L’ecosistema dell’innovazione:
Le Terapie Digitali

Bergamo 11 Aprile 2019

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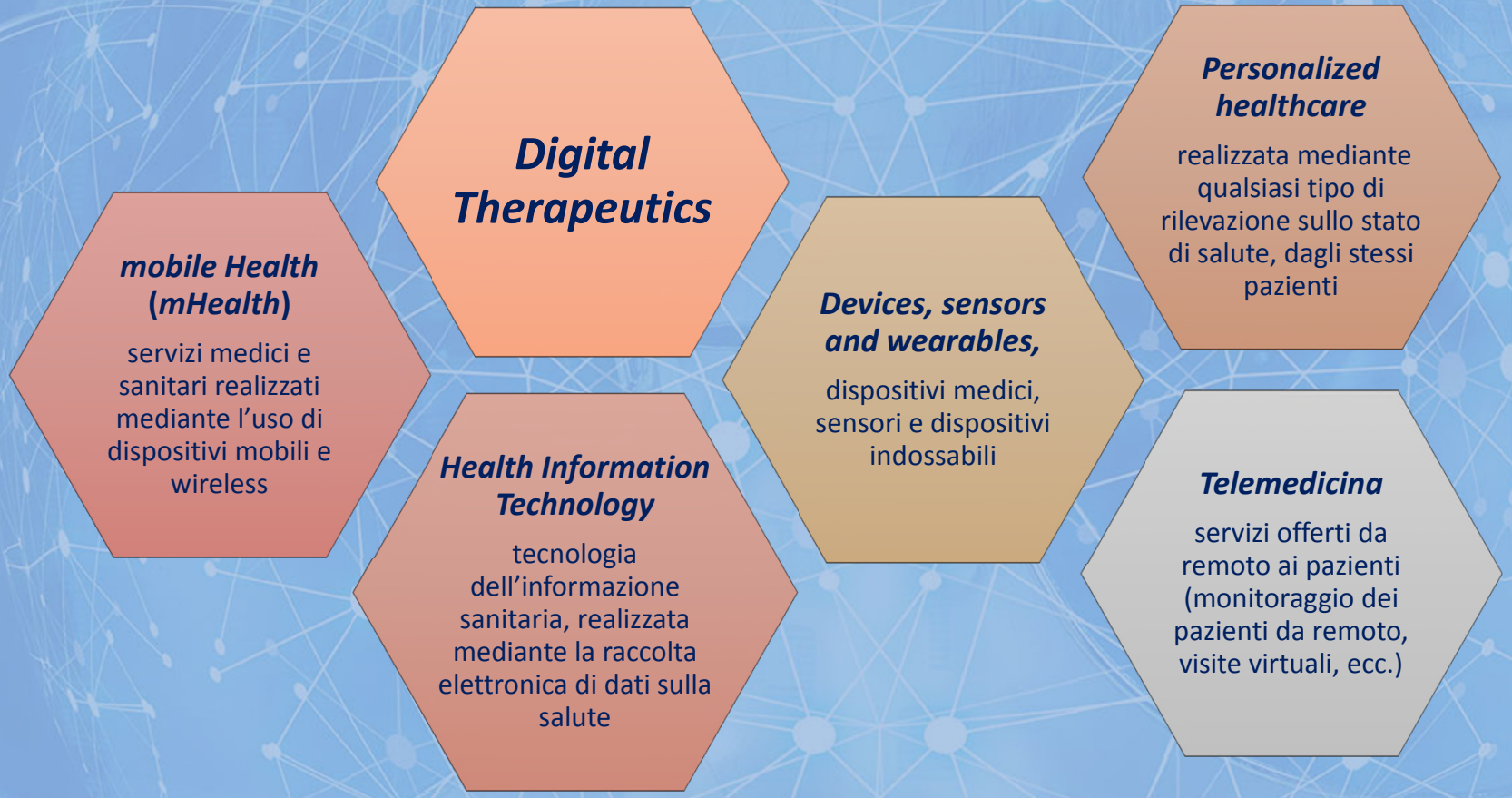
Perche’ occuparci di terapia digitale?

