



ASSOLOMBARDA

# Digital Health Observatory

23 marzo 2022

## Digital Health - Principi Fondamentali

Prospettive di sviluppo nello scenario internazionale



**daVi**

Digital Medicine



**daVinci**  
DIGITAL THERAPEUTICS

Giuseppe Recchia



**Digital Health ?**

**Sanità Digitale ?**

**Digital Medicine ?**

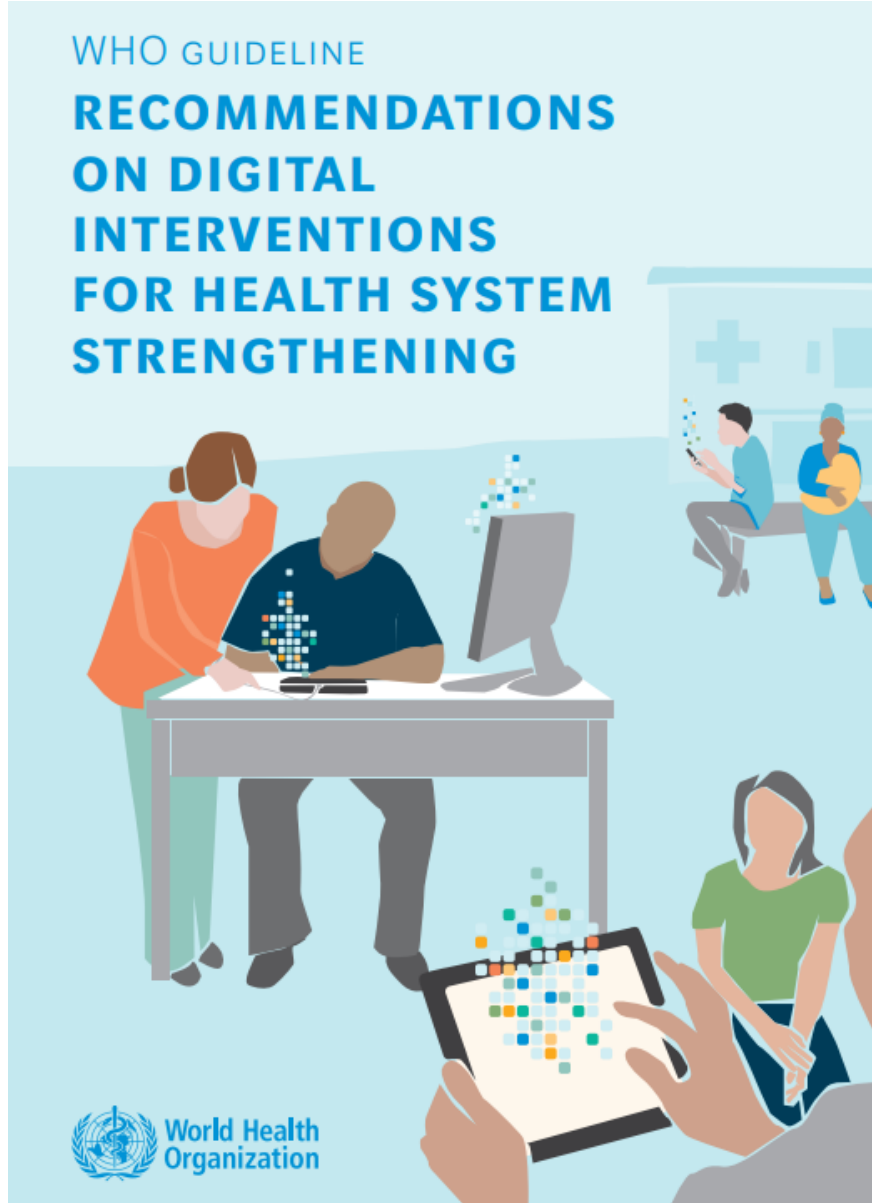
**Digital Therapeutics ?**

**Digital XYZ ?**



classificare : necessità di impresa o esercizio accademico?

# Digital Health - WHO



- **Digital health**, or the use of digital technologies for health, has become a salient field of practice for employing routine and innovative forms of information and communications technology (ICT) to address health needs.
- The term **digital health** is rooted in **eHealth**, which is defined as “**the use of information and communications technology in support of health and health-related fields**”.
- **Mobile health (mHealth)** is a subset of eHealth and is defined as “**the use of mobile wireless technologies for public health**”.
- More recently, the term **Digital Health** was introduced as “...a term **encompassing** eHealth (which includes mHealth), as well as emerging areas, such as the use of advanced computing sciences in ‘**big data**’, genomics and **artificial intelligence**”.



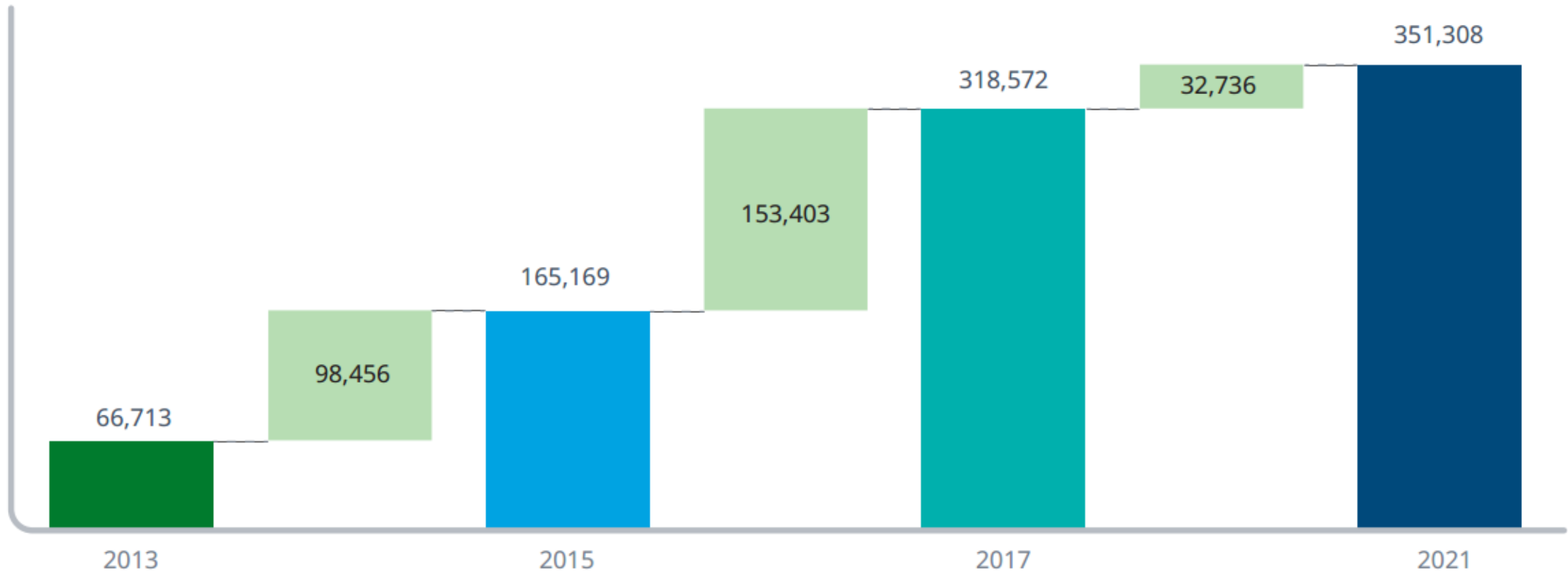
# classi diverse, regole diverse

## Digital Health

- Consumatore
- Benessere
- No prove
- No approvazioni

# «Apps»...Evoluzione 2017 – 2021

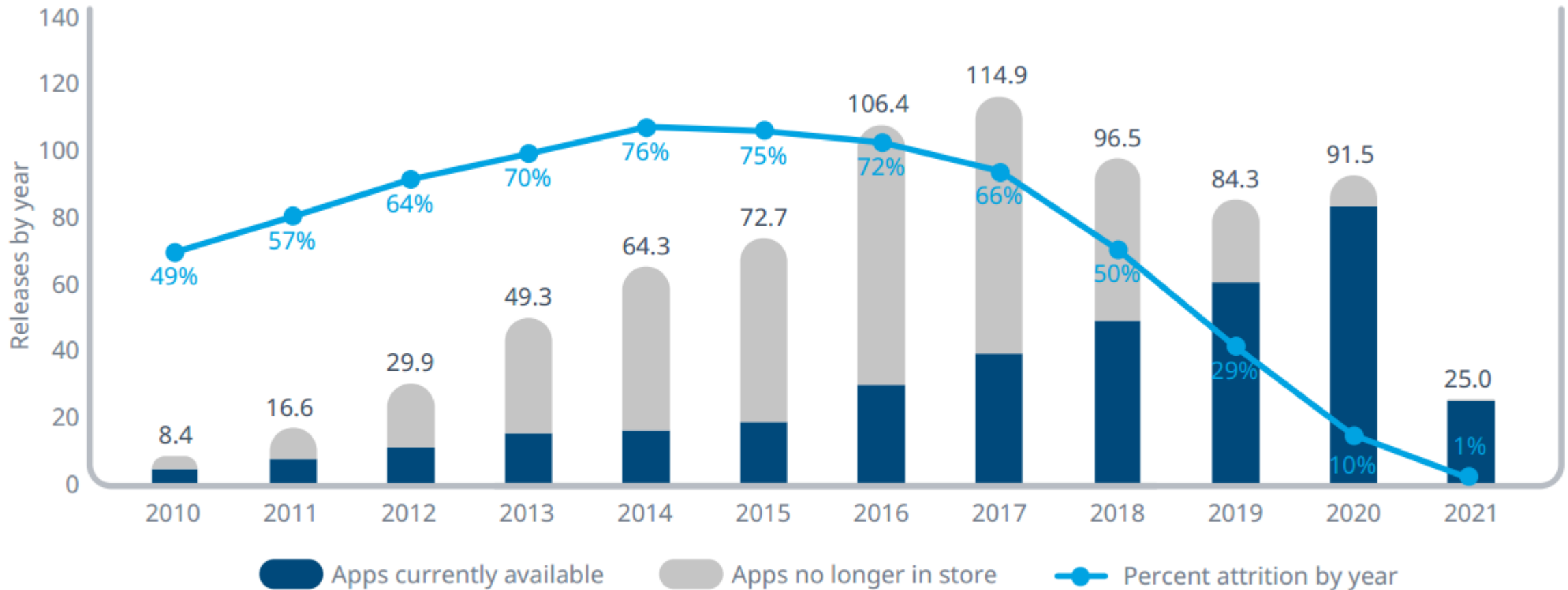
Number of Digital Health Apps 2013–2021



Source: 42 Matters, Jun 2021 and Jul 2017; Mevvy, Jun 2015; IQVIA AppScript App Database, Jun 2021; IQVIA Institute, Jun 2021

Notes: Includes digital health apps that are publicly available to consumers and categorized as Health & Fitness or Medical. Apps that have been removed from stores are not included.

