

Università degli Studi di Trieste

Corso di Laurea Magistrale in
INGEGNERIA CLINICA

mHealth e IoT

Corso di Informatica Medica

Docente Sara Renata Francesca MARCEGLIA



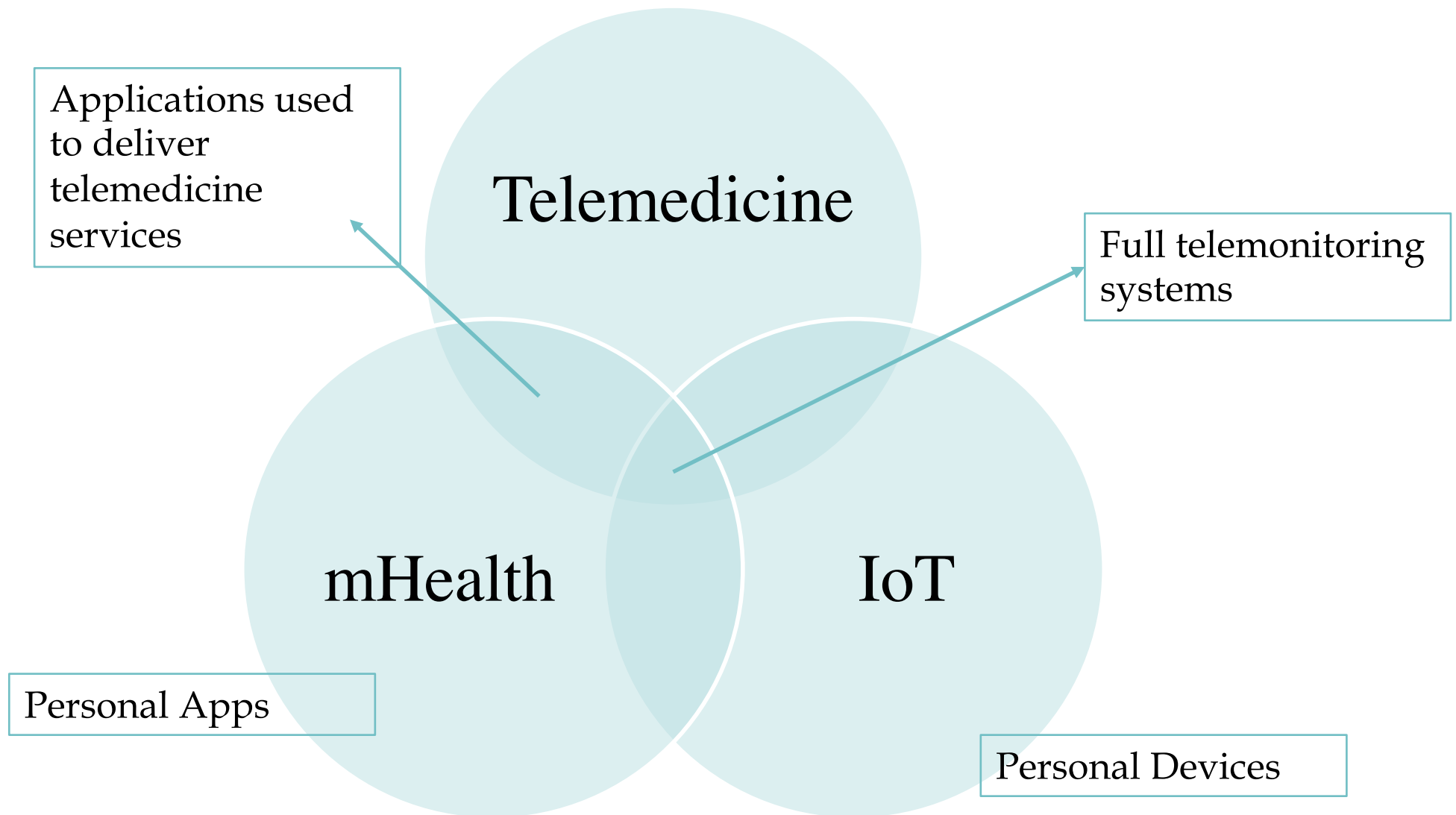
Dipartimento di Ingegneria e Architettura



