app' button. Below, there are featured articles like 'Quick LabRef app for Android' and 'Top 10 Free iPad Medical Apps'. A search bar is visible at the bottom of the page.

<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.

<http://www.rankedhealth.com>


31

## PRESCRIBING APPS

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



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

#### Trending Apps



40	8	2747
Prescribers	Departments	Apps Prescribed

Sinai App Lab App  
© 2016 Version 1.1.8 Updated 10/25/2016  
Programmed by: Misael Acosta

 **RxUniverse** 

Have you prescribed an app today?

Please choose your organization

Mount Sinai▾



[Forgot Password?](#)

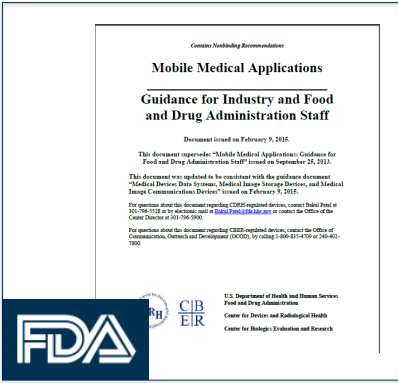
[New User? Register Here](#)

32



# GUIDELINES



33

**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**

EUROPEAN COMMISSION Brussels 10.4.2014 COM(2014) 219 final

**GREEN PAPER**

on mobile Health ("mHealth")

[SWD(2014) 135 final]

DIGITAL SINGLE MARKET  
Digital Economy & Society

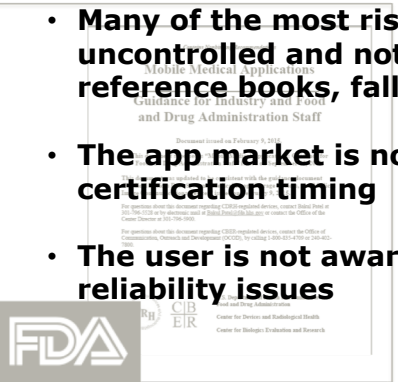
European Commission - Code of Conduct on privacy for mHealth apps has been finalised

Published on 07/06/2016

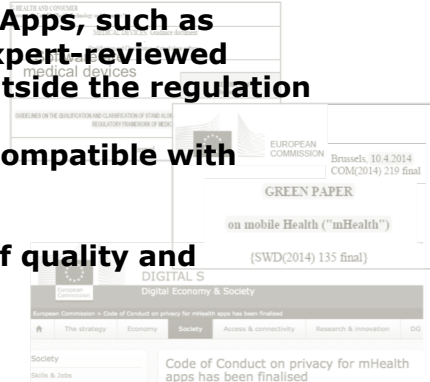
# GUIDELINES

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



34



## 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.**

35

## RISKS FOR USERS

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

### 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

36

## 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



37

## 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

38

## IOT AND ENLARGED NETWORKS



**ICS-CERT**

INDUSTRIAL CONTROL SYSTEMS CYBER EMERGENCY RESPONSE TEAM

**Advisory (ICSMA-17-250-02)**

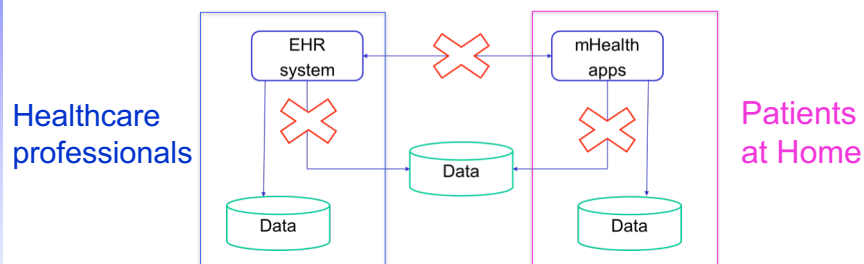
Smiths Medical Medfusion 4000 Wireless Syringe Infusion Pump Vulnerabilities

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.

39

## CHALLENGES: INTEGRATION



**Allowing the bi-directional exchange of information between mHealth applications and EHRs** has the potential to **enable patient-centered and home-settled care**, and to include patients, families, and communities in the care process.