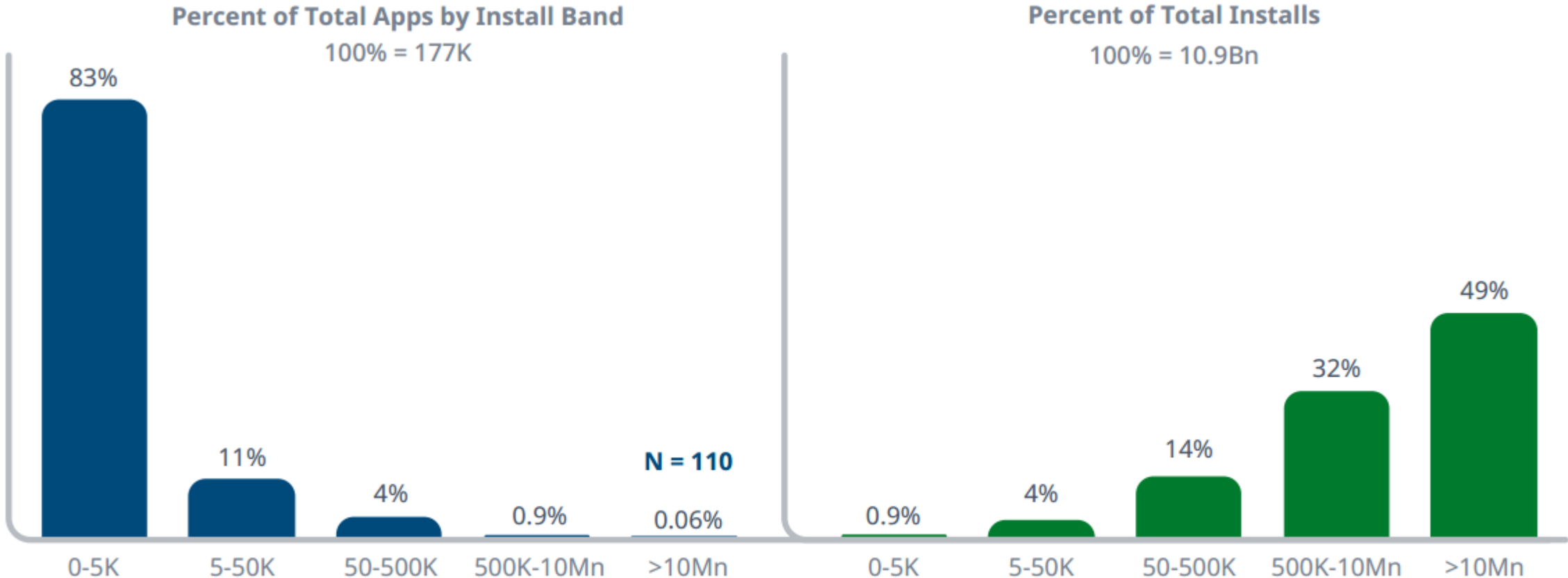
# «Apps»...Entran, Escono ...



Source: 42 Matters, Jun 2021 and Jul 2017; Mevvy, Jun 2015; IQVIA AppScript App Database, Jun 2021; IQVIA Institute, Jun 2021  
Notes: Includes digital health apps that are publicly available to consumers and categorized as Health & Fitness or Medical.

# «Apps»...Poche hanno successo

## Digital Health App Total Downloads in 2021



Source: 42 Matters, Jun 2021, Sep 2017; IQVIA AppScript Database, Jun 2021, Sep 2017; IQVIA Institute, Sep 2017  
Notes: Install data shown is from the Google Play app store only. App Store install data not available.



# «Apps»...Saranno valutate, anche in Italia.

## Use Caution When Choosing Apps

Many of the claims by mental health apps have never actually been studied or evaluated in feasibility or clinical trials <sup>23</sup>. The FDA has taken a largely hands-off approach to regulating these apps, and there is currently little-to-no oversight of mental health apps <sup>4</sup>. This can leave the user to distinguish a useful, safe, and effective app from an unhelpful, dan

**How can an app be dangerous or cause harm.** A few examples

- By offering incorrect or misleading information
- By claiming to offer therapeutic benefits that are ineffective, leading to belief that the app is helpful
- By not being secure, or improperly handling health data.
- By selling patient collected data to third parties without user consent.
- By not actually collecting clinical data
- By being a new technology without sufficient user understanding.

▼ Step 1: Access and Background

▼ Step 2: Privacy and Security

▼ Step 3: Clinical Foundation

▼ Step 4: Usability

▼ Step 5: Data Integration towards Therapeutic Goal

## Apps Can Be Appropriate and Useful in Care

**The goal of APA's App Advisor is to offer resources to help you and your patients make informed decisions about whether or not to use an app.** By asking the right questions and looking for the right information, picking an app can be a more informed process.

A particular app is right for you and your patient. A rating of 'A+' etc to an app is not useful for

Rating is only valid until that app is updated or replaced by a new app <sup>5</sup>.

A decision that depends on the needs of that patient. One app may be very helpful for one medication or therapy may be helpful for another.

With the experience on one user at one time, it is hard for different evaluators experience the



# classi diverse, regole diverse

- Paziente
- Malattia
- Operatore Sanitario
- Prescrizione
- Prove Cliniche
- Dispositivi Medici



Digital Medicine

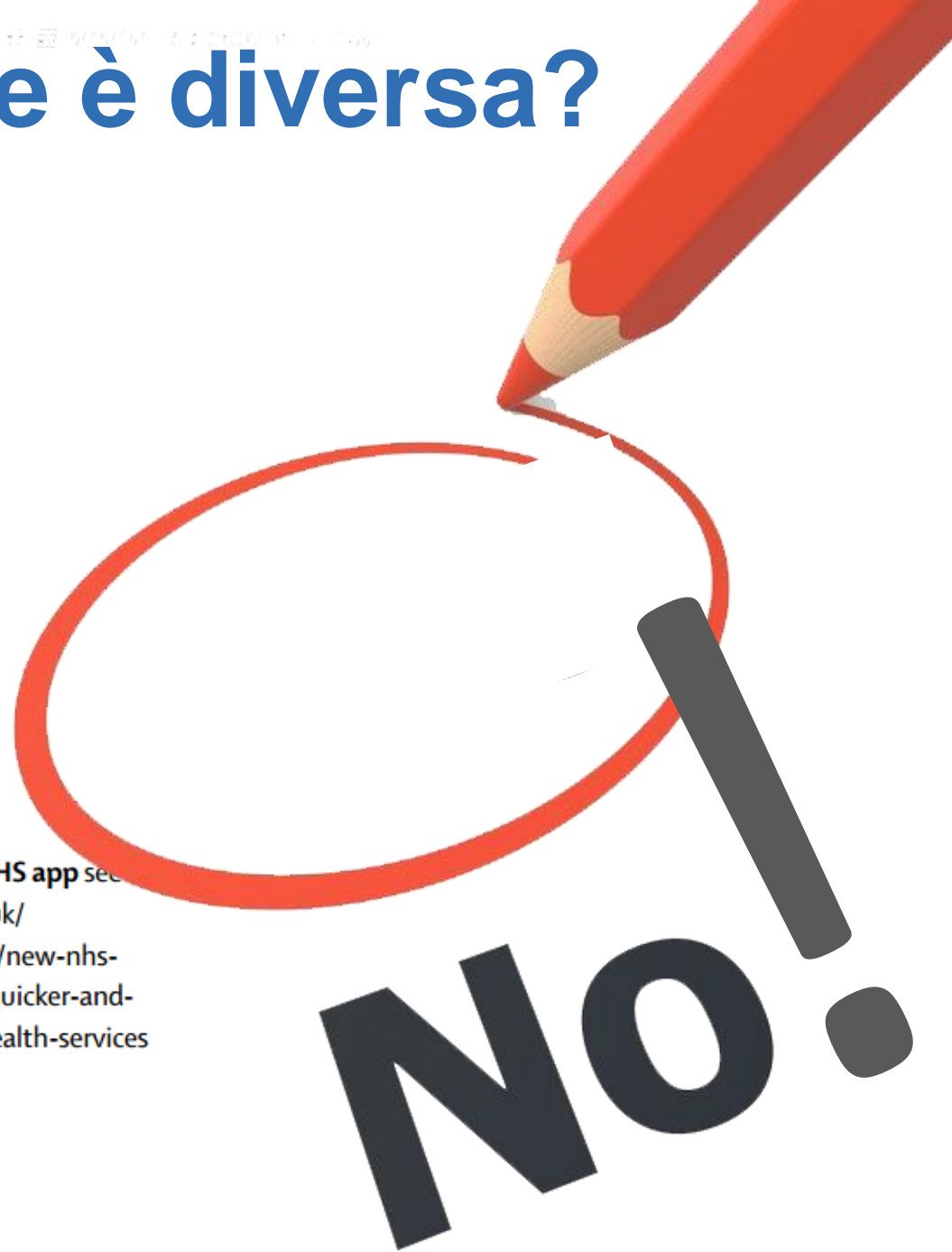
# Digital Medicine

# R&D. La Medicina Digitale è diversa?

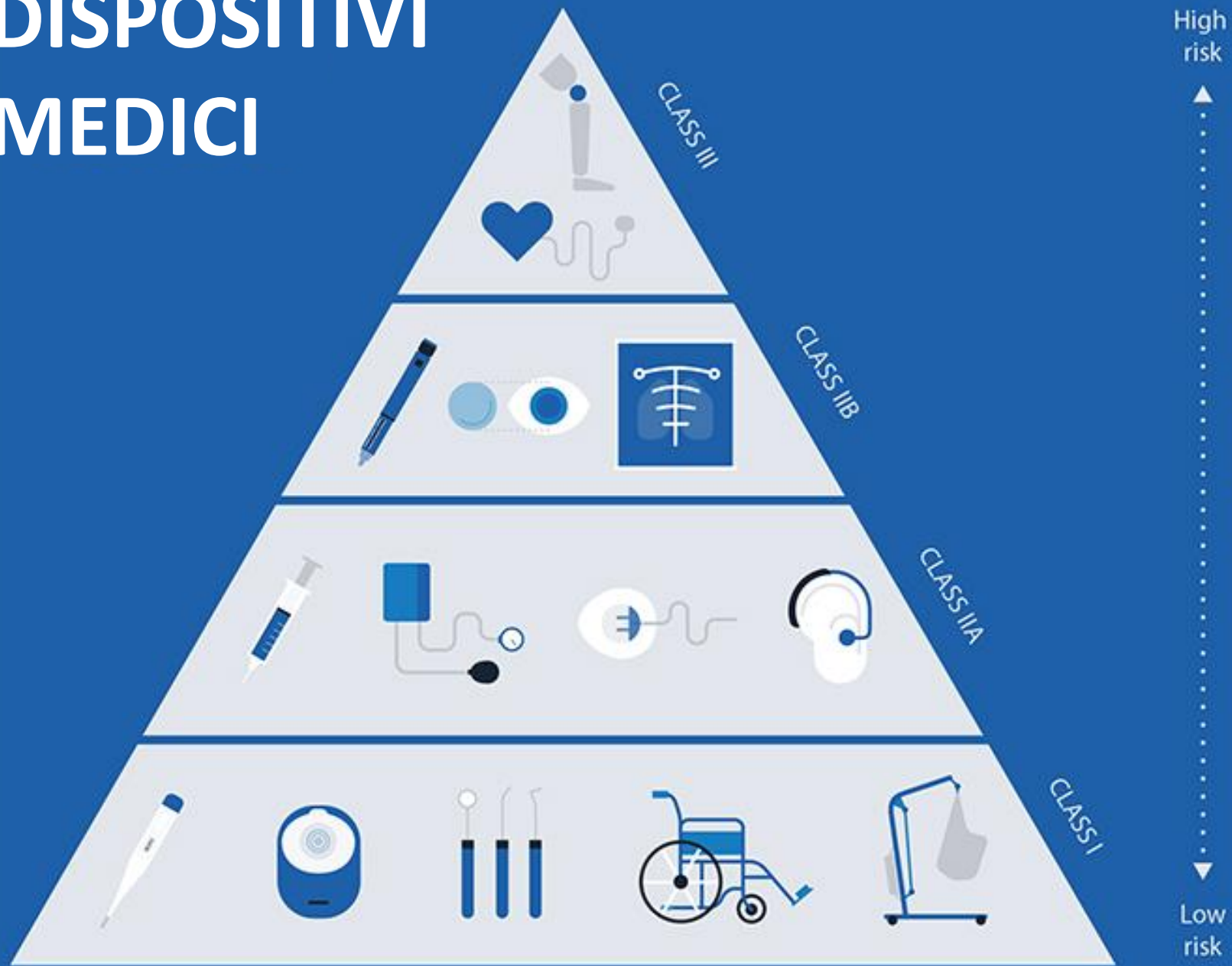
## Is digital medicine different?