Con il termine “salute digitale” si possono descrivere tutte le tecnologie che coinvolgono i pazienti per aspetti legati alla salute



Il panorama “salute digitale” secondo la Digital Therapeutics Alliance

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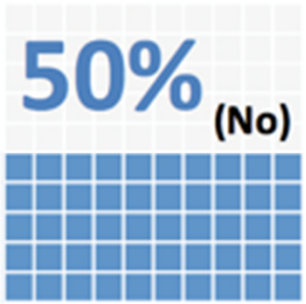
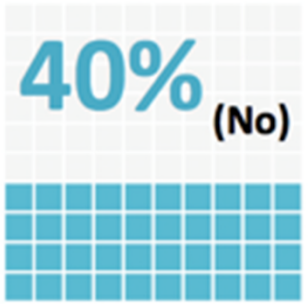
A significant number of practicing physicians are unaware of the term ‘digital therapeutics’

Neurologists (n=30)



Endocrinologists (n=30)



Source: Ipsos Healthcare

Le Terapia Digitali sono definite come quelle terapie che possono fornire interventi terapeutici diretti sui pazienti, generati dal software, per prevenire, gestire o curare disturbi o condizioni patologiche.

(DTA-Report_DTx-Industry-Foundations e 3 DTx - Digital Therapeutics Alliance)

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Come e’ stata definita la terapia digitale?

“Le terapie digitali sono una nuova categoria di applicazioni che aiutano a trattare le malattie modificando il comportamento del paziente e fornendo un monitoraggio remoto per migliorare i risultati a lungo termine sulla salute»
www.forbes.com, 2017

“La terapeutica digitale, un sottoinsieme della salute digitale, è una disciplina sanitaria e un'opzione di trattamento che utilizza tecnologie sanitarie digitali e spesso online per trattare una condizione medica o psicologica. Il trattamento si basa su cambiamenti comportamentali e di stile di vita»
Wikipedia, 2018

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Come e’ stata definita la terapia digitale?

“Un terapeutico digitale è un intervento basato sul software come ingrediente chiave, che ha un impatto diretto su una malattia»
Jörg Land, CEO, Sonormed, 2018

«Si tratta di soluzioni tecnologiche validate clinicamente, progettate per integrare o potenzialmente sostituire le terapie tradizionali, garantendo un maggiore coinvolgimento del paziente e migliorando al tempo stesso la qualità complessiva dell'assistenza sanitaria nel lungo periodo»
www.digitalhealthitalia.com, 2018

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Meccanismo di azione della terapia digitale

Le DTx utilizzano la tecnologia per integrare o sostituire la terapia clinica tradizionale:

1) Integrano il trattamento terapeutico tradizionale aiutando i pazienti a gestire le loro condizioni.

2) Offrono terapie alternative a quelle farmacologiche (es. trattamento insonnia, depressione) in cui tramite una o piu' interfacce digitali vengono forniti stimoli sensoriali.

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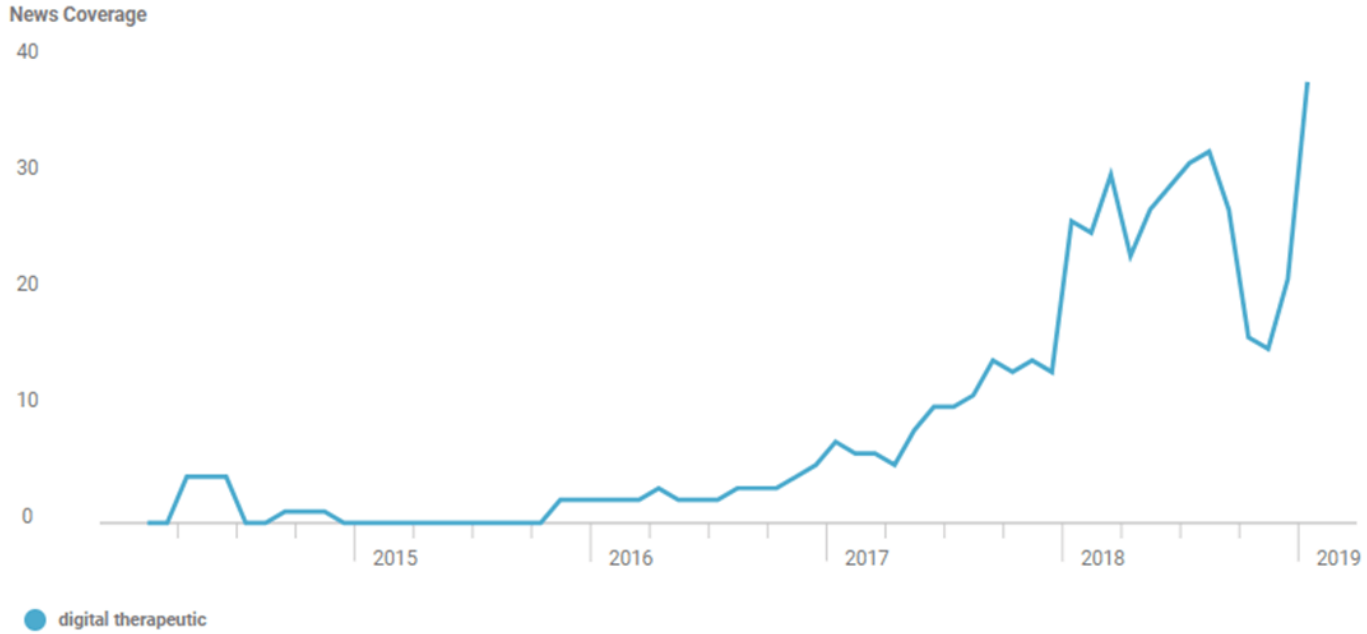
Interest in digital therapeutics is on the rise