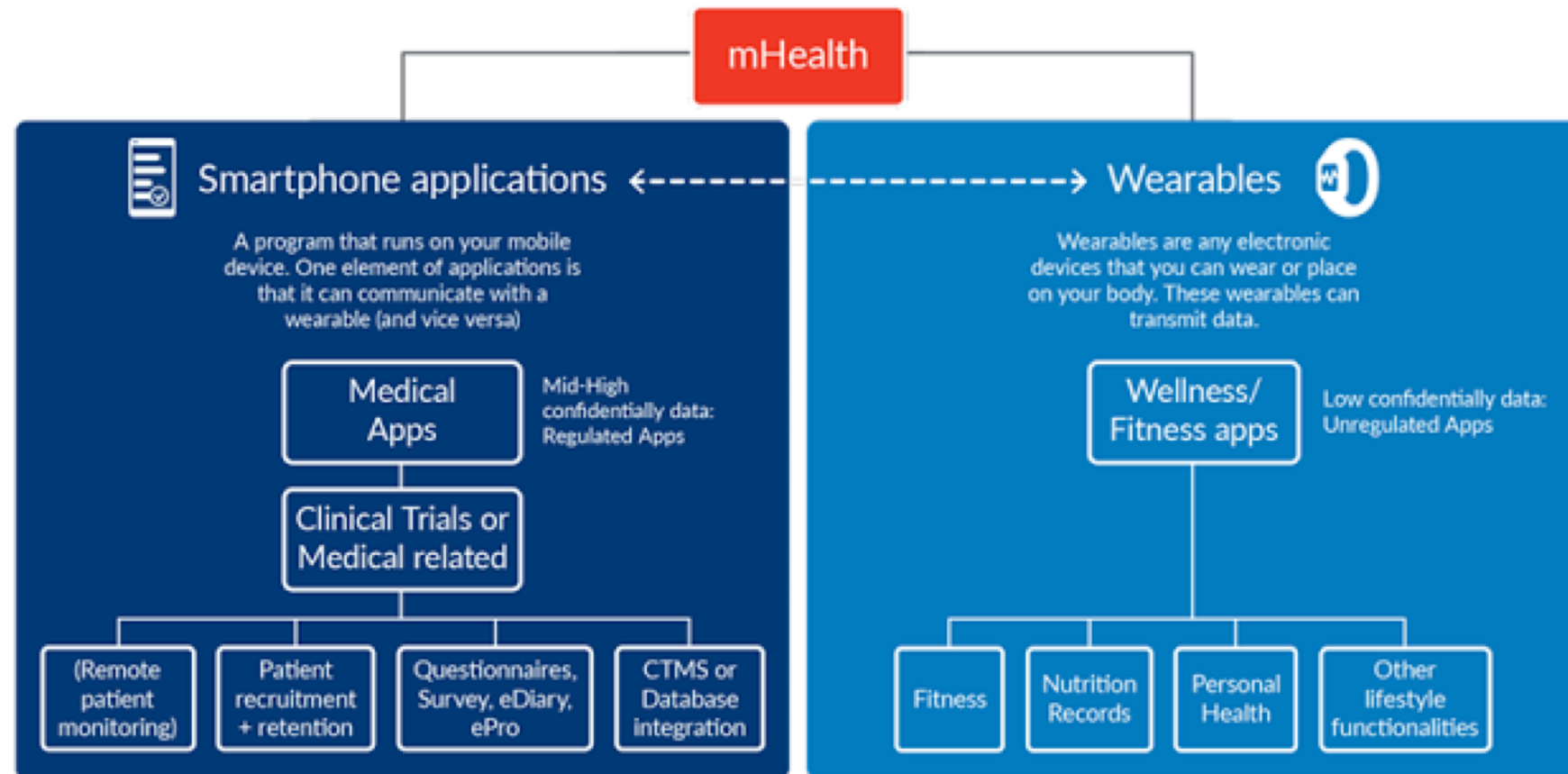
**UNIVERSITÀ
DEGLI STUDI DI TRIESTE**



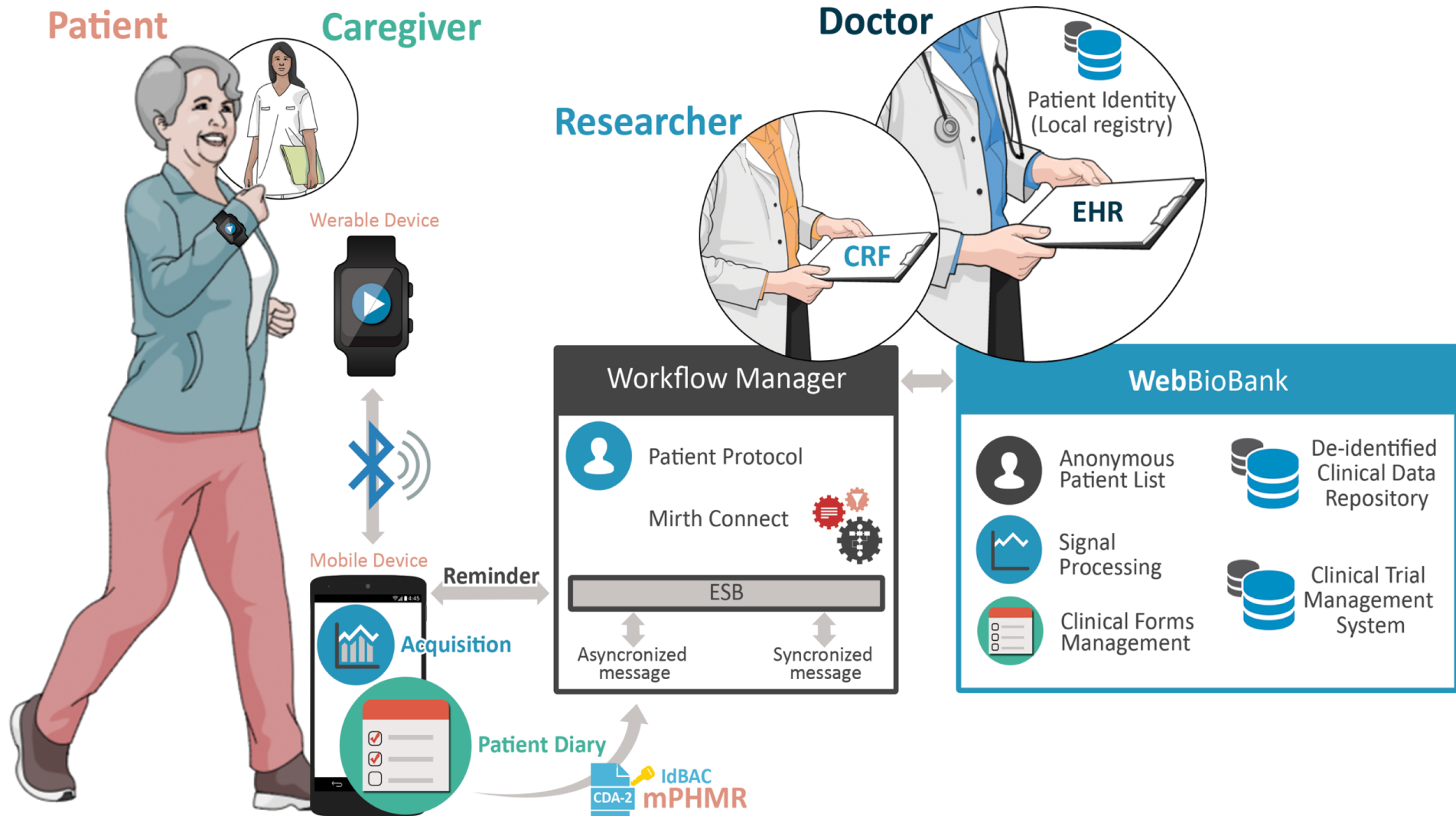
mHealth, IoT, and Telemedicine



mHealth, IoT, and Telemedicine



EXAMPLE: mHEALTH and TELEMEDICINE FOR CLINICAL TRIAL



EXAMPLE: System Components- WebBioBank



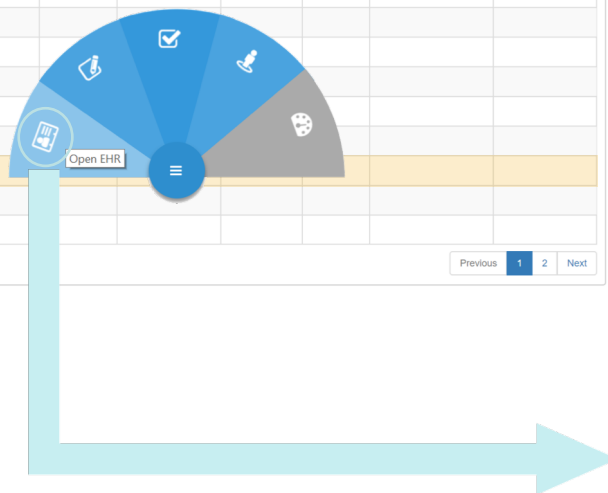
List Management

Upload an XML file for filling in the Patient's personal details

Patient List - ou_Dystal_Lock Show 10 entries Search:

IdEHR	IdBAC	Data	Protocols	Code	Surname	Name	Sex	DateOfBirth	TaxCode
2282	1410	30/10/2017 10:50:01							
2281	1409	30/10/2017 10:45:46							
2280	1408	30/10/2017 10:37:38							
2279	1407	30/10/2017 09:02:36							
2009	823	15/10/2015 07:45:42							
1957	771	07/07/2015 06:21:15							
1946	760	16/06/2015 10:01:38							
1279	526	06/02/2015 14:25:28							
1278	525	06/02/2015 14:07:43							
1277	509	06/02/2015 14:04:50							

Showing 1 to 10 of 13 entries Previous 1 2 Next



Ospedale Maggiore Policlinico-Centro Clinico per la Neurostimolazione Ospedale Maggiore Policlinico - U.O. di Neurofisiopatologia Clinica, Neurochirurgia Istituto C...

Dottore

Dati Clinici - Parkinson UPDRS

UPDRS III

Stai inserendo nuovi dati

DATA

Minuti trascorsi dall'ultima dose di terapia Farmaco Dosaggio

ON OFF

18. PAROLA

19. ESPRESSIONE FACCIALE

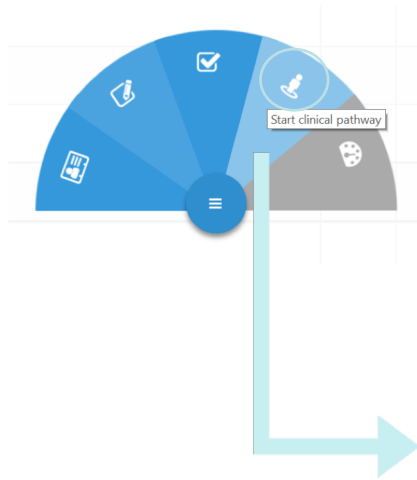
20. TREMORE A RIPOSO

21. TREMORE D'AZIONE E POSTURALE DELLE MANI

22. RIGIDITA'

23. DESTREZZA DIGITALE

EXAMPLE: System Components- Workflow Manager



Cliniket Neuro
CLINICAL TRIAL

Powered by Jamio openwork

CaGranda Administrator
CaGranda (23) (0)

Percorsi Clini... Percorsi Clini... Percorso Clin...

Nuova Ricarica Salva Elimina Avvia Altro Esporta

Percorso Clinico del Paziente 11465

Da Avviare

Paziente: Paziente 11465 Centro: IRCSS CA' GRANDA

ID di Paziente: 11465

Percorso: Selezionare un elemento...

ID di Modello:

UniquelD: 11465

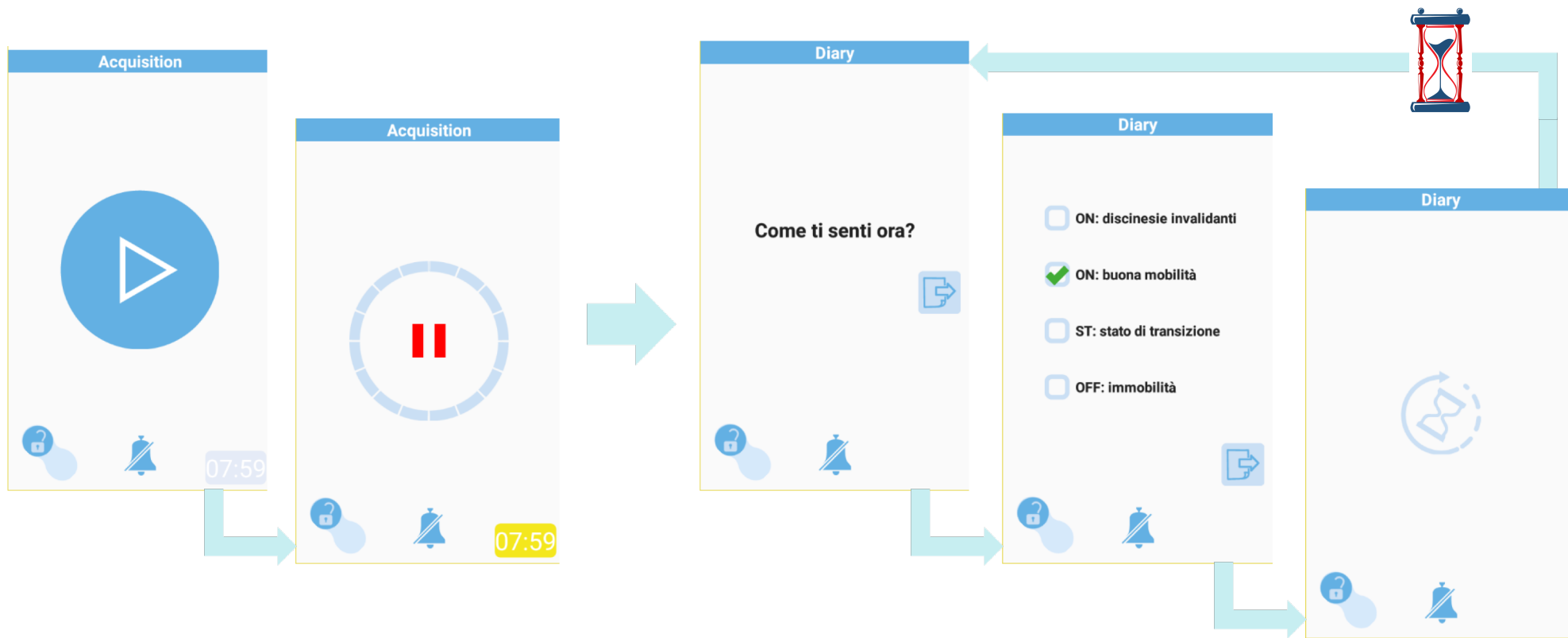
Data Avvio Percorso: 30/10/2017 18:07:15

Seleziona un elemento da Modelli di Protocollo

Filtra Cerca...