Without a clear framework to differentiate efficacious digital products from commercial opportunism, companies, clinicians, and policy makers will struggle to provide the required level of evidence to realise the potential of digital medicine. The risks of digital medicine, particularly use of AI in health interventions, are concerning. Continuing to argue for digital exceptionalism and failing to robustly evaluate digital health interventions presents the greatest risk for patients and health systems. ■ *The Lancet*

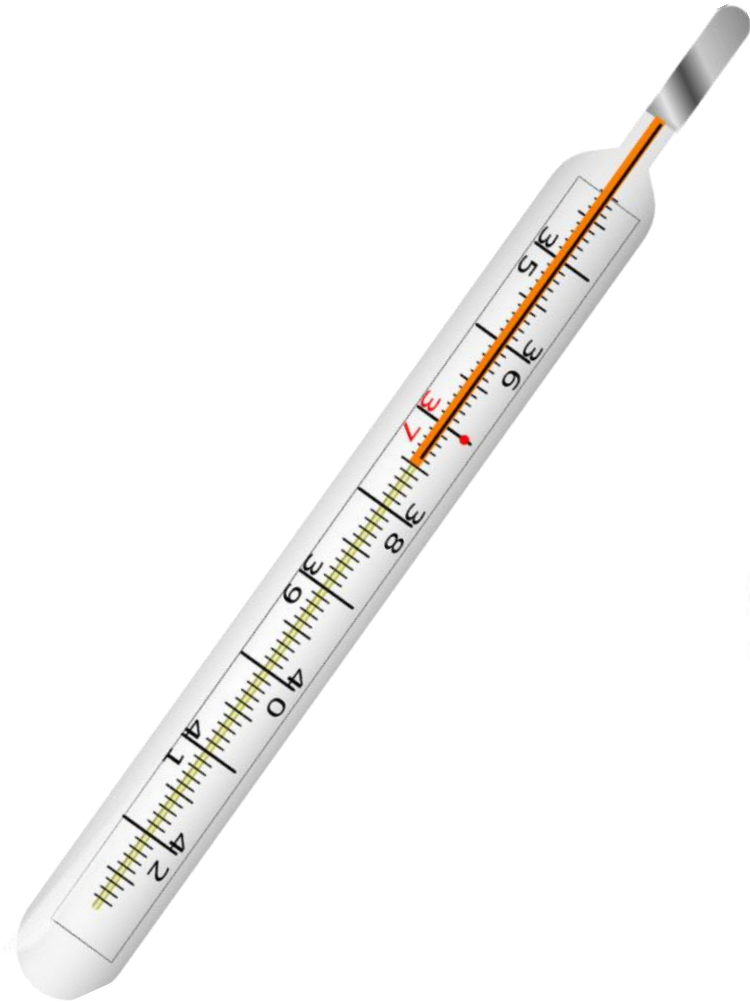
For more on the NHS app see  
<https://www.gov.uk/government/news/new-nhs-app-will-make-it-quicker-and-easier-to-access-health-services>



# DISPOSITIVI MEDICI



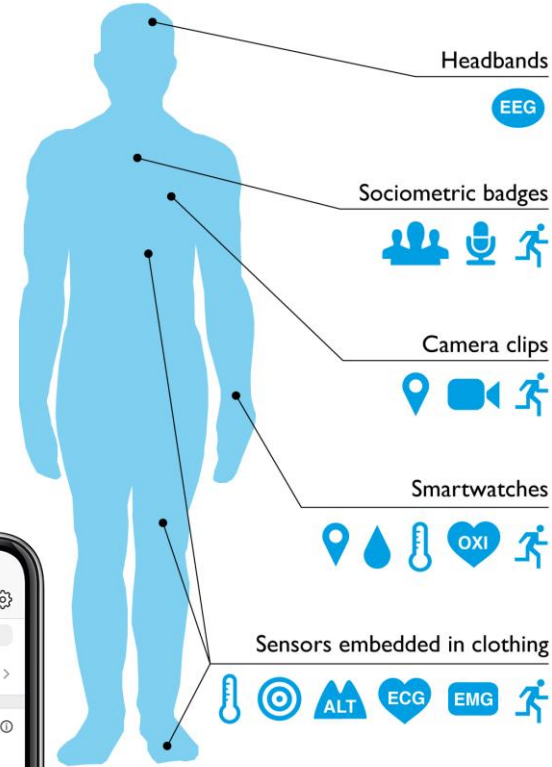
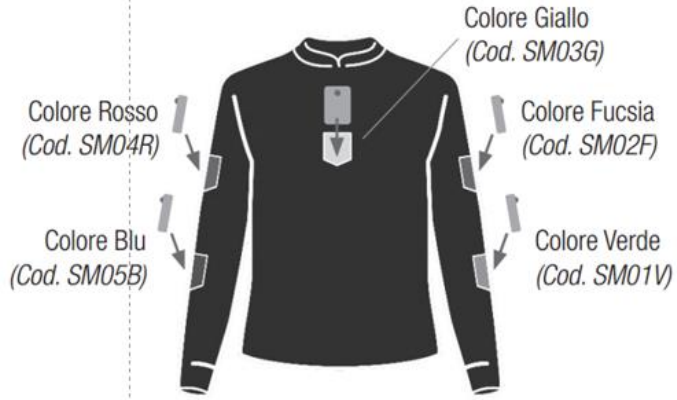
# Misurare o Trattare, questo è il problema...





# Misurare

## Maglia e Sensori



- Accelerometer
- Altimeter
- Digital camera
- Electrocardiogram
- Electromyograph
- Electroencephalogram
- Electrodermograph
- Location GPS
- Microphone
- Oximeter
- Bluetooth proximity
- Pressure
- Thermometer





# Misurare

## Health Evaluation

Answers marked with a \* are required.