News coverage from February 2014 – January 2019



Source: cbinsights.com

CBINSIGHTS

Classificazione delle terapie digitali (Berman 2019)

1. ***Servizi digitali***
   Prodotti che aiutano i pazienti a migliorare i loro esiti clinici, attraverso cambiamenti dello stile di vita.

2. ***Dispositivi di supporto farmaceutici***
   Terapie che migliorano in maniera indiretta i benefici derivanti dai farmaci tradizionali.

3. ***Sostituti farmaceutici***
   Realizzano un effetto terapeutico diretto, senza ulteriori forme di trattamento, possono esser prescritti in alternativa alle cure tradizionali.

Steven Berman, Gennaio 2019. Aequitas Partners *"Digital Therapeutics. Why Your Next Pill May Be an App…"*,

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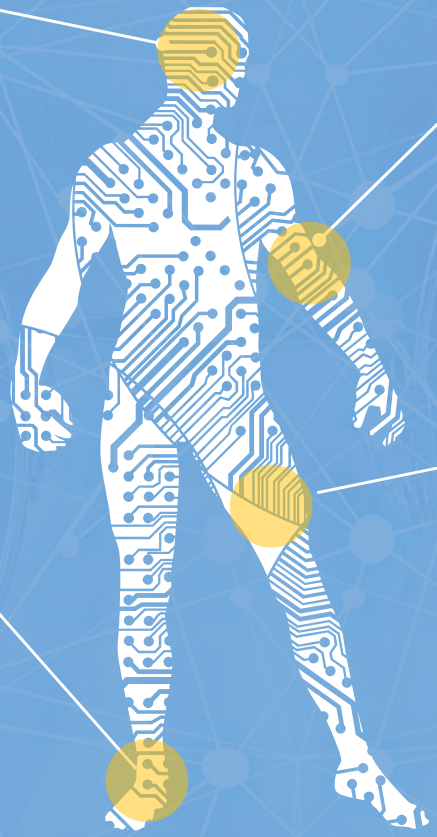
Classificazione delle terapie digitali (DTA Report)

Partendo dal presupposto che ogni DTx possa esser classificata sulla base di claims ed usi previsti, è possibile distinguere 4 macro-categorie:

DT per migliorare una patologia

DT per ottimizzare trattamenti farmacologici (un farmaco specifico o una classe di farmaci),



DT per gestire o prevenire un disturbo medico o una malattia

DT per curare una malattia o un disturbo.