	Identificativo	Nome	Data Creazione	Data Ultimo Aggiornamento
☆	123456	Days 4 to ...	26/09/2017 14:56:...	27/09/2017 12:56:57
☆	1	Short Ter...	28/09/2017 16:13:31	17/10/2017 17:20:34

EXAMPLE: System Components - mobile App



EXAMPLE: clinician's use



WB - wH_PatientPrivacy_ x Pierluigi

localhost:82/PatientPrivacy/Pages/WorkbenchDefault.aspx#

App Connectome Toolbox desincronizzazione Le cose che ho impar cerca libri pdf RealtimeBoard | Onlin xcode dysgraphia projects Altri Preferiti

Profile PatientList_new Rossi Lorenzo 31/10/2017 19:20:26

List Management

Upload an XML file for filling in the Patient's personal details

Select a XML File Clear sensitive data New Patient Download XML Patient Data

Patient List - Ospedale Maggiore Policlinico - U.O. di Neurofisiopatologia Clinica, Neurochirurgia

Show 10 entries Search:

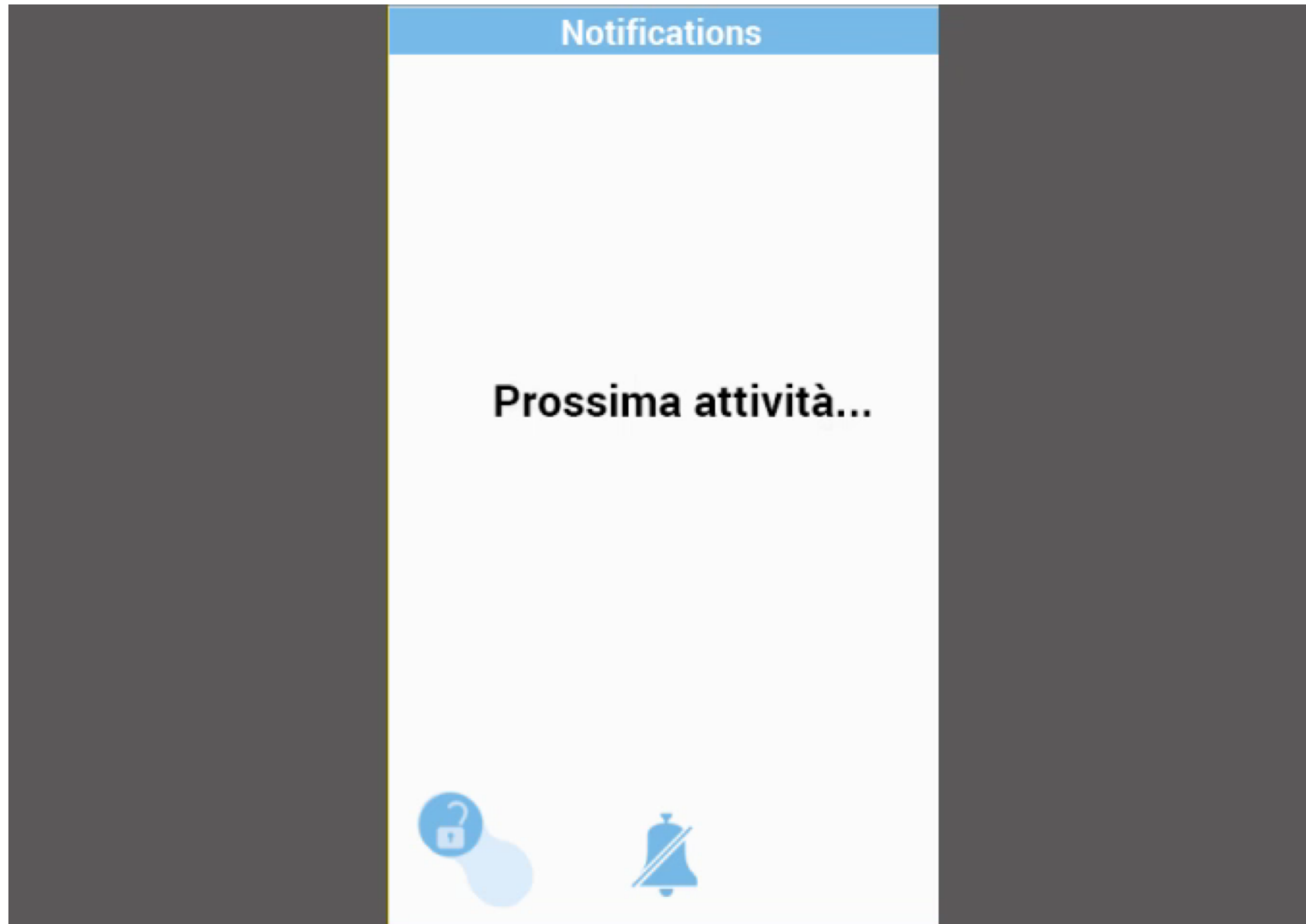
IdEHR	IdBAC	Data	Protocols	Code	Surname	Name	Sex	DateOfBirth	TaxCode
3317	11461	10/07/2017 23:02:48		722					
3321	11465	18/10/2017 17:41:39		P004					
3316	11460	10/07/2017 23:01:40		122					
3320	11464	13/07/2017 16:57:25		123					
3318	11462	11/07/2017 11:39:04		812					
3319	11463	11/07/2017 17:30:14		890					
3323	11467	19/10/2017 15:36:11		P001					
3322	11466	19/10/2017 15:23:06		P002					
3324	11468	21/10/2017 16:48:32		P003					
98	42	22/10/2011 17:49:37							