2 / 4

50%

### Page 2

6. Have you had a medical examination within the past five years?

- Yes  
 No

7. Are you under a doctor's care for any diagnosed condition?

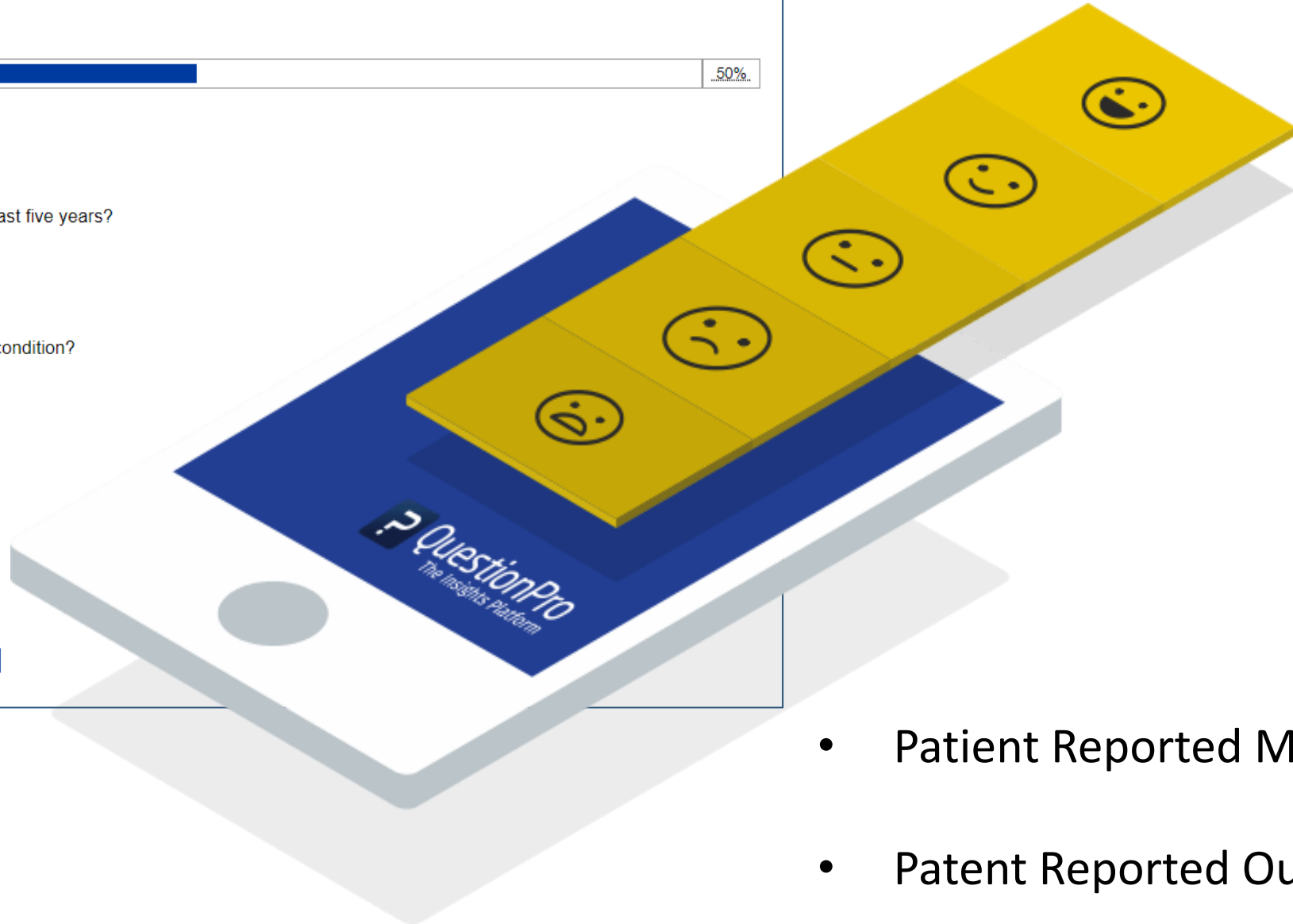
- Yes  
 No

8. Are you taking prescription medications?

- Yes  
 No

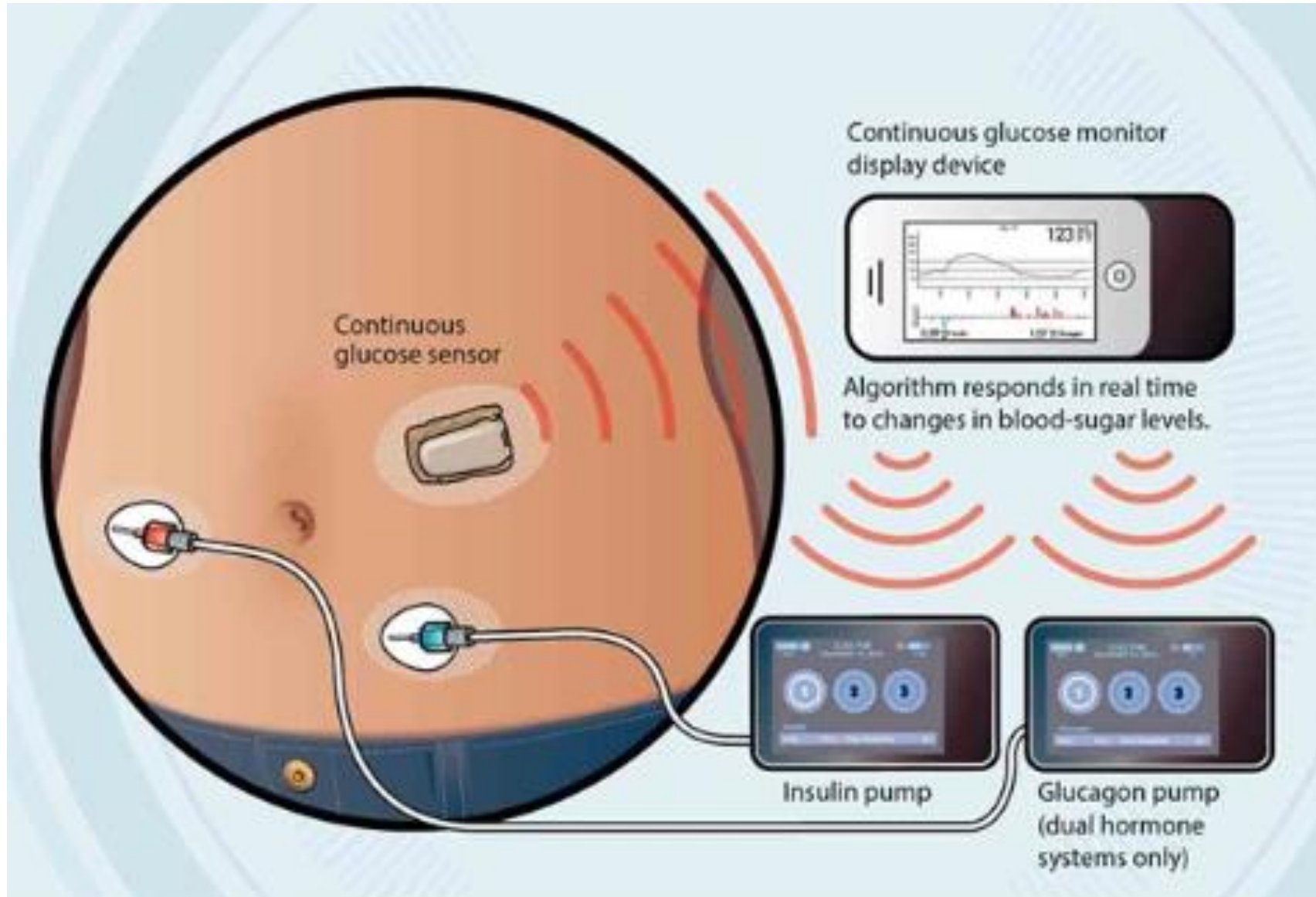
9. What was your last B/P (blood pressure) reading

160/95

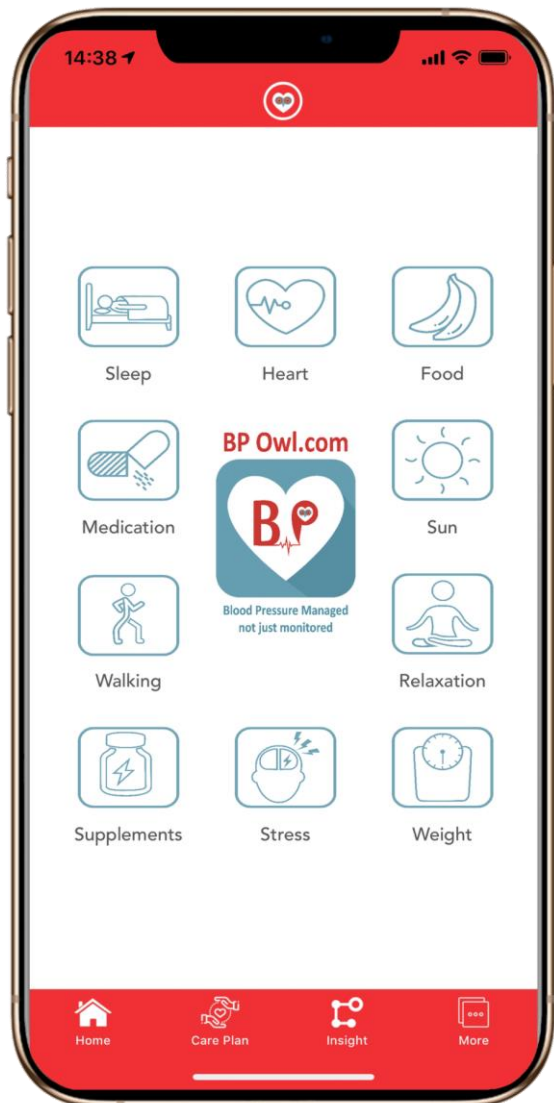


- Patient Reported Measures
- Patient Reported Outcomes

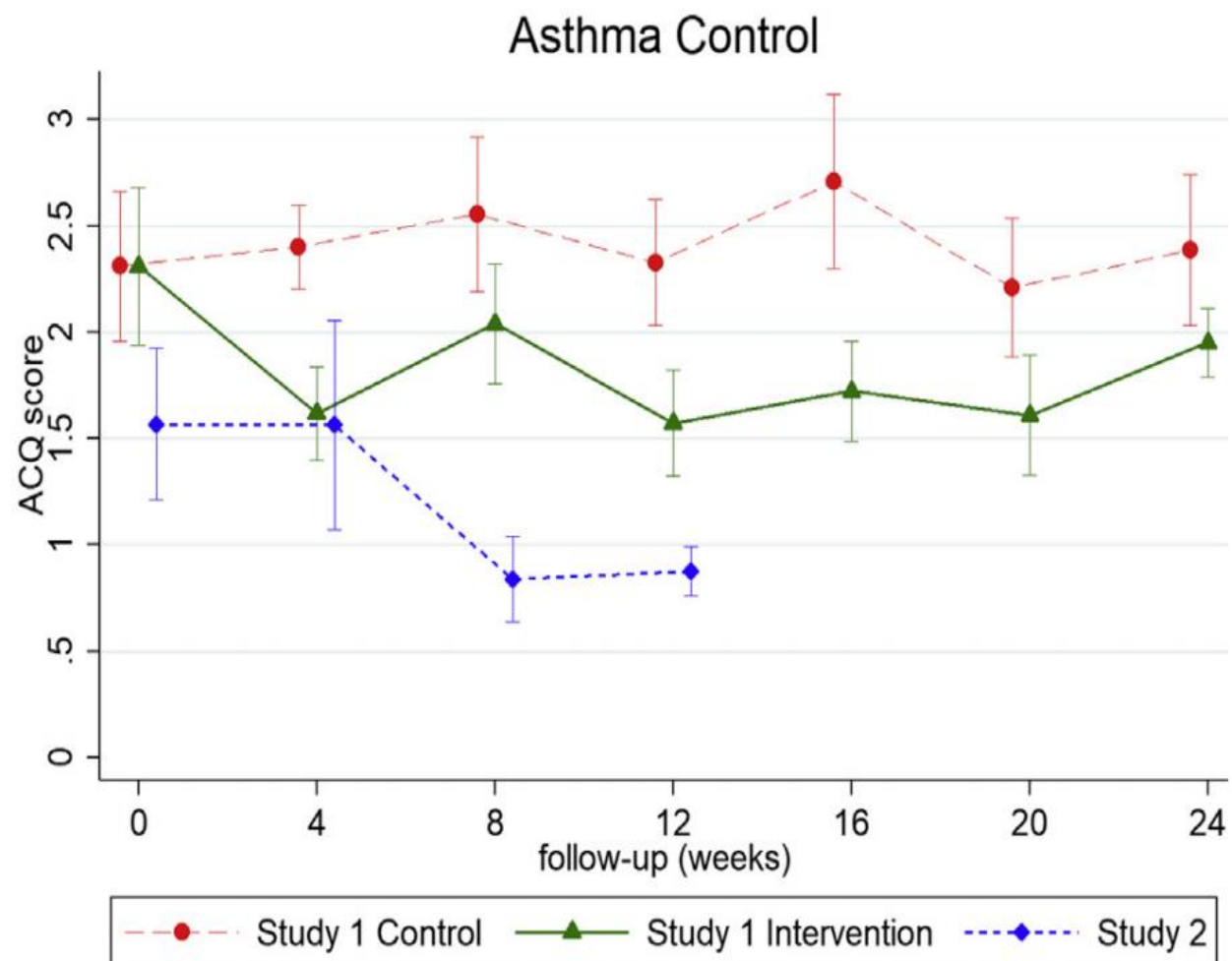
# Misurare e Trattare, questa è la soluzione...