40

## DATA EXCHANGE REQUIREMENTS

### Exchange accurate information

- Preserve the original meaning intended by the author.

### Data protection

- Confidentiality (protection from unwanted access), Integrity (transmission and maintenance of accurate data), Availability (data accessibility and usability upon demand by authorized request), Accountability (traceability of responsibility on data content) and Disaster Recovery.

### Interoperability and flexibility

- Technological interoperability (e.g., standard communication architectures), and Semantic interoperability (e.g., shared terminologies/ontologies).

### Patient education

- Support patients to both enhance their "health literacy" and to create a "culture of custodianship" related to the nature of personal health information.

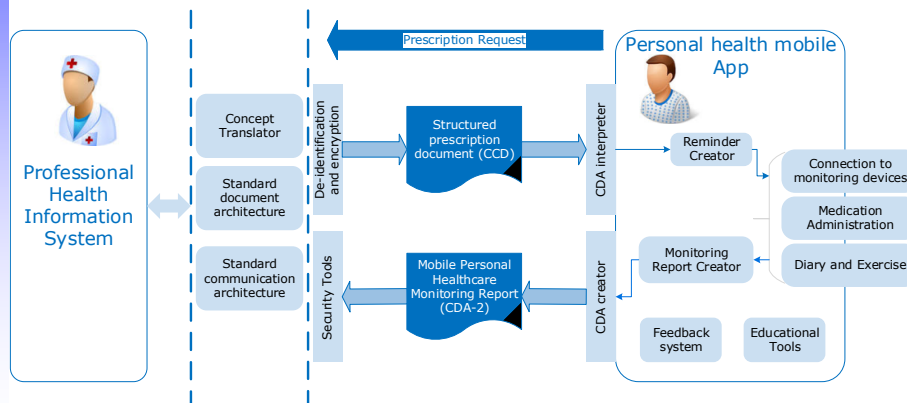
### Research and evidence-based practice

- Ensure the availability of information necessary for establishing the benefits and limitations mHealth App-EHR two-way exchange.

41

Marceglia, Fontelo, and Ackerman, JAMIA 2015

## THE STANDARDS-BASED ARCHITECTURE



- Data exchange based on structured standards-based documents
- No data storage on the mHealth App
- Only de-identified data are transmitted
- The mHealth App provides access to health information for patients (e.g., Medline Plus)

42

Marceglia, Fontelo, and Ackerman, JAMIA 2015

## FHIR TECHNOLOGY

**1.9 Getting Started with FHIR**

FHIR is a platform specification that defines a set of capabilities use across the healthcare process, in all Jurisdictions, and in lots of different context. While the basics of the FHIR specification are relatively straight-forward (see the Overviews: [General](#), [Developers](#), [Clinical](#), and [Architects](#)), it can still be difficult to know where to start when implementing a solution based on FHIR.

### SMART on FHIR® – Open Platform Architecture

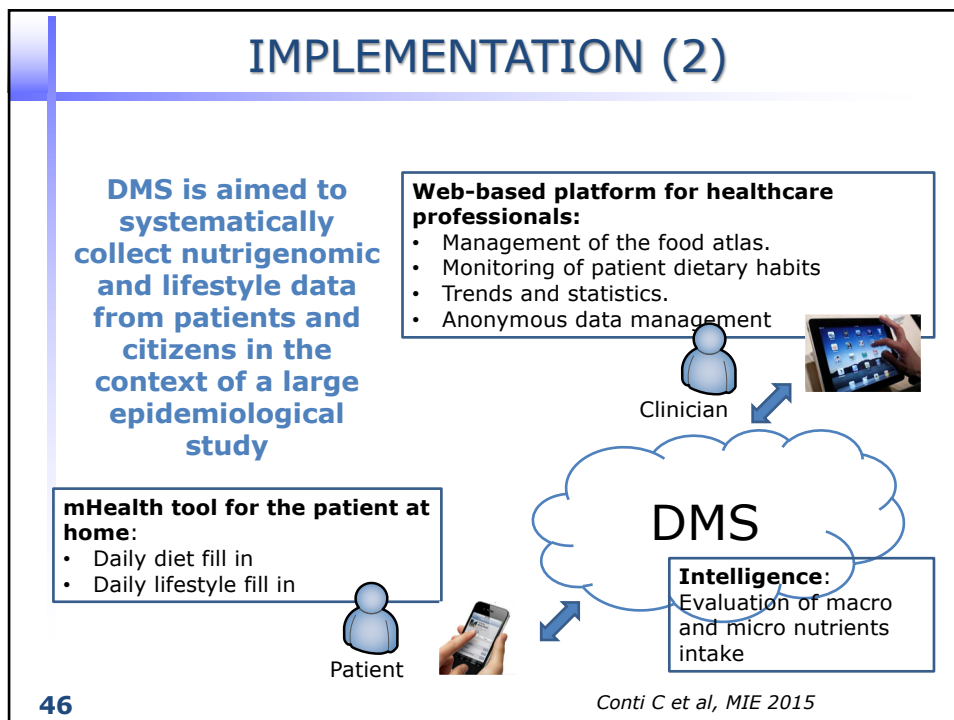
## IMPLEMENTATION (1)