Showing 1 to 10 of 257 entries

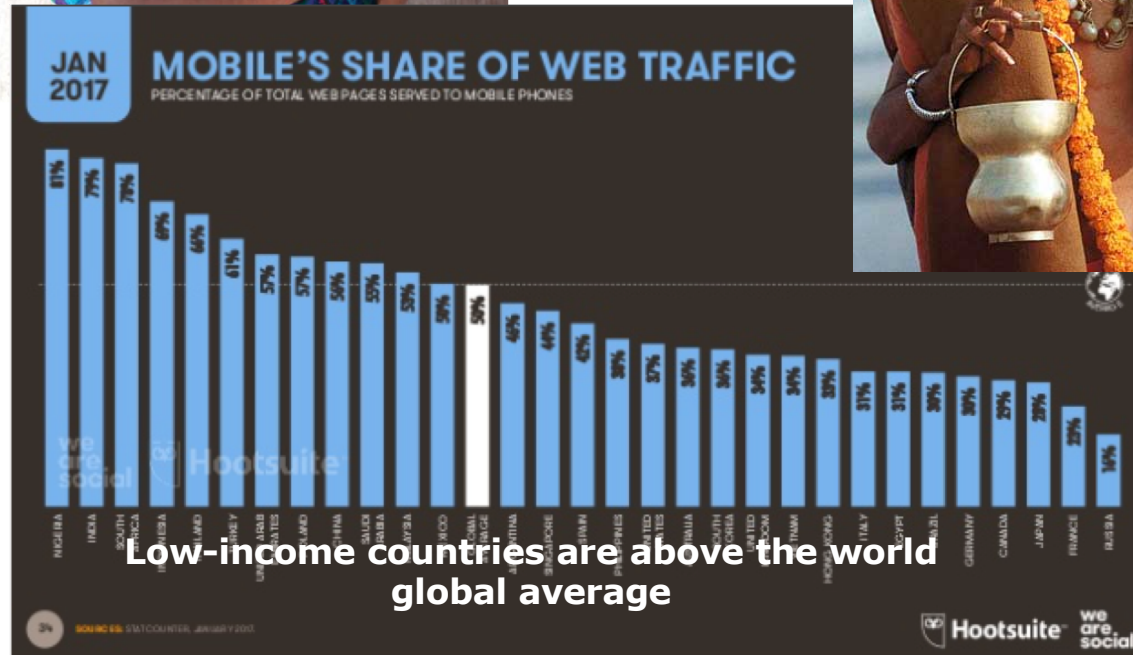
Previous 1 2 3 4 5 ... 26 Next



EXAMPLE: patient's use



WHY MOBILE: HEALTHCARE INCLUSION



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

WHY MOBILE: REAL-TIME COMMUNICATION

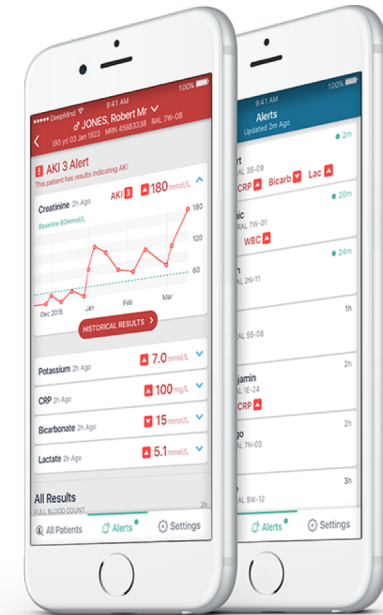


INTERACTIVE JOURNAL OF MEDICAL RESEARCH

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



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



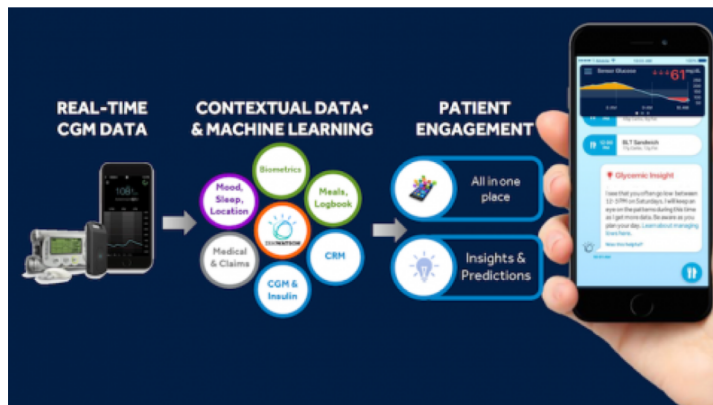
'breaking news' alerts doctors' attention is on patients who need it at that moment.

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

WHY MOBILE: PATIENT-CENTERED MEDICINE

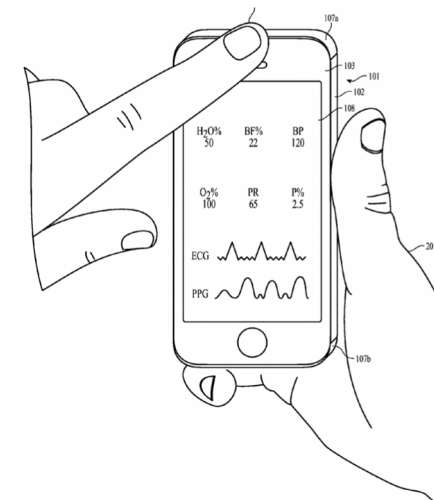


- Patient inclusion in healthcare delivery
- Increased education capability
- Services for non-patients (wellness, healthy lifestyle)
- Moving some health responsibilities to patients



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

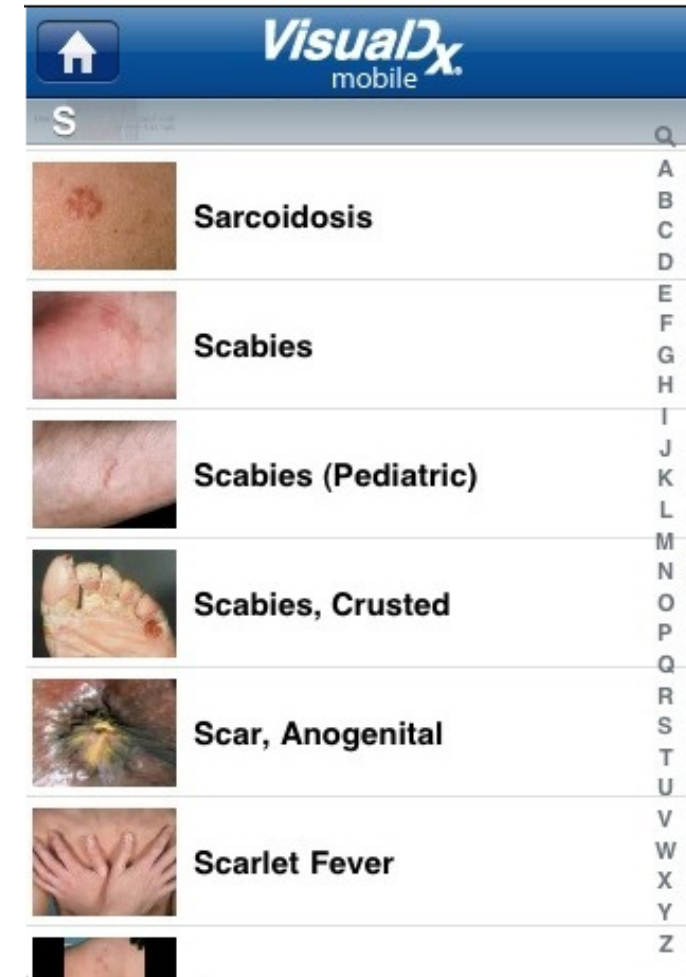
Cochlear Limited launches FDA-cleared, Apple-compatible cochlear implant
By [Jeff Lagasse](#)



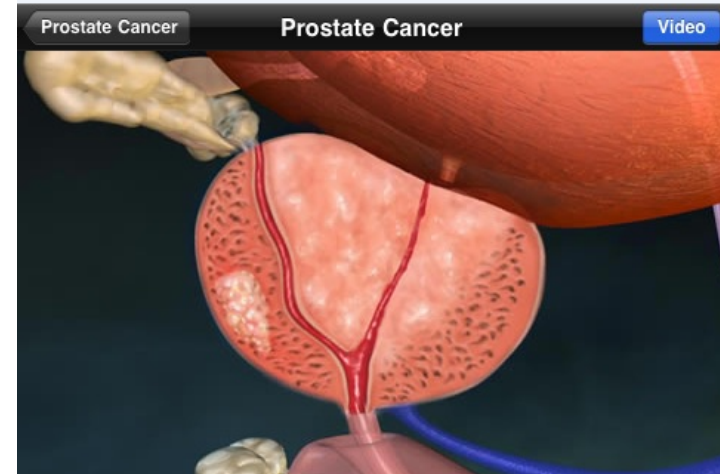
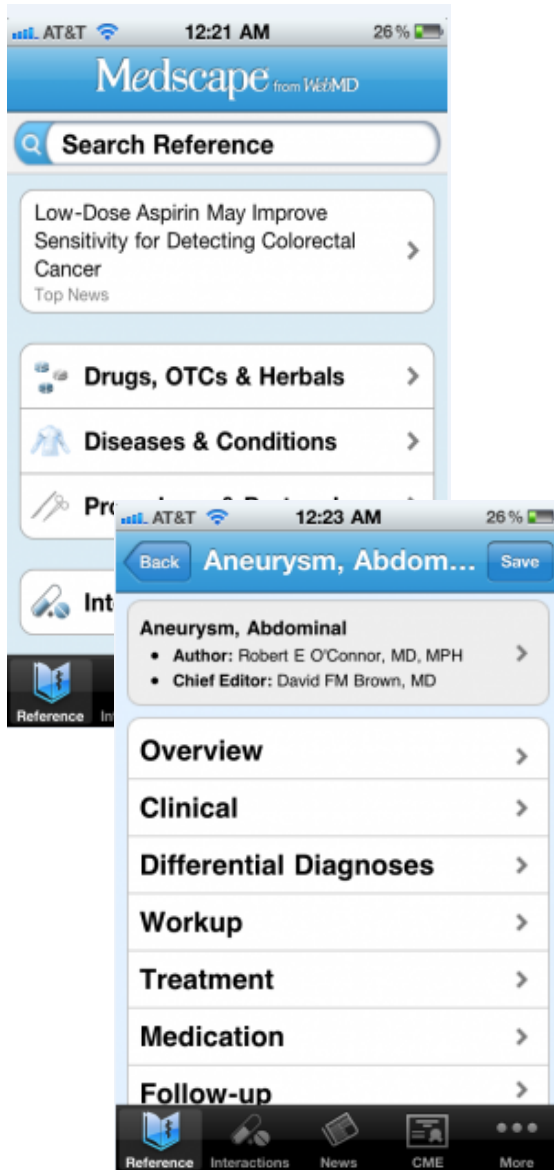
WHY MOBILE: MEDICAL PRACTICE



UNIVERSITÀ
DEGLI STUDI DI TRIESTE



WHY MOBILE: MEDICAL EDUCATION



WHY MOBILE: COLLECTING DATA FOR RESEARCH



UNIVERSITÀ
DEGLI STUDI DI TRIESTE

Crowdsourcing for research

A Wandering Mind Is an Unhappy Mind



Matthew A. Villanow and Daniel 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

evidation HEALTH

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.