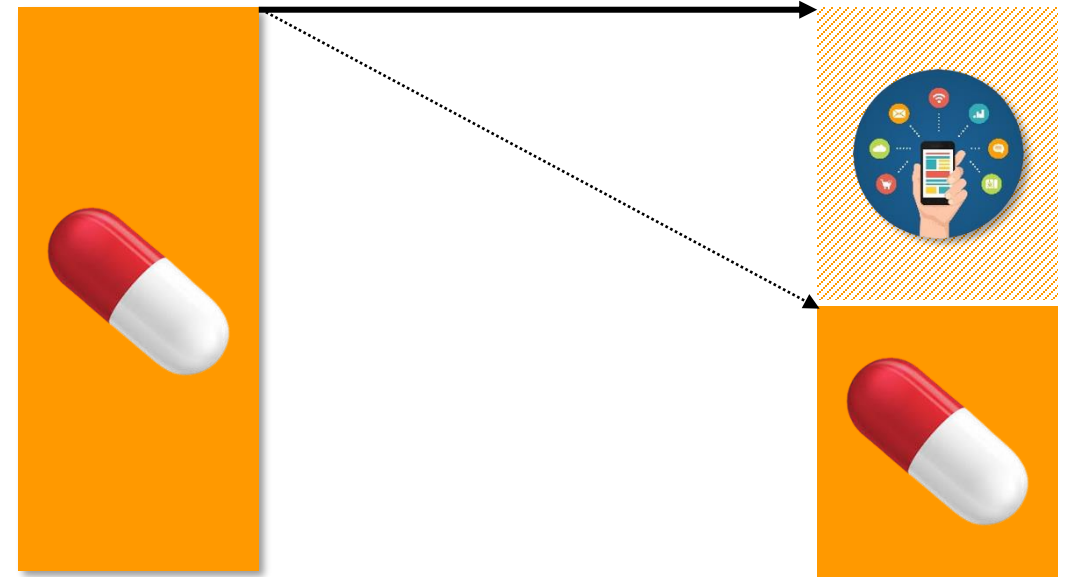
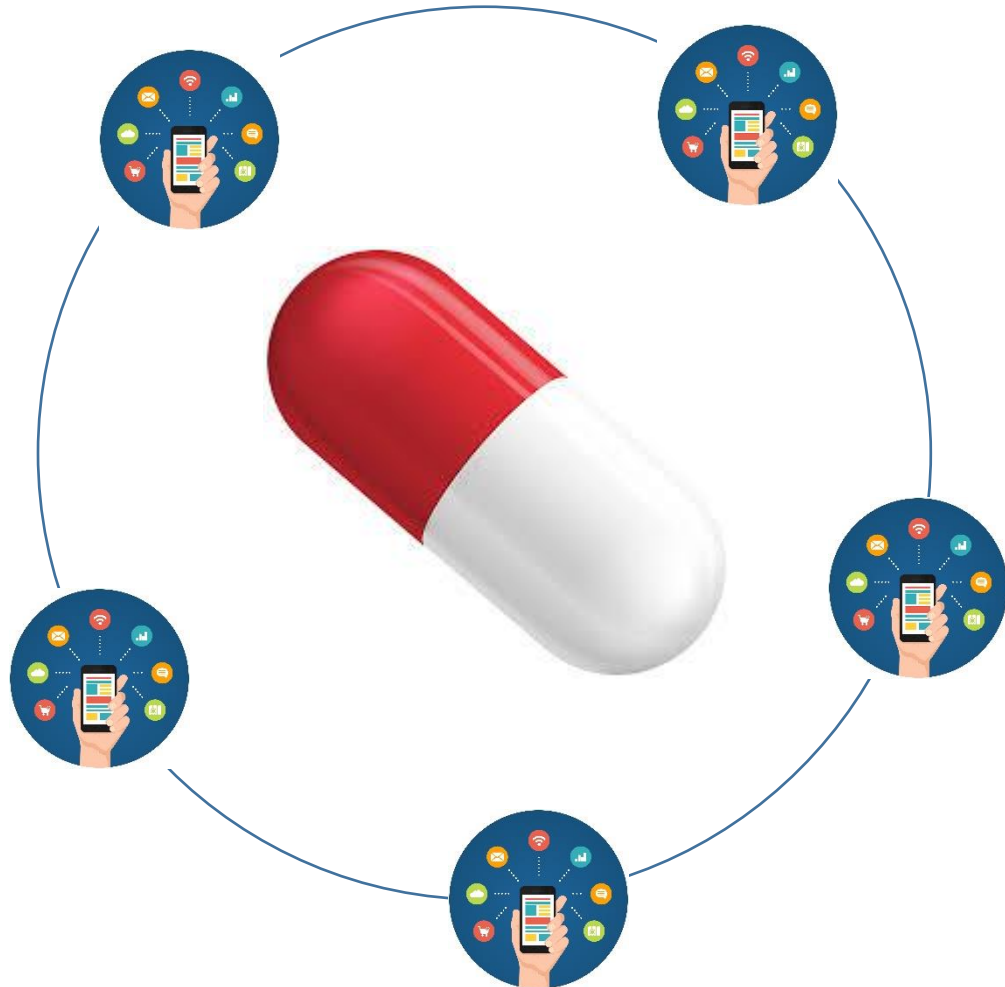
# Trattare - Autogestione Digitale



- Auto
- Gestione
- Digitale
- Formazione
- Supporto



# Trattare - Digital Drug Supports



Sperimentazione  
Clinica

Vita Reale

**Around the Pill Approach**

# Trattare - Digital Drug Supports

Conferenza online

## Digital Medicine e Digital Drug Supports

Verso la Pipeline Bio-Digitale

5 aprile 2022

promossa ed organizzata da

*Cloud-R Milano,*

*daVi DigitalMedicine Verona,*

*Fondazione Ricerca e Salute Roma*

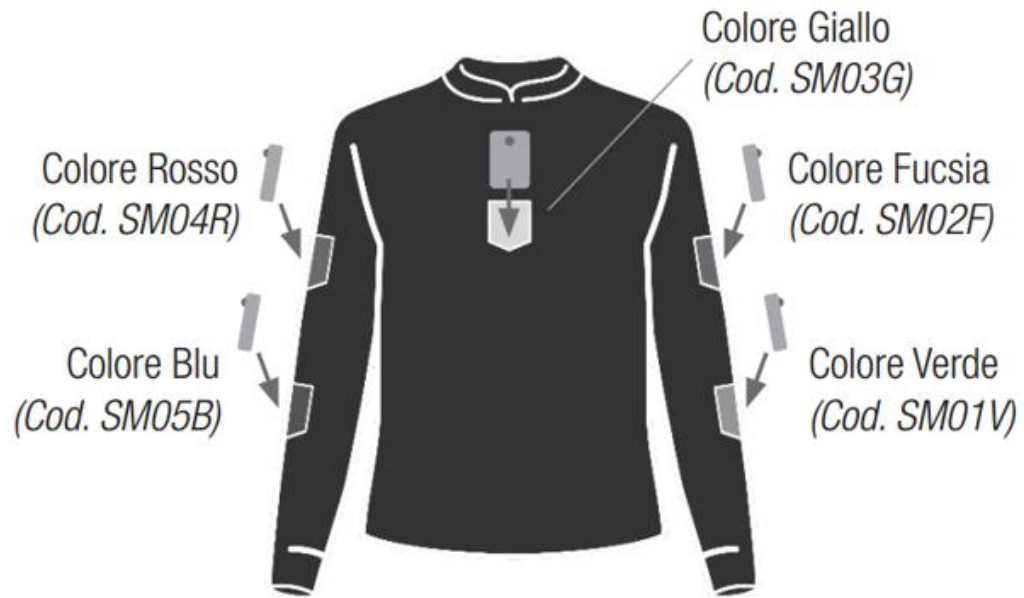
Orario	Argomento	Relatore
14.00	Introduzione alla Conferenza	Ruggero Di Maulo, Cloud-R
14.15	Tassonomia della Digital Health	Giuseppe Recchia, daVi Digital Medicine
14.30	Digital Drug Supports - Dispositivi Medici o giocattoli ?	Martina Mandorlini, Politecnico Milano
14.45	Digital Drug Supports, Dispositivi Medici ed uso dei dati	Silvia Stefanelli, Studio Legale Stefanelli& Stefanel
15.00	Requisiti regolatori e Sviluppo del SaMD	Ruggero Di Maulo, Cloud-R
15.15	My DT MyEvry	Alessandra Ghirardini, Roche
15.30	Pipeline Biodigitale – Progetto Ipertensione Arteriosa	Silvana D’Alessio, Polifarma
15.45	Quale rimborso per i dispositivi medici digitali?	Nello Martini, Fondazione RES
16.00	Tavola Rotonda e Discussione	Giuseppe Recchia, daVi Digital Medicine
16.30	Conclusioni	Nello Martini, Fondazione RES



# Trattare - Digital Rehabilitation

1

## Maglia e Sensori

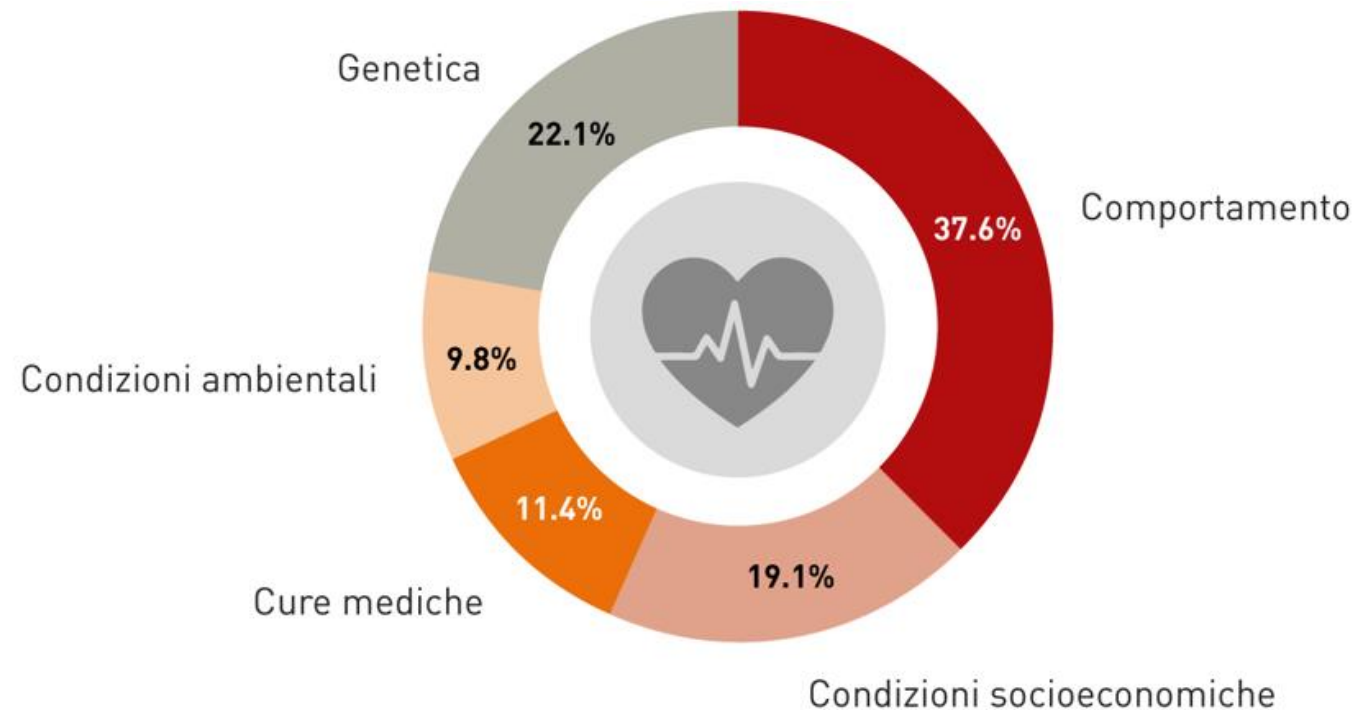


2



# Trattare - Digital Therapeutics

- Health Technologies to treat / manage a disease
- Designed to modify behaviours → wrong lifestyles
- Developed with RCTs
- Approved by regulatory bodies
- Covered by health insurances
- Prescribed by physicians
- **Active Ingredient is an Algorithm...**