**TELEMONITORING OF PARKINSON'S PATIENTS**

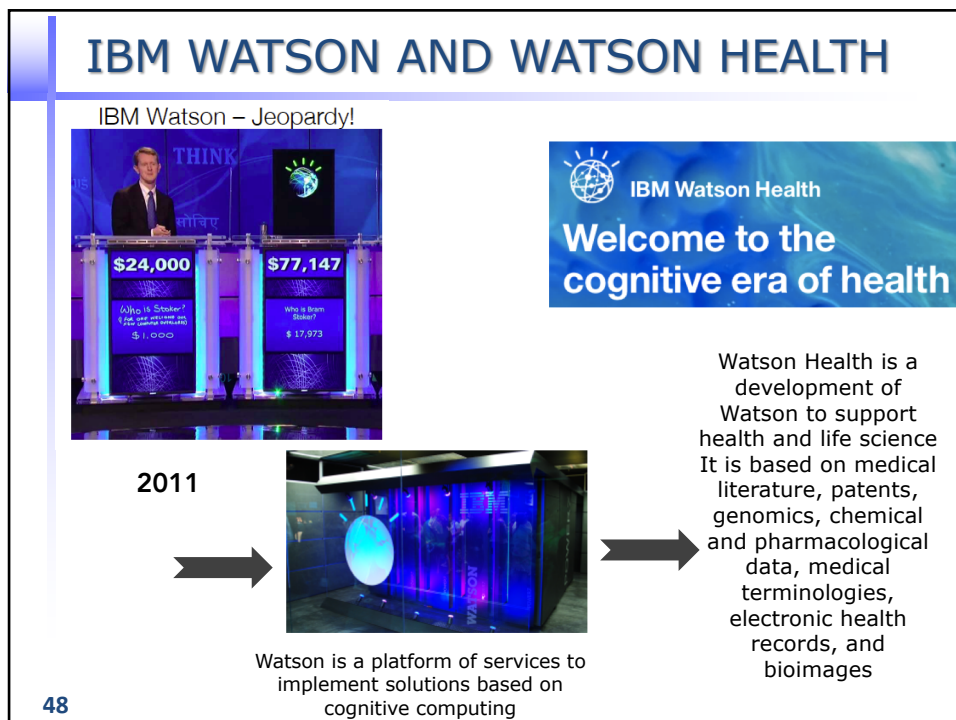
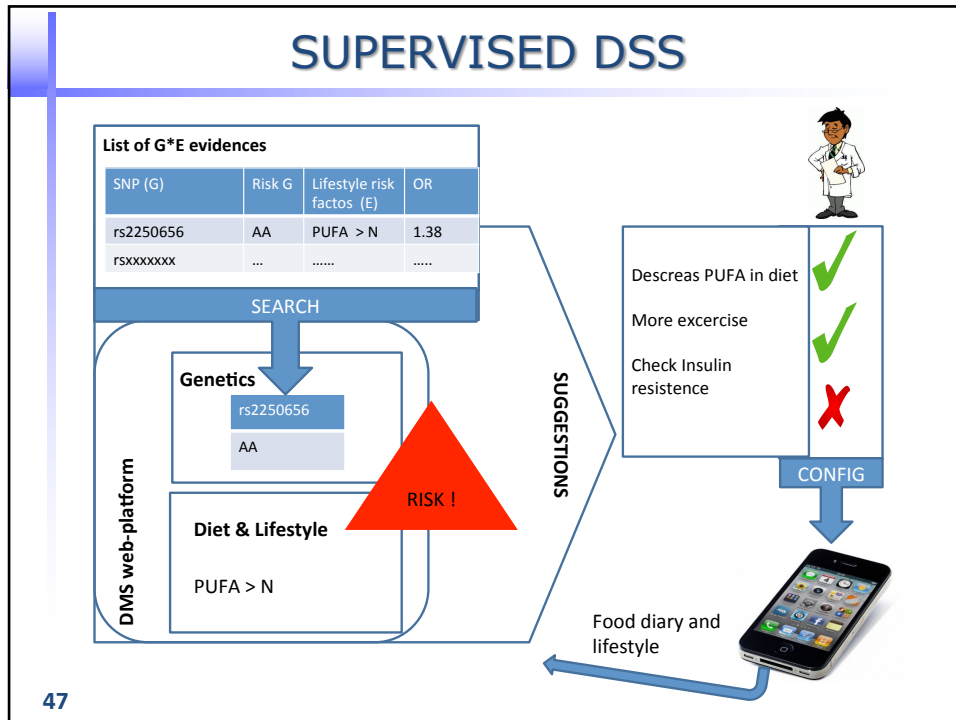
*Marceglia et al, AMIA 2017*