Collecting data for epidemics

Boston research company collecting COVID-19 data in new app

Coronavirus: NHS contact tracing app to target 80% of smartphone users

By Leo Kelion



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...

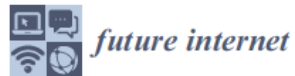


Brigham and Women's partners with Evidation Health to research impact of digital tools in clinical trials

By Heather Mack | October 21, 2016

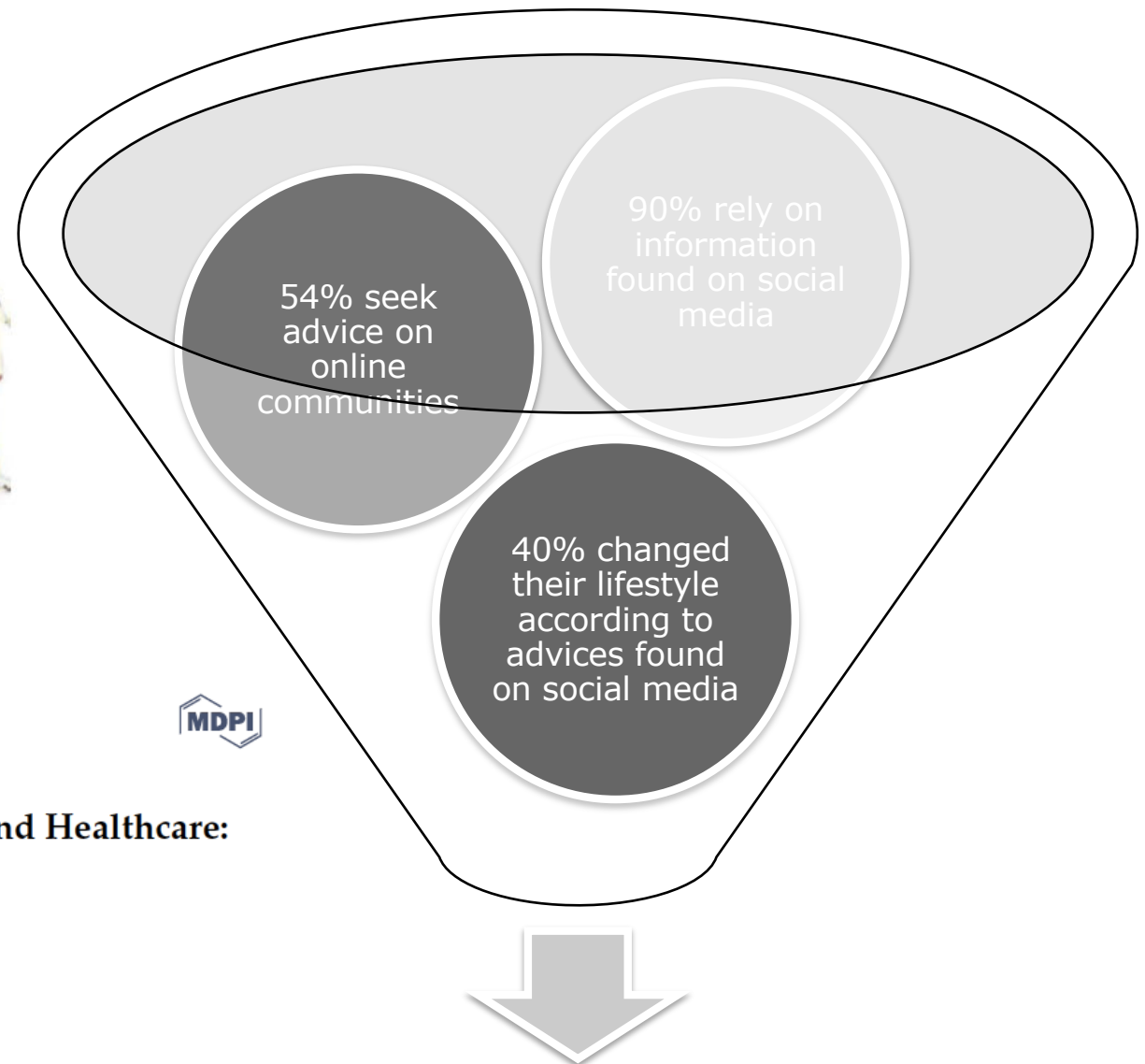
The innovation arm of Brigham and Women's Hospital has partnered with efficacy-focused digital health company Evidation Health to collaborate on a project measuring the real life impact of digital health solutions on clinical and financial outcomes. The idea is to combine forces to develop methods of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

HEALTH SOCIAL MEDIA



Review

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



Citizens use social media as a reliable source

HEALTH AND SOCIAL MEDIA



UNIVERSITÀ
DEGLI STUDI DI TRIESTE

CORONAVIRUS
Fake news

IMN ISTITUTO DI RICERCHE
FARMACOLOGICHE
MARIO NEGRI · IRCCS

Istituto Ricerca Forma:

**ISTITUTO
AUXOLOGICO
ITALIANO**
Istituto di ricovero e cura a carattere scientifico

VIDEO OPINION: IL MEDICO È ONLINE ▶

COR
Leggi
REFERTO
ONLINE

CHI SIAMO DIAGNOSI E CURA EQUIPE RICERCA E FORMAZIONE SEDI CONVENZIONI GALLERY CONTATTI EVENTI



CORONAVIRUS E VITAMINA C: STOP ALLE BUFALÉ

April 17, 2020

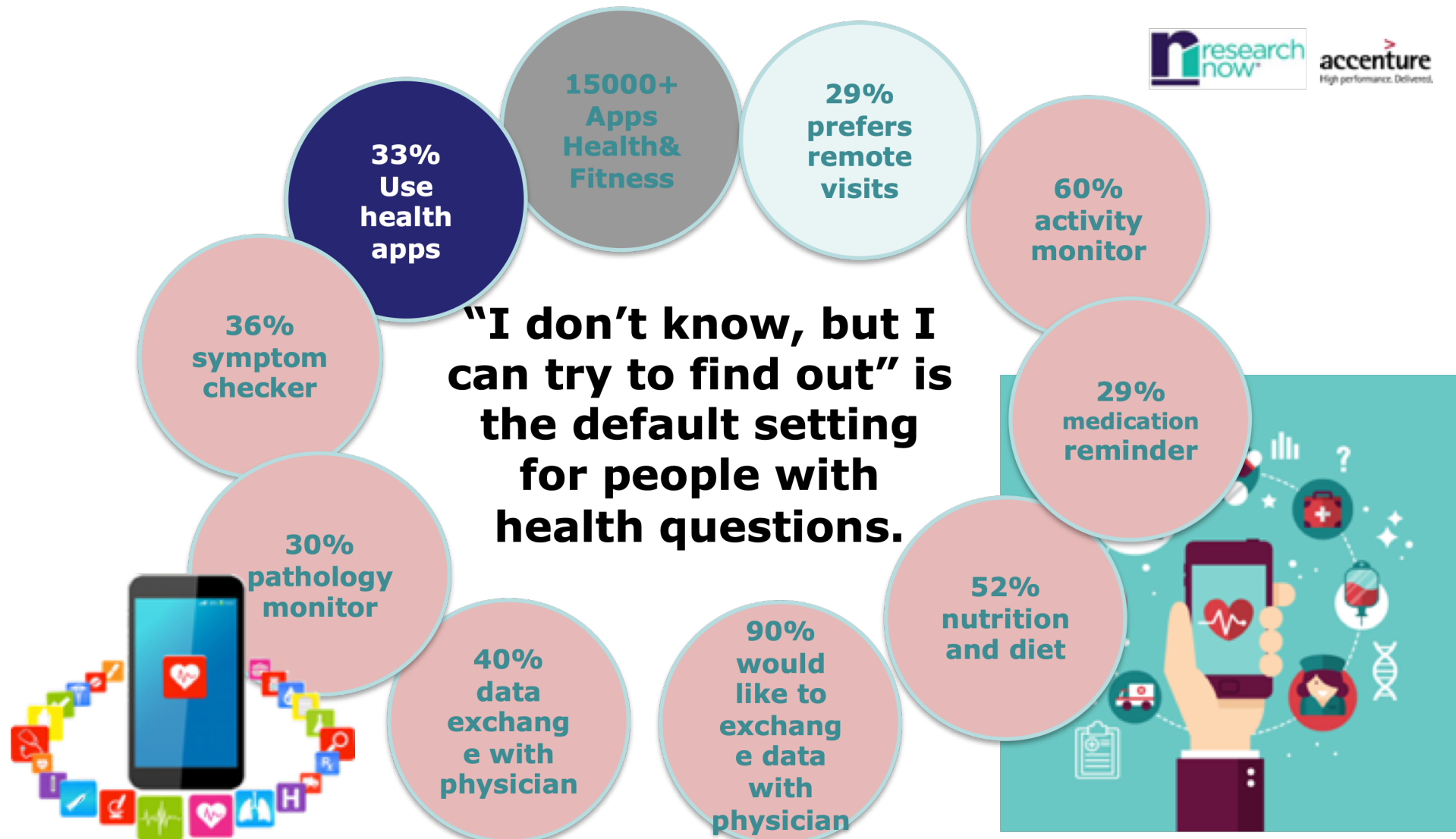
Coronavirus: attenzione
alle bufale su social e chat