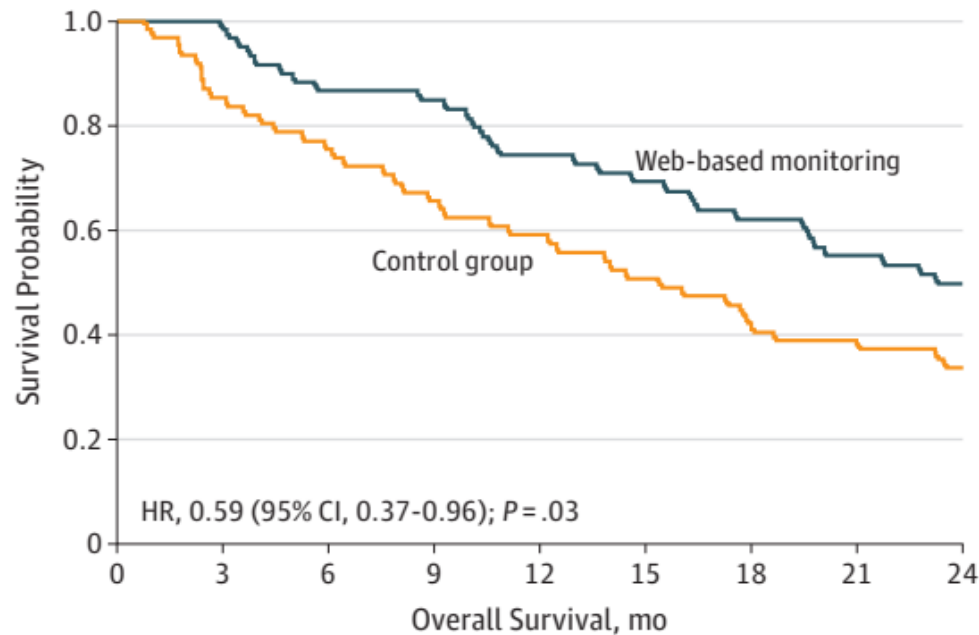
# Prescription Digital Therapeutics

Digital Therapeutic	Company	Phase	Therapeutic Indication
Deprexis	GAIA AG	Approved 2009	Depression
Sleepio	Big Health	Approved 2013	Insomnia
Reset	Pear Therapeutics	Approved 2017	Substance Use Disorder
Reset-O	Pear Therapeutics	Approved 2018	Opioid Use Disorder
Oleena	Voluntis	Approved 2019	Oncology
Somryst	Pear Therapeutics	Approved 2020	Chronic Insomnia
Endeavor	Akili Laboratories	Approved 2020	ADHD
Smoking Cessation	CureApp	Approved 2020	Smoking
Parallel	Mahana	Approved 2020	Irritable Bowel System
Hypertension	Cure App	Approved 2021	Hypertension
EaseVRx	AppliedVR	Approved 2021	Chronic Low Back Pain

# Sono efficaci? Oncologia

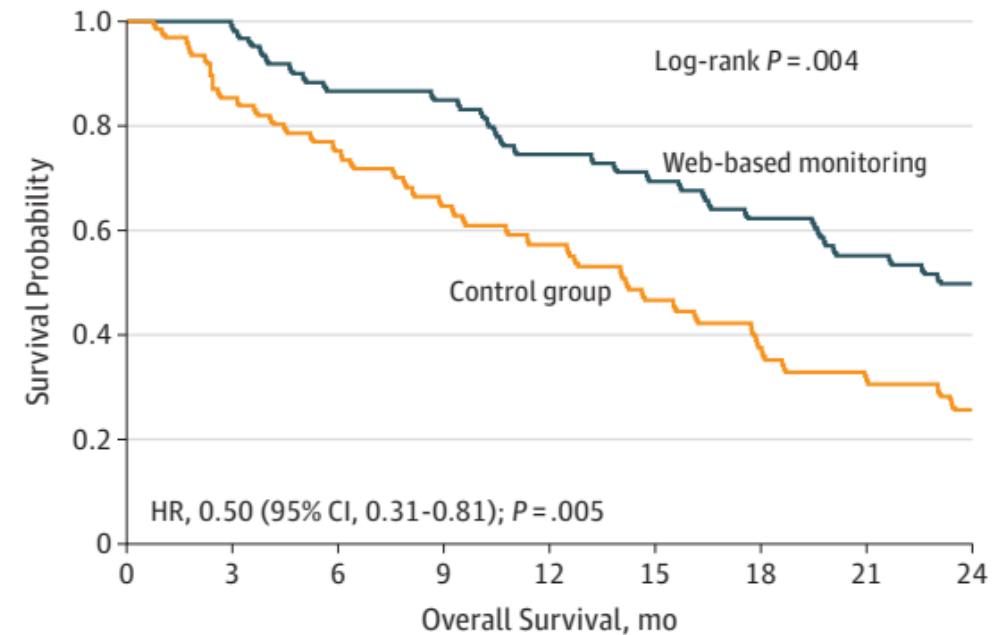
Denis E et al. *Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer* **JAMA** 22 Jan 2019, 321(3)

**A** Intention-to-treat analysis



Source	Median OS	12-mo OS, %	24-mo OS, %
Web-based monitoring	22.5 mo	75	50
Control	14.9 mo	56	34

**B** Censoring of crossover analysis

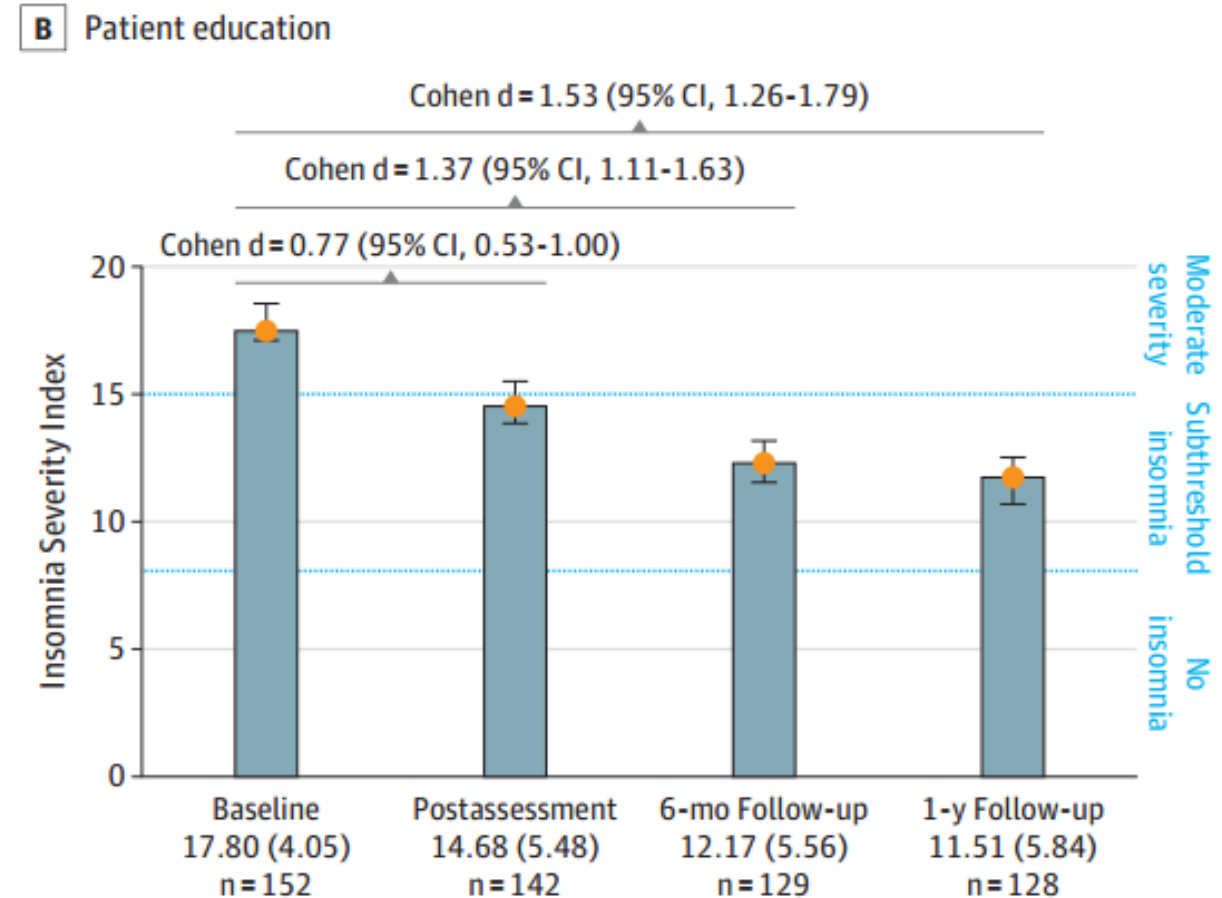
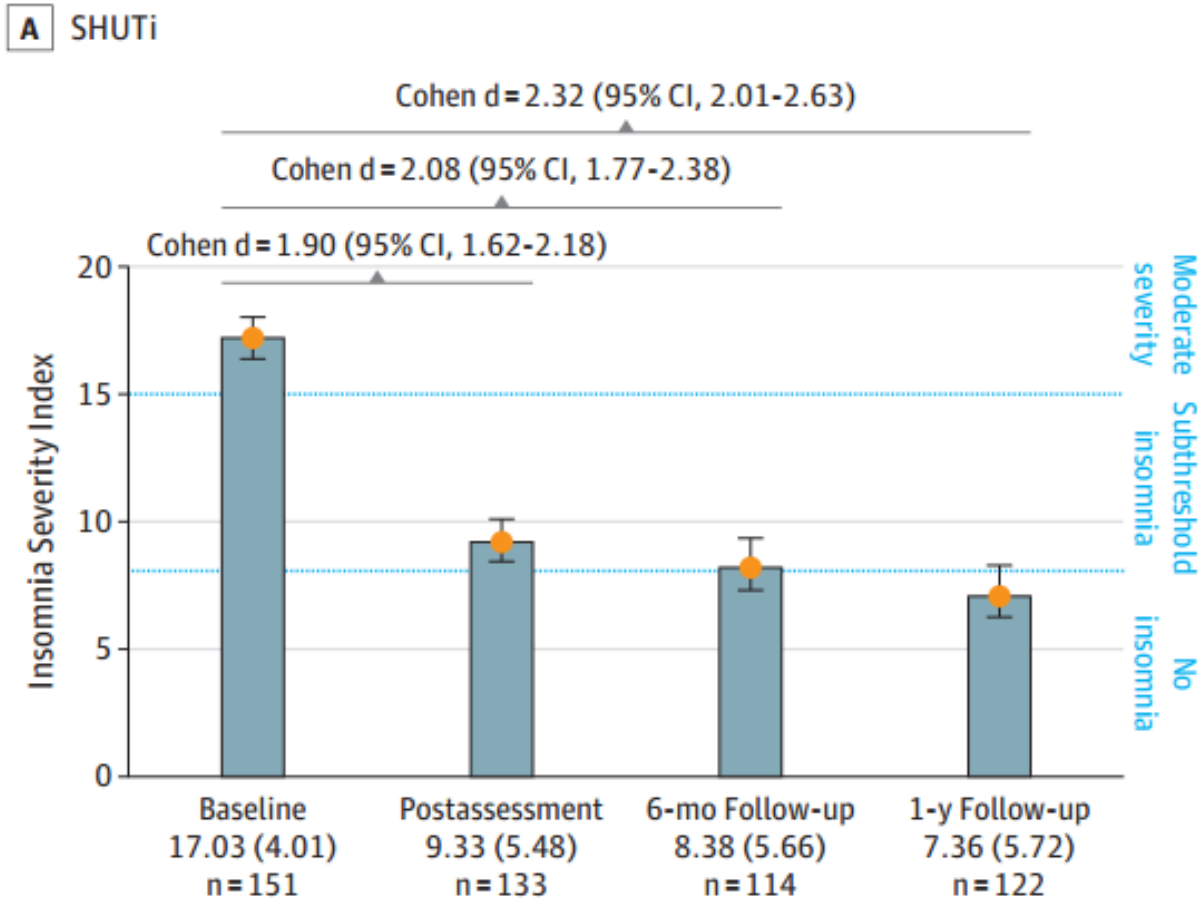