45



46



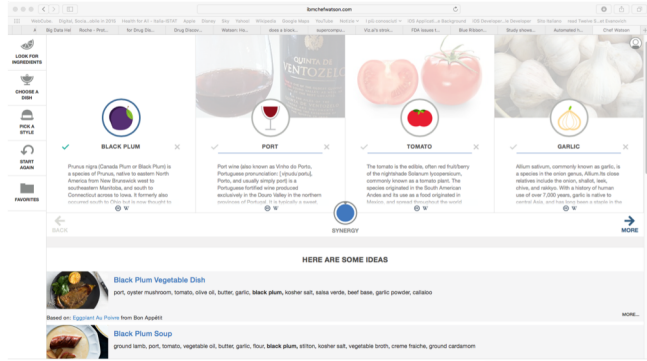


# WATSON FOR NUTRITION

**IBM Chef Watson with bon appétit**

## Ready to do some cognitive cooking?

Discover and create unique dishes with Chef Watson and share with your friends!



Watson Chef can be the basis for giving smart tips on food and nutrition to patients and citizens

49
<https://www.ibmchefwatson.com/>

# WATSON FOR ONCOLOGY

### MEETING LIBRARY

ASCO University

Early experience with IBM Watson for Oncology (WFO) cognitive computing system for lung and colorectal cancer treatment.

Presented Saturday, June 3, 2017

- 362 cancer cases at the Memorial Sloan Kettering Cancer Center (New York, USA)
- Treatment recommendations concordant in 96.4% of lung, 81.0% of colon and 92.7% of rectal cancer cases.

Clinical Information for: Stage IIB neoadjuvant with Case Notes

Summary	All Attributes	Notes
<p>Demographics: Required</p> <p>Primary Care: Required</p> <p>Specialty: Required</p>	<p>IBM Cancer Disease Group: Required</p> <p>Election Factor: Required</p>	<p>Please Verify: Attributes below correctly reflect the patient's condition.</p> <p><b>Patient characteristics</b></p> <p>Gender: Female <span style="float: right;">name: 40000020 AdditionDate: 9/29/2016 <a href="#">View Full Report</a></span></p> <p>Age: 62 <span style="float: right;">DATE: 07/09/2013 INITIAL CONSULTATION CHIEF COMPLAINT: The patient is a 62-year-old male from New York, accompanied by her daughter today to discuss neoadjuvant therapy for her stage IIB...</span></p> <p>Performance status: ECOG 0 (asymptomatic) or KPS 10 <span style="float: right;">name: 40000020 AdditionDate: 9/29/2016 <a href="#">View Full Report</a></span></p>