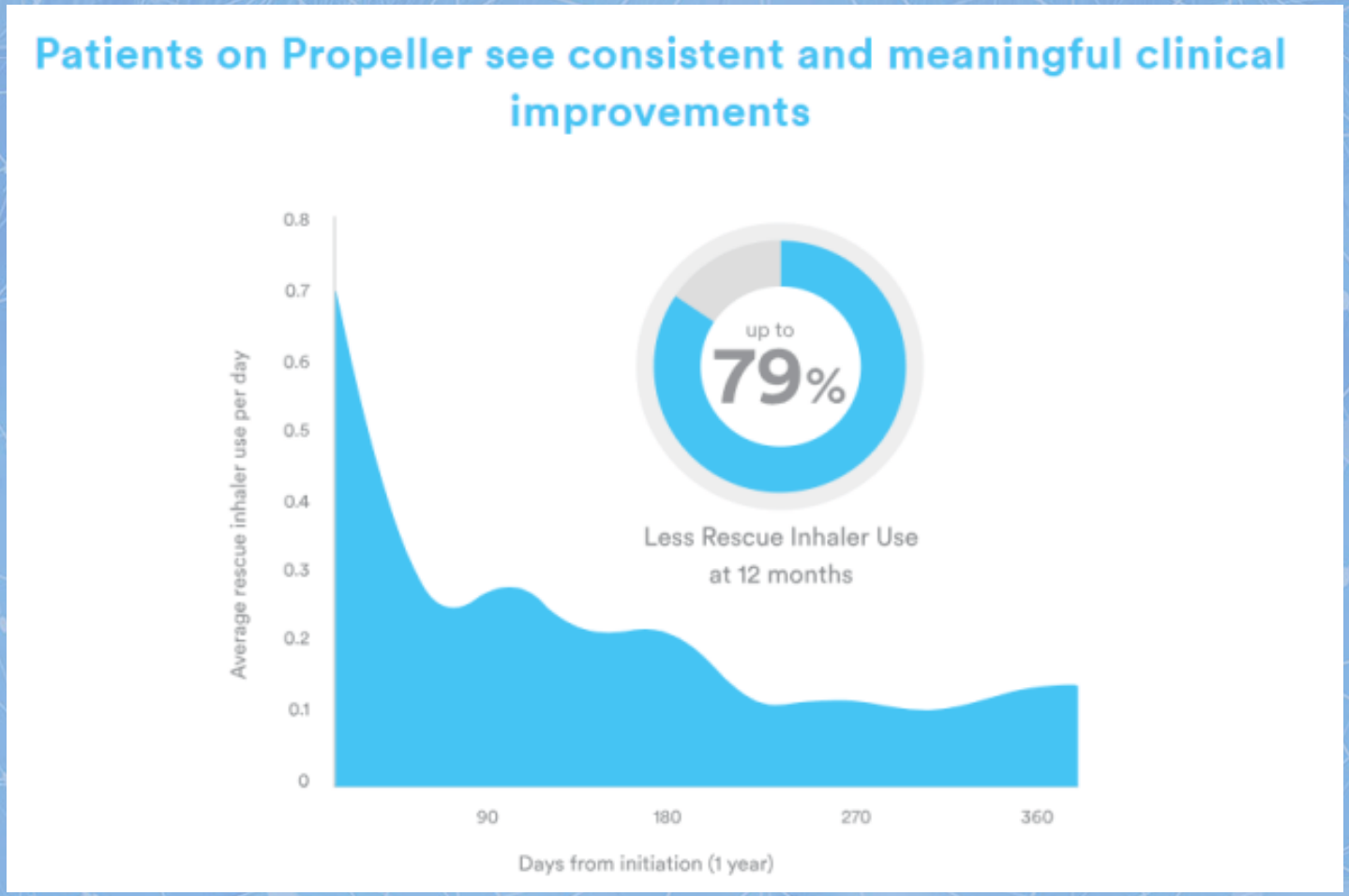
DTA-Report_DTx-Industry-Foundations

Evidenze cliniche a favore delle terapie digitali

- *FDA ha approvato sulla base di studi clinici una App ideata per il trattamento di pazienti con dipendenza da sostanze d'abuso (come alcool, marijuana e cocaina).*
- *I clinical trials hanno dimostrato che oltre il 40% dei pazienti utilizzatori dell'App si sono astenuti dal consumo di sostanze per un periodo di tre mesi, contro il solo 17,6% dei pazienti trattati con la terapia standard.*

Ref. DTx - Digital Therapeutics - Preparing for takeoff
(http://fortune.com/2017/09/14/fda-alcohol-marijuana-cocaine-mobile-app)