Source	Median OS	12-mo OS, %	24-mo OS, %
Web-based monitoring	22.5 mo	75	50
Control	13.5 mo	53	26

Symptom monitoring via weekly web-based PROs following treatment for lung cancer was associated with increased survival compared with standard imaging surveillance. A potential mechanism of action is that symptoms suggesting adverse events or recurrence were detected earlier

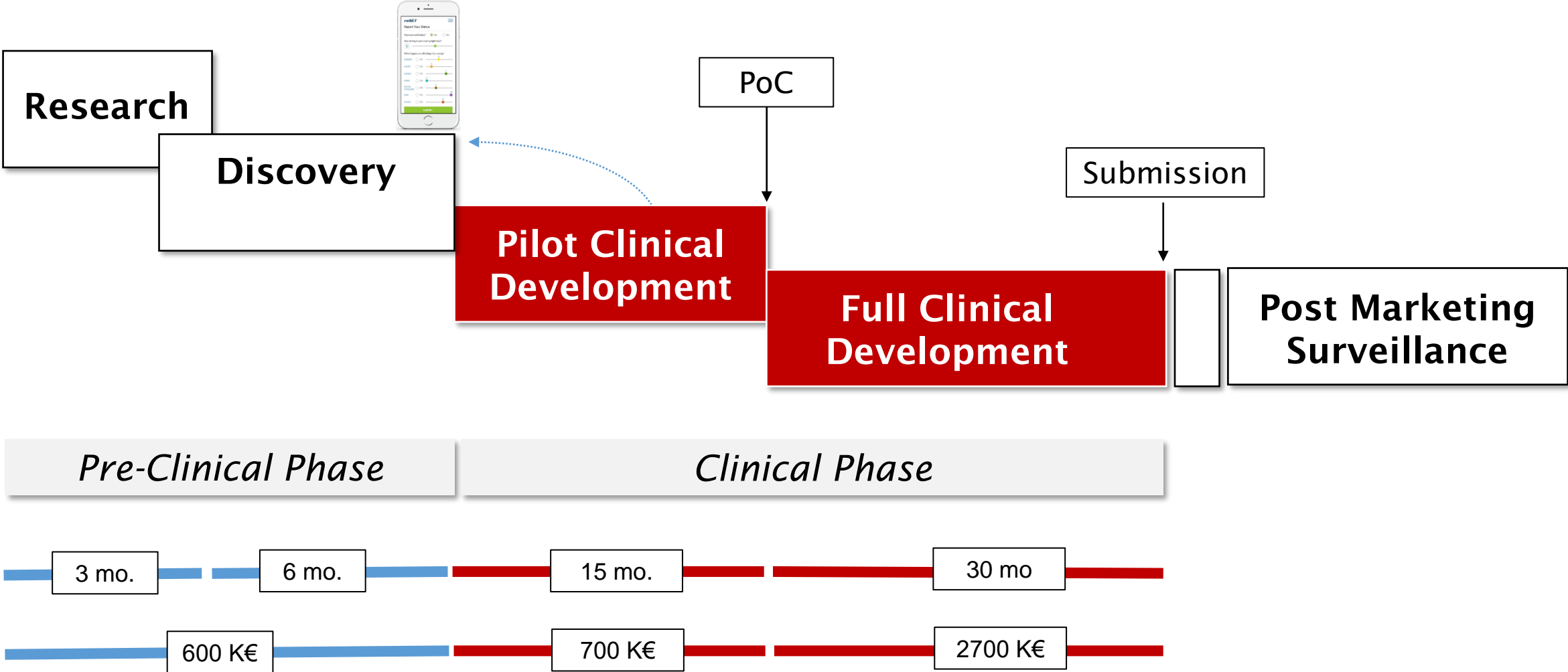
# Sono efficaci? Insonnia Cronica

Lee M Ritterband et al. *Effect of a Web-Based Cognitive Behavior Therapy for Insomnia Intervention With 1-Year Follow-up. A Randomized Clinical Trial. JAMA Psychiatry* 2017; 74(1):68-75

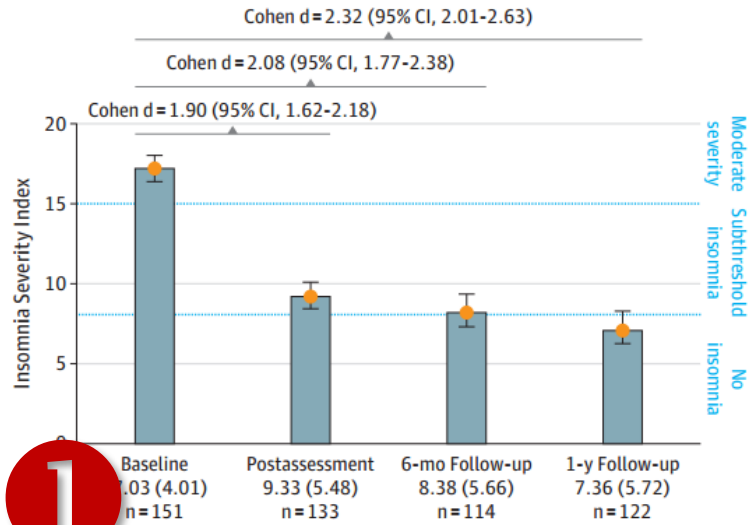




# Quale Ricerca & Sviluppo?



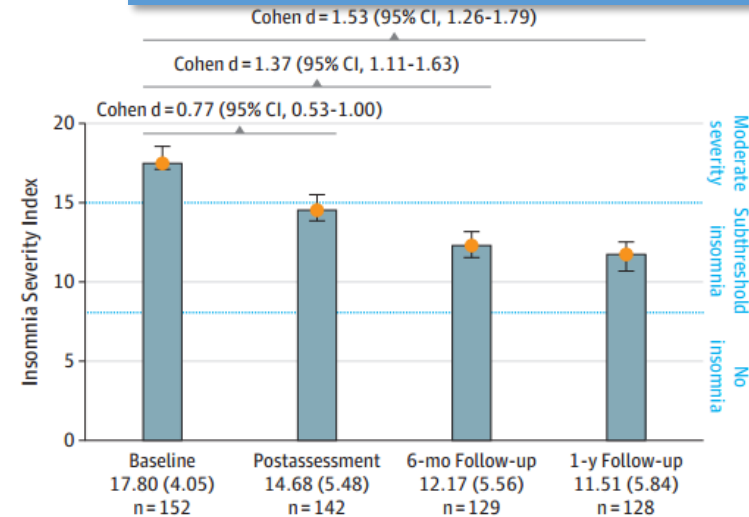
A SHUTi



1

## Level of Evidence

B Patient e



Digital Health London

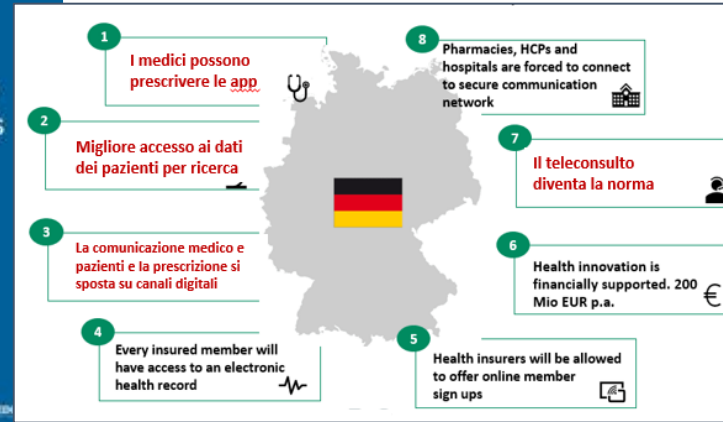
### Digital Therapeutics in the NHS: The rise of digital therapies & the evidence that proves they work

Tuesday, 24 April 2018

#DHLCOLLABORATE  
#DigitalHealthLondon

## Reimbursement

2



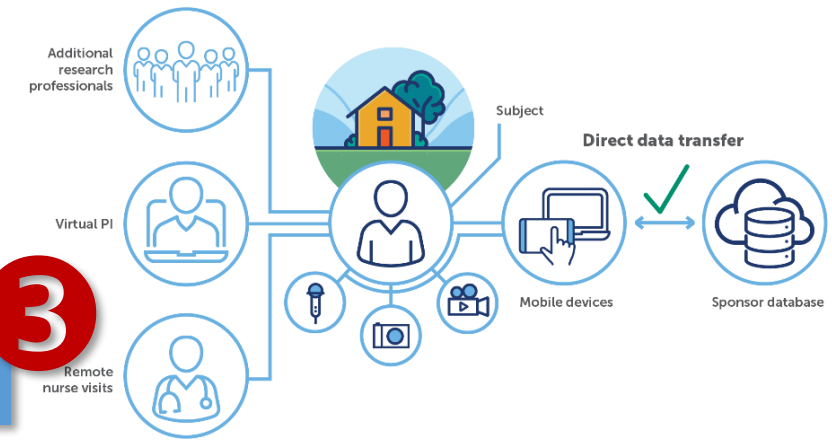
Moovcare® becomes the first digital therapy reimbursed in France!

Read more →

Follow us

## Decentralized Clinical Trial

3



Si possono sperimentare Tecnologie Digitali per la Salute con studi clinici «analogici»?

1. Commercialization & Reimbursement
2. Partnership
3. Clinical Insight & Regulation
4. Adoption
5. User Engagement & Consumer Awareness



Defining the New Age of Digital Therapeutics

28th-29th June 2022

London, UK & Online | 4th Annual

# Commercialization & Reimbursement

## **1. The Current Landscape of the European DTx Market: Where Are We Now?**

- a. How does DiGA in Germany differ from other reimbursement pathways coming to life within Europe e.g France, Belgium, UK, Italy?

## **2. The Future of Digital Health Reimbursement Pathways in Europe**

- a. Is a centralised reimbursement pathway a viable option for the future of the European market?

## **1. Key Considerations of Pharma Partnerships Working with DTx Companies**

- a. How can digital tools be incorporated into a pharmaceutical company's product range to benefit business?



## 1. Can AI Bridge The Gap Between Regulation and Precision Medicine in Digital Therapeutics?

- a. Regulatory requirements state all patients must receive the same version of a treatment

## 2. Need for Change of Clinical Trials in Digital Medicine

*The current framework for clinical trials in digital health falls under an umbrella of one size fits all. There is an unwritten dichotomy between regularly updated software based digital health products and how regulatory frameworks are designed*

- a. How do decentralized clinical trials compare to traditional studies?
- b. Where can changes be made within the clinic to develop more efficient trials for DTx?
- c. What changes must be made in regulation to accommodate for new digital medicine?

## **1. DTx Value Assessment & Integration Guide**

- a. Due to a lack of frameworks defining what “good” looks like, many HCDMs have taken it upon themselves to develop their own methods to evaluate DTx products.

## **2. Breaking DTx into The Mainstream Healthcare System**

- a. What commercial barriers are holding DTx companies back from entering the popular market?
- b. How must we innovate commercial models to grow a company's revenue?

## **1. Barriers to Physician Adoption in Digital Therapeutics**

- a. What are the key obstacles within physician adoption?
- b. How has COVID-19 changed people's perspective and engagement of digital health tools?
- c. Has increased awareness and necessity of digital health tools had a significant impact on adoption?