NEWS

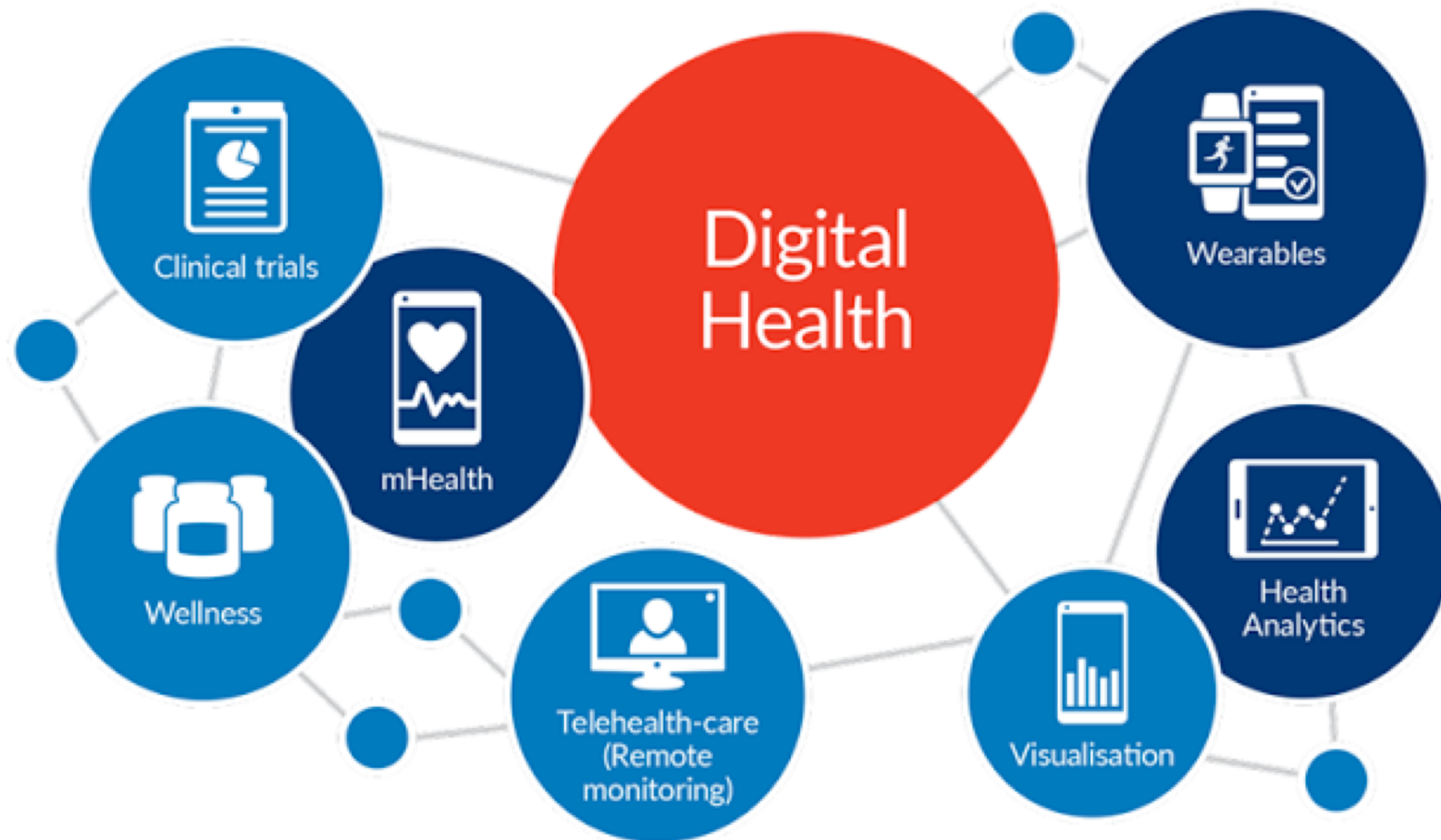


HEALTH MOBILE APPS

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



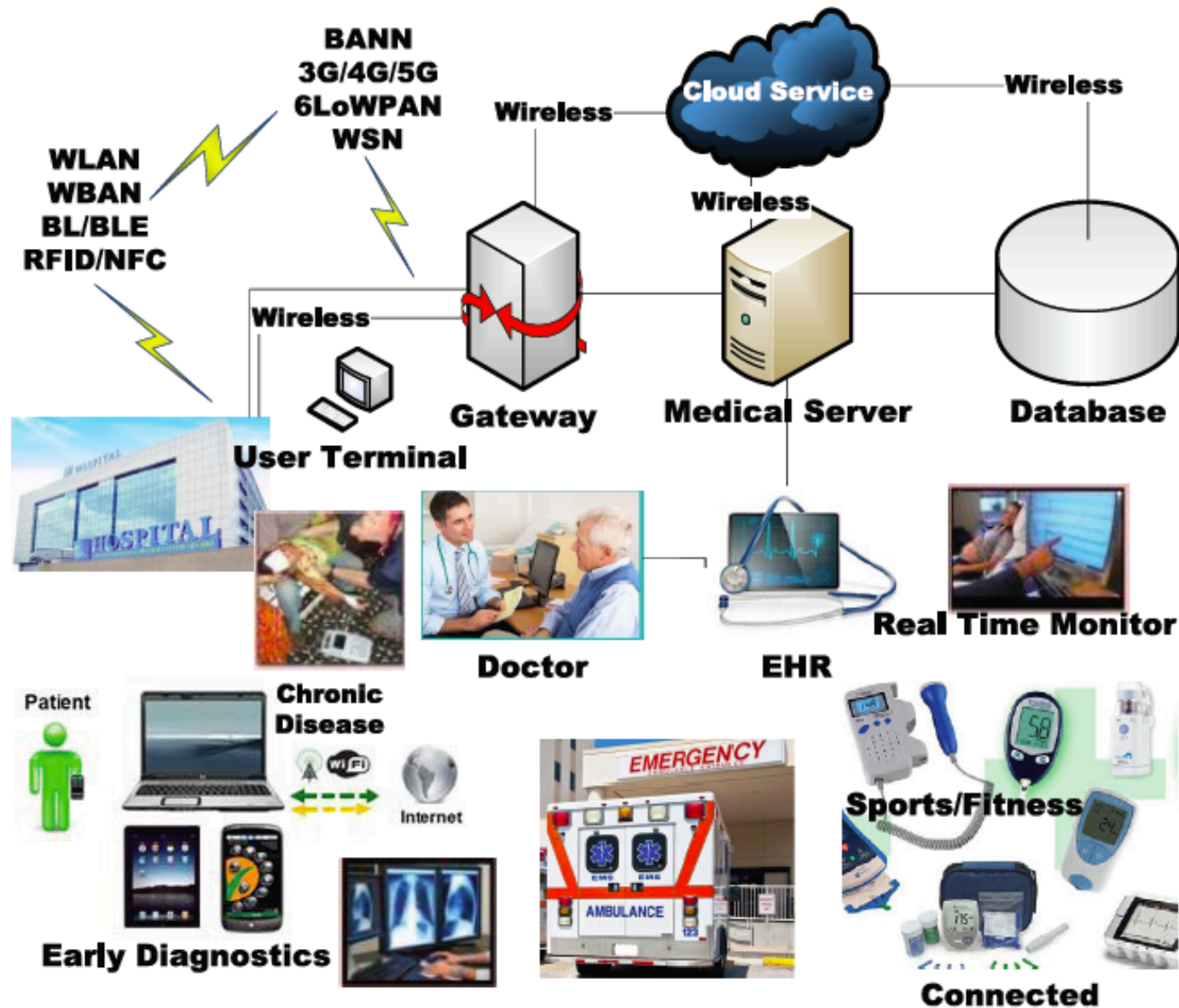
mHEALTH AND IoT



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

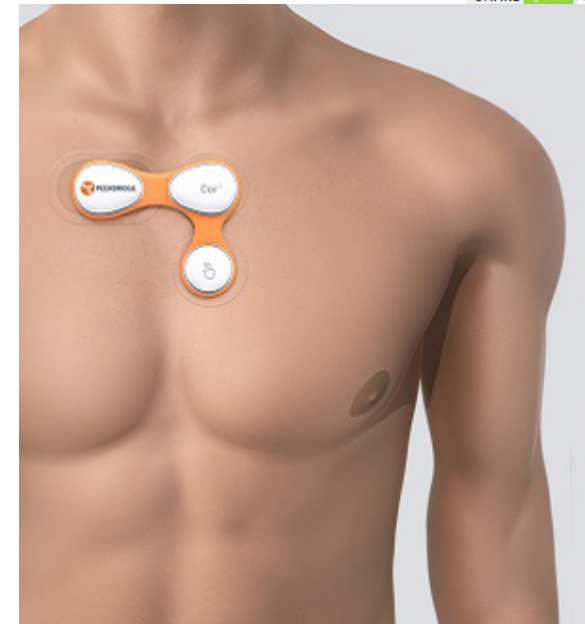


SHARE < >

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.