People with asthma who used Propeller's digital therapeutic, used their rescue inhaler up to 79% fewer times



https://www.propellerhealth.com/

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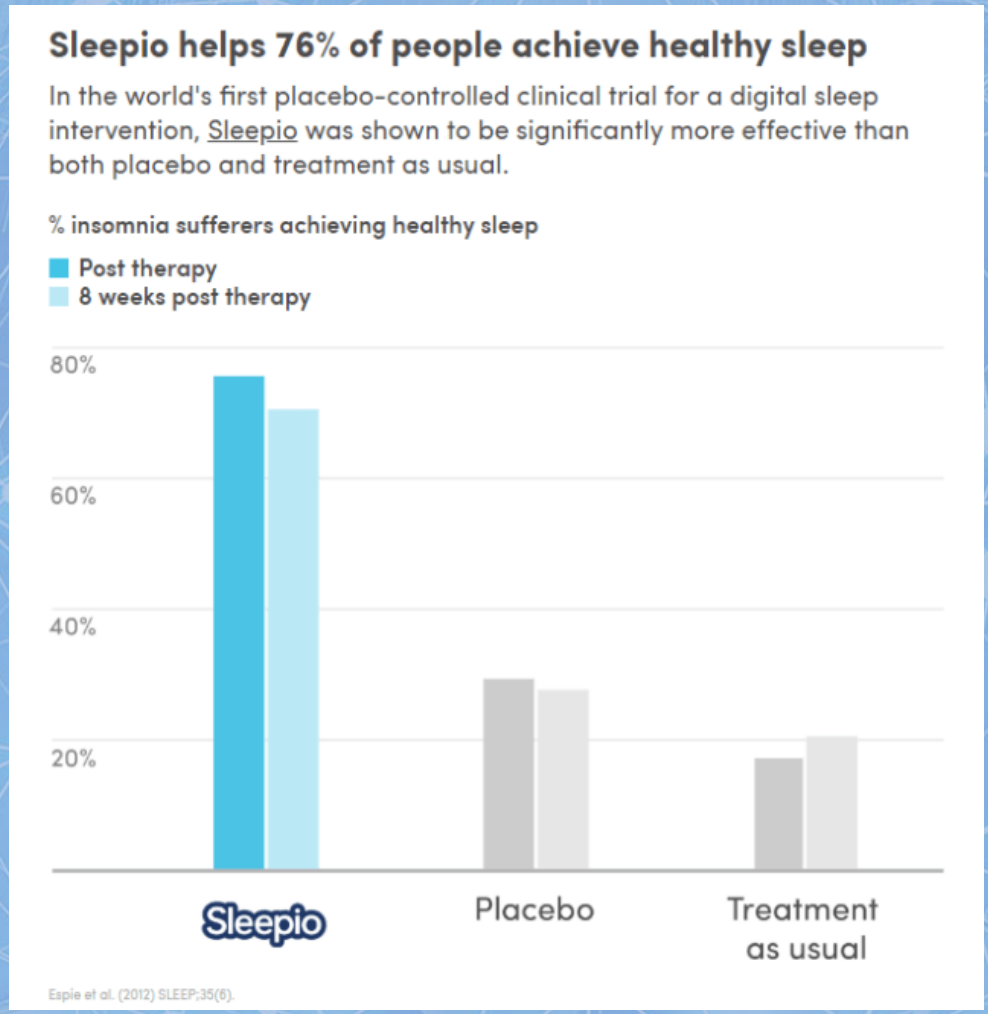