50
50

## WATSON FOR DRUG DISCOVERY

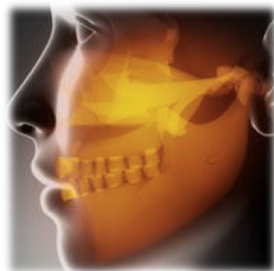
The screenshot displays the IBM Watson for Drug Discovery interface. The top section shows a network graph with nodes and edges representing relationships between entities. Below this, there is a circular visualization of relationships, with a legend on the left listing various entities such as 'Glucocorticoids', 'Lymphoid System', 'Prostaglandin', etc. A 'Link Strength' slider is visible at the bottom of the circular visualization.

- Searches scientific abstracts for genes, proteins, target chemical compounds, or interesting conditions and provides dynamic mapping of the links between them.
- Explore predictions for new entity relationships by applying predictive algorithms to existing relationship networks

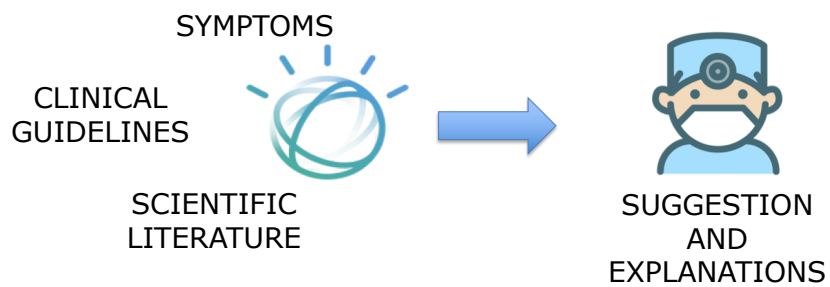
51

<https://www.ibm.com/us-en/marketplace/ibm-watson-for-drug-discovery>

## STARTING FROM THE SCRATCH



Implementing a Watson-based Decision Support System for the diagnosis of temporomandibular disorders



52

## WORKING PHASES

Text	Relevance
annual TMD management	0.91
Pain-related TMD	0.72
significant public health	0.62
common musculoskeletal condition	0.59
Temporomandibular disorders	0.43
psychosocial functioning	0.41
low back pain	0.39
daily activities	0.33

53

## THE RESULT

54

## REGULATIONS FOR AUTOMATED DSS

### Clinical and Patient Decision Support Software

#### Draft Guidance for Industry and Food and Drug Administration Staff

- Regulated devices based on the degree of human involvement, as opposed to doing so based on risk.
- CDS won't be regulated if the physician can independently review and understand the basis of the software's decision
- Even low-risk products would be subject to FDA regulation if they are all automatic

**Voluntary Industry Guidelines for the Design of Medium Risk Clinical Decision Support Software to Assure the Central Role of Healthcare Professionals in Clinical Decision-Making**



Developed by the CDS Coalition

55

## Caveats: regulations for automated DSS

### FDA permits marketing of AI software that autonomously detects diabetic retinopathy

By **Dave Muoio** | April 12, 2018

### Viz.ai's stroke-detecting CDS app receives FDA nod

By **Dave Muoio** | February 14, 2018

SHARE 339



FDA Cleared. CE Marked.

[www.mobilehealthnews.com](http://www.mobilehealthnews.com)

56

## CONCLUSIONS



57

## CONCLUSIONS

- mHealth is a promising field that would promote inclusion of patients in the healthcare process
- Integrating patient-generated information to EHRs will
  - enable patient-centered and home-settled care
  - provide inclusion of patients, families, and communities in the care process.

...HOWEVER...

- There are **concerns about data security, app quality**
- There are challenges still to be addressed
  - There is the **technological challenge** of creating a standards-based architecture for data exchange (HL7-FHIR)
  - There is the **analytic challenge** of collecting information appropriately and finding powerful tools for creating personalized suggestions for families/patients

58

THANK YOU FOR THE ATTENTION!

**CONTACTS:**  
[smarceglia@units.it](mailto:smarceglia@units.it)