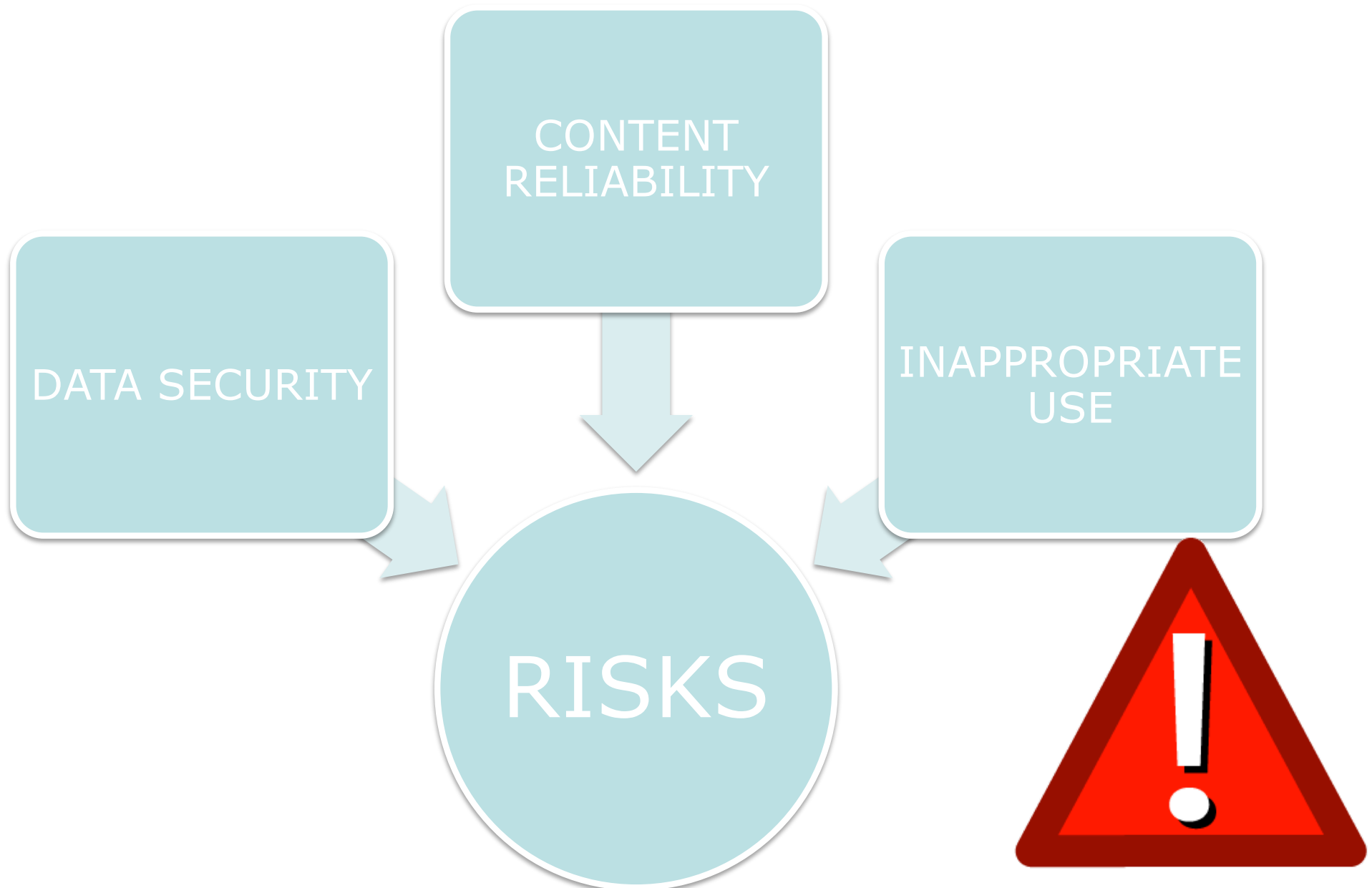
A historic clearance

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.



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



About



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

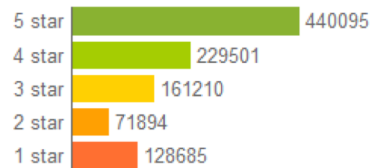




PATIENT'S QUALITY EVALUATION

WIRED APPS

User Reviews



Average rating:

3.8



1,028,105

Cerca

Cerca

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



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

Donna Moderna

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



UNIVERSITÀ
DEGLI STUDI DI TRIESTE

iMedicalApps
the leading physician publication on mobile medicine

LOGIN

submit an app
we'll check it out.

Quick LabRef
Quick LabRef app for Android contains a wealth of information for free

Top 10 free iPad Medical Apps

Top 20 Free iPhone Medical Apps For Health Care Professionals

Join iMedicalApps!
Subscribe to receive customized content and product giveaways
It's easy. Click here.

Visit the
iMedicalApps Forum
www.imedicalapps.com/forum

Advertisement

find a review

All iPhone Android iPad Blackberry

Forums Videos Top Apps About Contact

search

by App Type by Medical Specialty Visit our mHealth page New!

<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 app review site launches

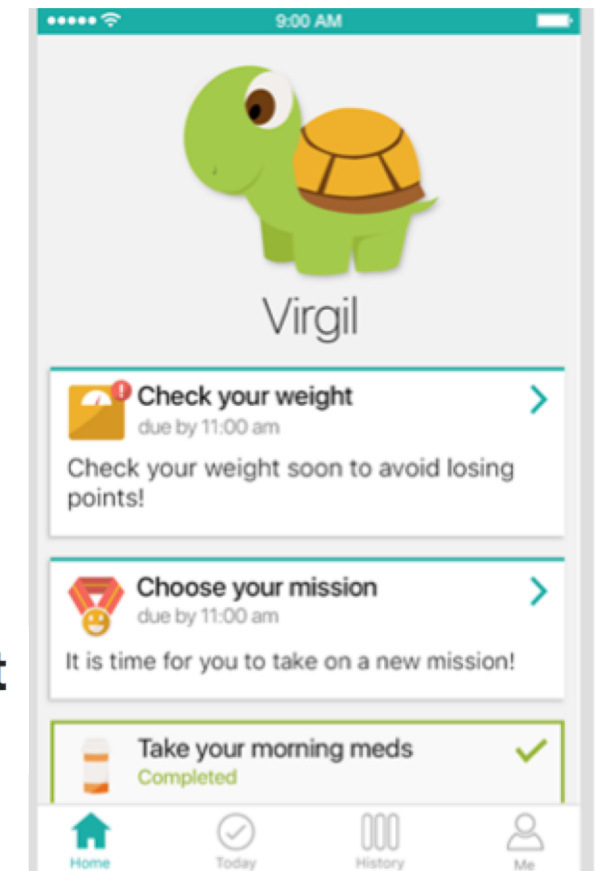
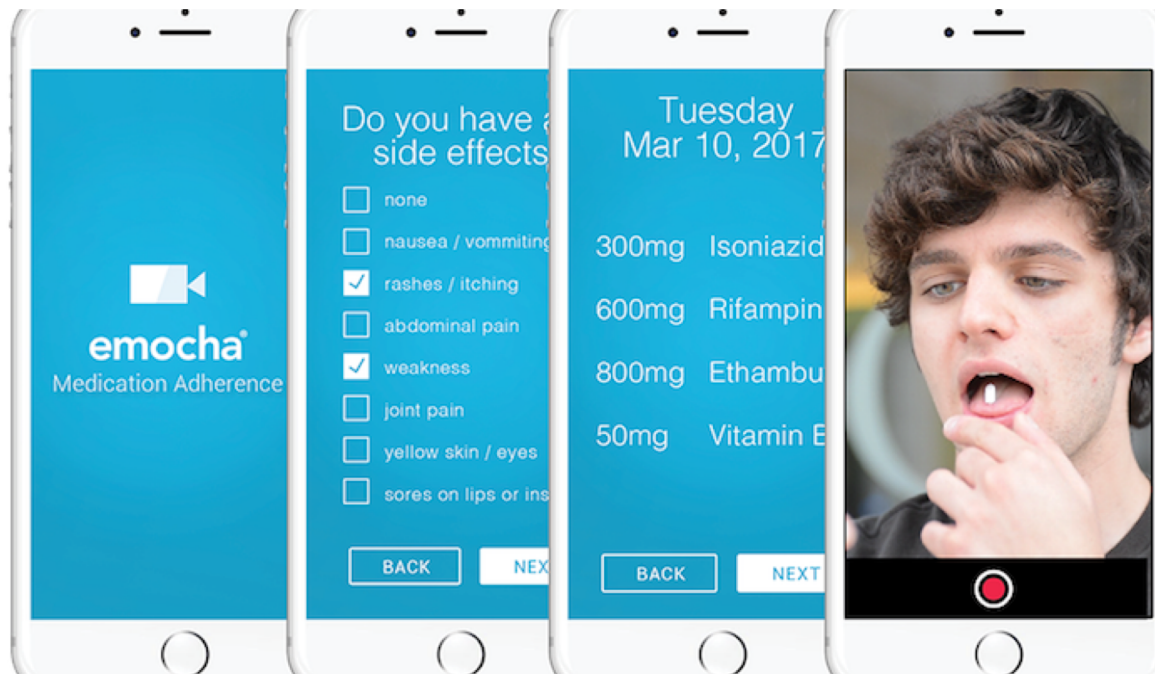
By Jonah Comstock | May 03, 2016

SHARE 1

<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 health...