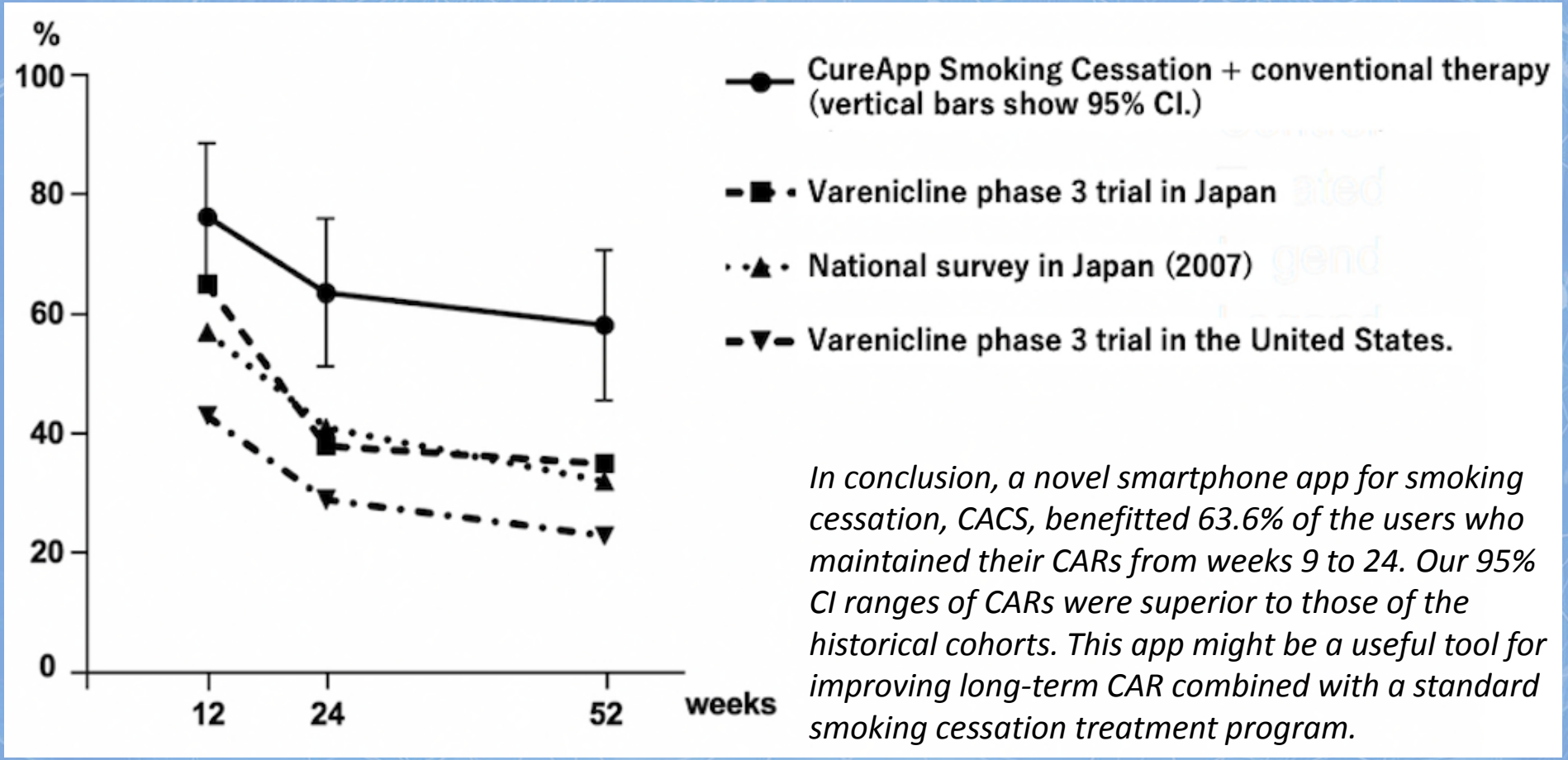
Big Health used a placebo-controlled clinical trial to document the effect of its Sleepio digital therapeutic aimed at improving sleep quality