## **2. Putting the Product in Patients Hands: How to Increase Physician Adoption**

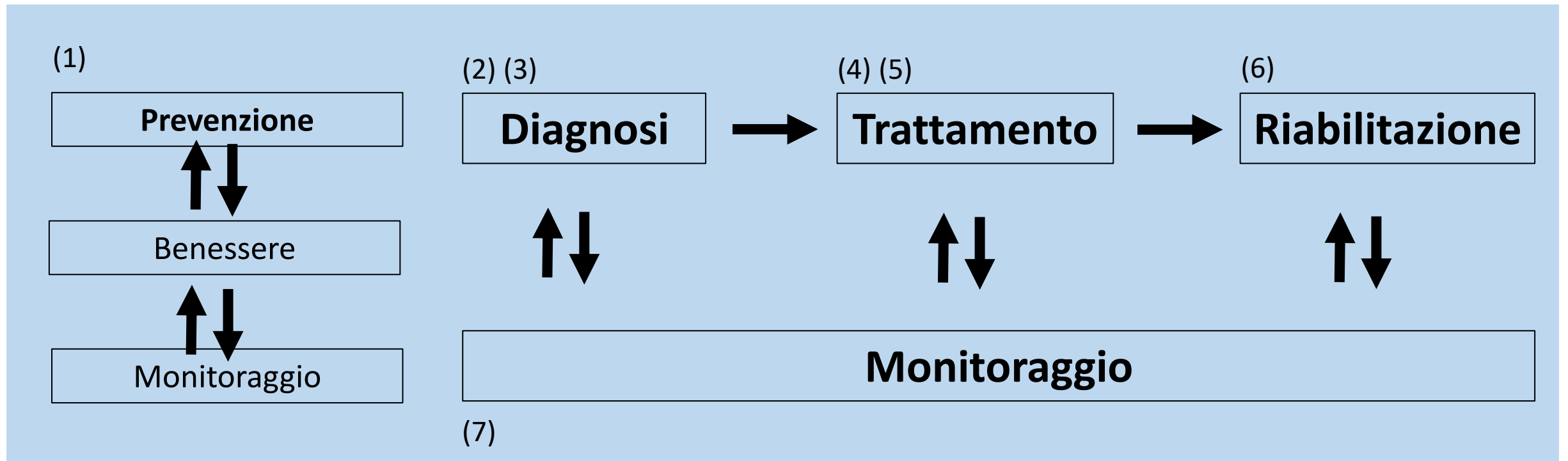
- a. Even with developments like DiGA physician adoption is still low
- b. How can physicians adapt their workflow to make digital health a reality?
- c. What do physicians need to see to begin incorporating digital therapeutics into their workflow?
- d. Are education campaigns going to be the final hurdle to take DTx products to the next phase?

# User Engagement & Consumer Awareness

- 1. Gamification: A Tool for Increasing User Engagement in Digital Health**
- 2. A Behavioural Change Focused Approach to Digital Health**
- 3. How Can We Ensure Longevity of Digital Health Products Through Consistent User Engagement?**
  - a. What strategies are in place to keep users engaged over long periods of time?
  - b. How are DTx companies trying to increase consumer awareness and intimacy?
  - c. how companies can gather and utilise patient engagement, usage, and retention data to increase consistent engagement with new users

# Trasformare la gestione della malattia

1. «App» Benessere
2. Dispositivi digitali di supporto alla diagnosi
3. Dispositivi digitali Auto-gestione malattia
4. Digital Drug Supports
5. Digital Therapeutics
6. Digital Rehabilitation
7. Digital Monitoring



# Tele Medicina Digitale

## INFORMAZIONI

- Rapporti (A)
- Sensori (P)
- Questionari (A)
- Narrativa (A)



## PRESCRIZIONI

- Digital Therapeutics
- Digital Pills
- Digital Rehabilitation
- Digital Drug Supports
- Farmaci
- Ed altro

## TERAPIE DIGITALI UNA OPPORTUNITÀ PER L'ITALIA

Editor

**Gualberto Gussoni**

### Tendenze nuove

Numero speciale 1/2021

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# 1. Informazione e Sensibilizzazione

## 2. Formazione

- Pazienti Esperti
- Operatori Sanitari
- Ricercatori
- Comitati Etici
- Imprese
- Altri

The screenshot shows the website header for UnitelmaSapienza (Università degli Studi di Roma). The navigation menu includes 'Dove siamo', 'Contatti', 'English Courses', 'WEBMAIL', 'AREA AMMINISTRATIVA', 'ACCESSO AI CORSI', and 'FAQ'. The main navigation bar features 'Ateneo', 'Fai la tua scelta', and 'Area studenti'. The breadcrumb trail is 'HOME > FAI LA TUA SCELTA > CORSI DI FORMAZIONE > PAZIENTE ESPERTO IN TECNOLOGIE DIGITALI PER LA SALUTE'. The main heading is 'PAZIENTE ESPERTO IN TECNOLOGIE DIGITALI PER LA SALUTE'. Below it, the text reads 'Sono aperte le preiscrizioni.' and 'Il corso avrà avvio a partire dal 15 Aprile 2022'. A paragraph describes the course's goal: 'Il Corso di Formazione intende promuovere lo sviluppo del paziente esperto in tecnologie digitali per la salute in Italia, con l'obiettivo finale di migliorare – attraverso il contributo del paziente esperto in terapia digitale – la qualità della tecnologia offerta al paziente per poter condurre la propria vita nel miglior stato di salute possibile.' On the right, there is a red button labeled 'PIANO DEGLI STUDI' with a '> DOWNLOAD' link, and a dark red button labeled 'Iscriviti ora'.

- Medico di Medicina Generale
- Telemedicina e Medicina Digitale

# 1. Informazione e Sensibilizzazione

## 2. Formazione

## 3. Progetti Verticali

- Decentralized Clinical Trials
- Medicina Generale e Medicina Digitale
- Osservatorio Nazionale Terapie Digitali
- Riabilitazione Digitale
- Farmacista Ospedaliero e dei Servizi Territoriali
- Dossier per il Rimborso del Digital Therapeutic
- DDL Sanità e Medicina Digitali



**UnitelmaSapienza**

Università degli Studi di Roma



FONDAZIONE  
**RICERCA  
E SALUTE**

1. Informazione e Sensibilizzazione

2. Formazione

3. Progetti Verticali

4. Comunicazione Istituzionale

5. Ricerca

- Progetti RD
- Sperimentazione Clinica

1. Informazione e Sensibilizzazione

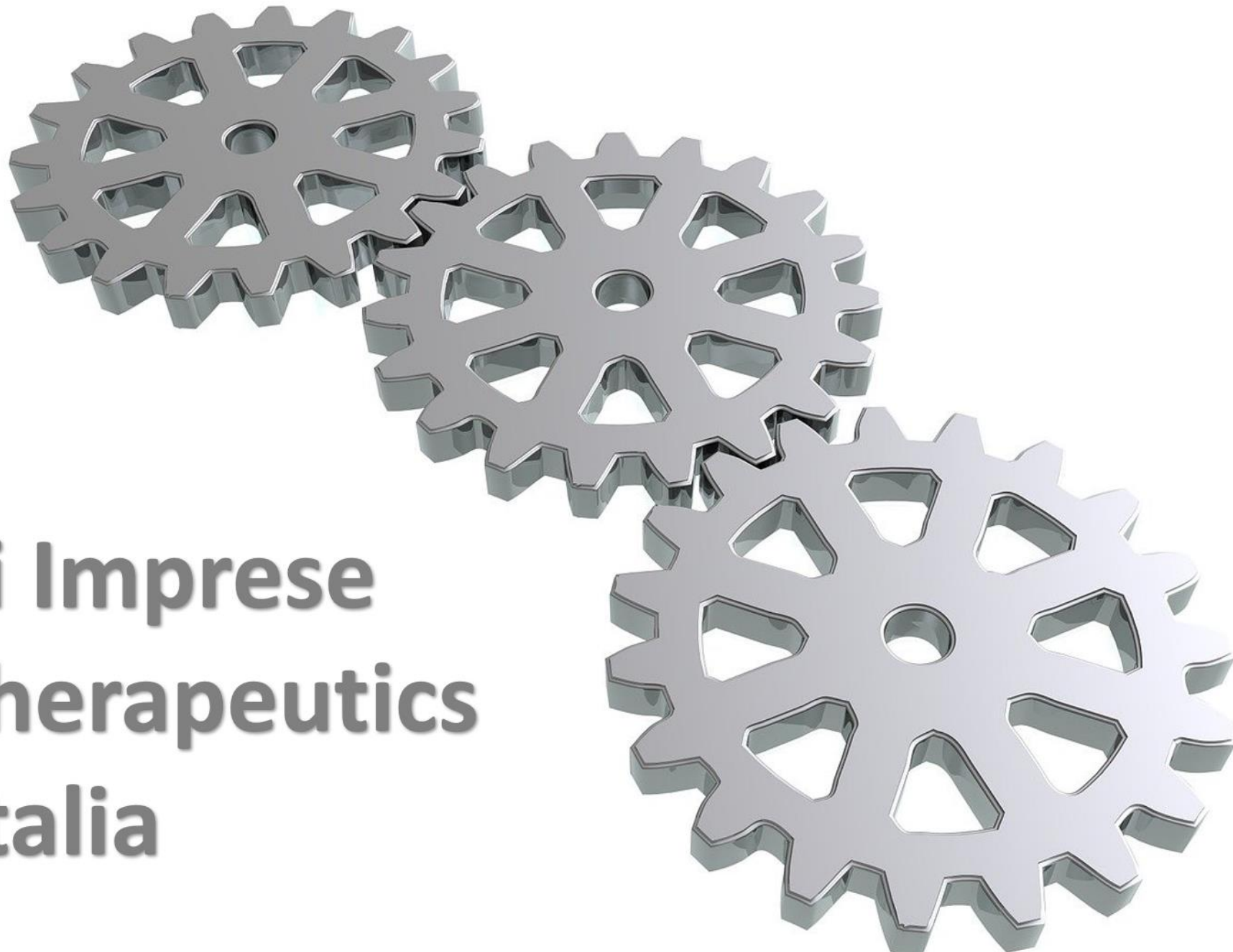
2. Formazione

3. Progetti Verticali

4. Comunicazione Istituzionale

5. Ricerca

6. Imprese



**Rete di Imprese**  
**Digital Therapeutics**  
**Italia**

1. Informazione e Sensibilizzazione

2. Formazione

3. Progetti Verticali

4. Comunicazione Istituzionale

5. Ricerca

6. Imprese

7. Legge sulla Salute e Sanità Digitali

# Legge sulla Salute e Sanità Digitale in Italia

- Ispirata al *Digitale Versorgung Gesetz* (legge sulla sanità digitale) della Germania
- Incorporata nella legislazione sanitaria italiana
- Adattata al Servizio Sanitario Nazionale italiano
- Redatta da esperti di diritto costituzionale, medicina digitale, pazienti, medici, farmacisti, altri
- Discussa con tutte le parti interessate
- Aperta ai contributi di tutte le parti sociali
- Sostenuta da una rete di istituzioni, università, associazioni, aziende
- Presentata in tempo utile per la valutazione / approvazione entro la fine dell'attuale legislatura.