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.**

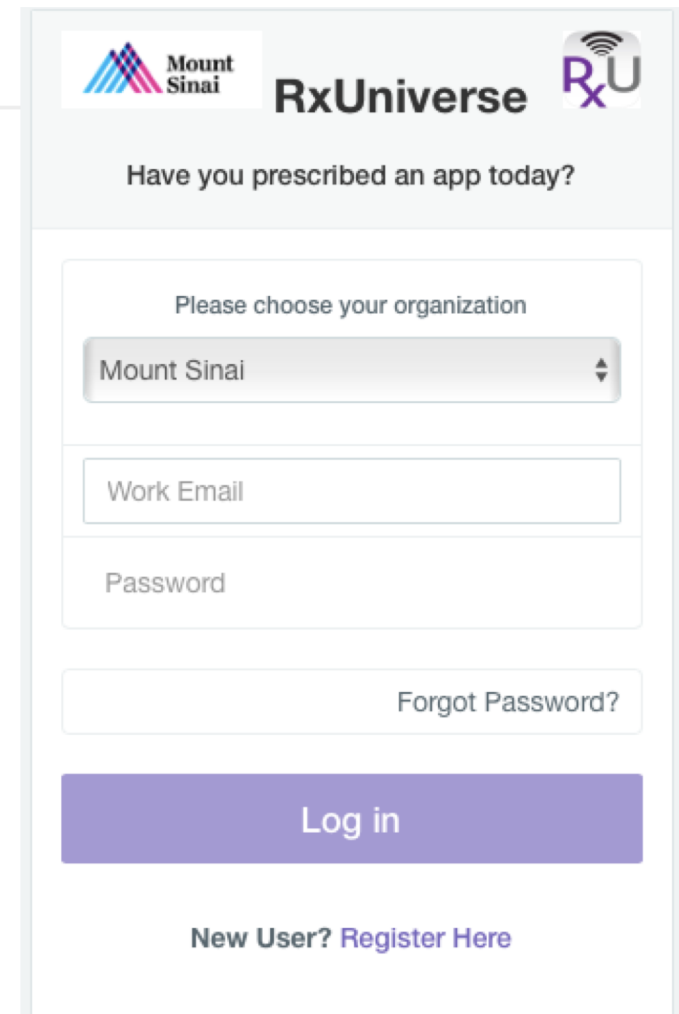


https://www.healthcareitnews.com/news/apple-unveils-watch-series-4-fda-approved-ecg?mkt_tok=eyJpIjoiWXPFeE5EQTFaalJrTjJSayIsInQiOiJ4bDRrb2M5ckZYK1V2SIJwbkxvaXUwak9WbDdRUEJ0VjIXNDI5VTBVdmNtTTJpWnRwenRuSmNkaGUyU0lVWW15TFJXajU3TU13UjU0NE5KQ013TERESVRHREhVNVdcL2cwVjV2c2J6TkdrRVhDV2FtMEVmVEMrXC9Fcm5FbDFzUTFHIIn0%3D

PRESCRIBING APPS

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

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

Mount Sinai RxUniverse RxU

Have you prescribed an app today?

Please choose your organization

Mount Sinai

Work Email

Password

[Forgot Password?](#)

Log in

[New User? Register Here](#)

GUIDELINES



Contains Nonbinding Recommendations

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 CDH-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




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

Home
The strategy
Economy
Society
Access & connectivity
Research & innovation
DG

Society

Skills & Jobs

eHealth and Ageing

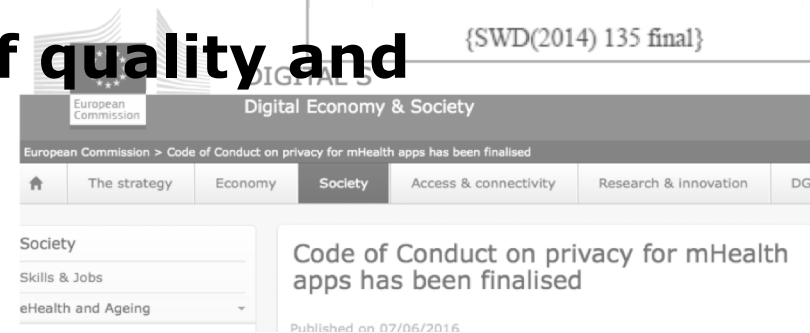
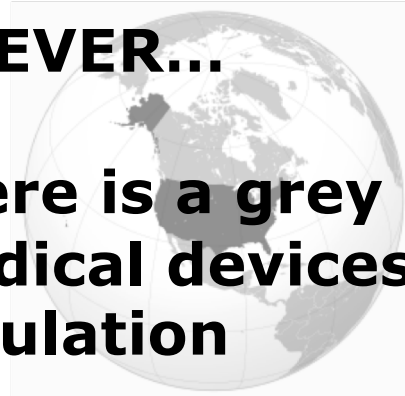
Code of Conduct on privacy for mHealth apps has been finalised

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



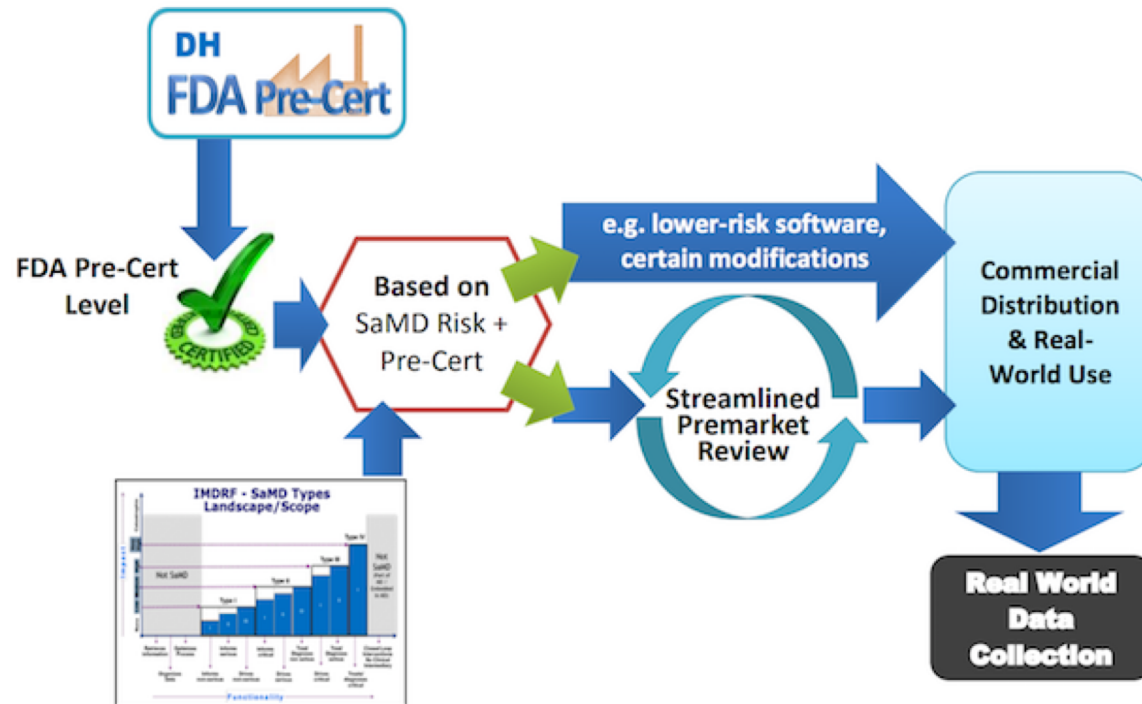
EU REGULATION

Software 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>

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

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,”

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



UNIVI
DEGLI



- 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.