Impact of a Novel Smartphone App (CureApp Smoking Cessation) on Nicotine Dependence: Prospective Single-Arm Interventional Pilot Study.

Masaki K, Tateno H, Kameyama N, Morino E, Watanabe R, Sekine K, Ono T, Satake K, Suzuki S, Nomura A, Betsuyaku T, Fukunaga K.
JMIR Mhealth Uhealth. 2019 Feb 19;7(2):e12694.



In conclusion, a novel smartphone app for smoking cessation, CACS, benefitted 63.6% of the users who maintained their CARs from weeks 9 to 24. Our 95% CI ranges of CARs were superior to those of the historical cohorts. This app might be a useful tool for improving long-term CAR combined with a standard smoking cessation treatment program.

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I bisogni medici insoddisfatti

E’ importante sottolineare che le terapie digitali tendono a rivolgersi principalmente verso patologie o disordini verso cui fino ad oggi i sistemi sanitari hanno rivolto poca attenzione.

Bisogni medici insoddisfatti piuttosto che sottostimati, quali malattie croniche o disordini neurologici, rappresentano il principale bersaglio di questi terapie altamente innovative, che potrebbero fornire spesso trattamenti più economici di quelli tradizionali.

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Vantaggi per gli operatori ed i sistemi sanitari

- Aumentare l'accesso a nuove opzioni terapeutiche;
- Integrare le *DTx* nei sistemi di assistenza sanitaria, in conformità alle linee guida;
- Prescrivere tali terapie innovative in associazione o in alternativa alla terapie tradizionali, per ottimizzare la cura dei pazienti;
- Fornire dati sicuri sull'impegno ed aderenza del paziente e sulla risposta della stessa terapia;
- Abilitare la gestione inteligente dei dati e quindi del processo decisionale clinico;

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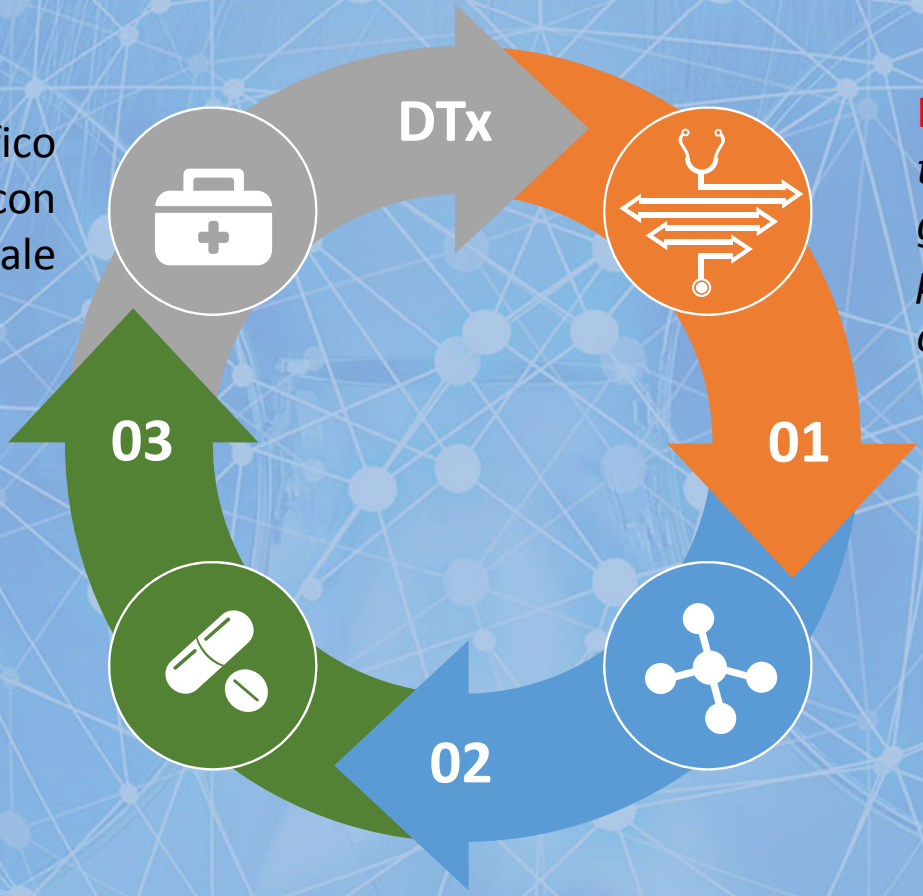
Come la Terapia Digitale crea valore

Prescrizione di un specifico intervento terapeutico con soluzioni di terapia digitale clinicamente validate.



Digital Therapy *intervento terapeutico diretto ai pazienti generato da un software, per prevenire, gestire o curare disturbi o condizioni patologiche.*

Aggiustamento delle terapie in funzione delle condizioni

Monitoraggio dell'andamento della terapia, valutazione risultati clinici. Analisi stato del paziente

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La cura basata sulle evidenze

- Realizzate seguendo tutte le *best practices* relative alle tecnologie avanzate, dal design, passando per quelle di convalida clinica, fino ad usabilità e sicurezza dei dati.
- Le *Digital Therapeutics* presentano al mercato tecnologie *evidence based* in grado di migliorare la buona pratica clinica, soddisfare esigenze insoddisfatte, ampliare l'accesso all'assistenza sanitaria e migliorare i risultati clinici ed economici rispetto alle terapie tradizionali.

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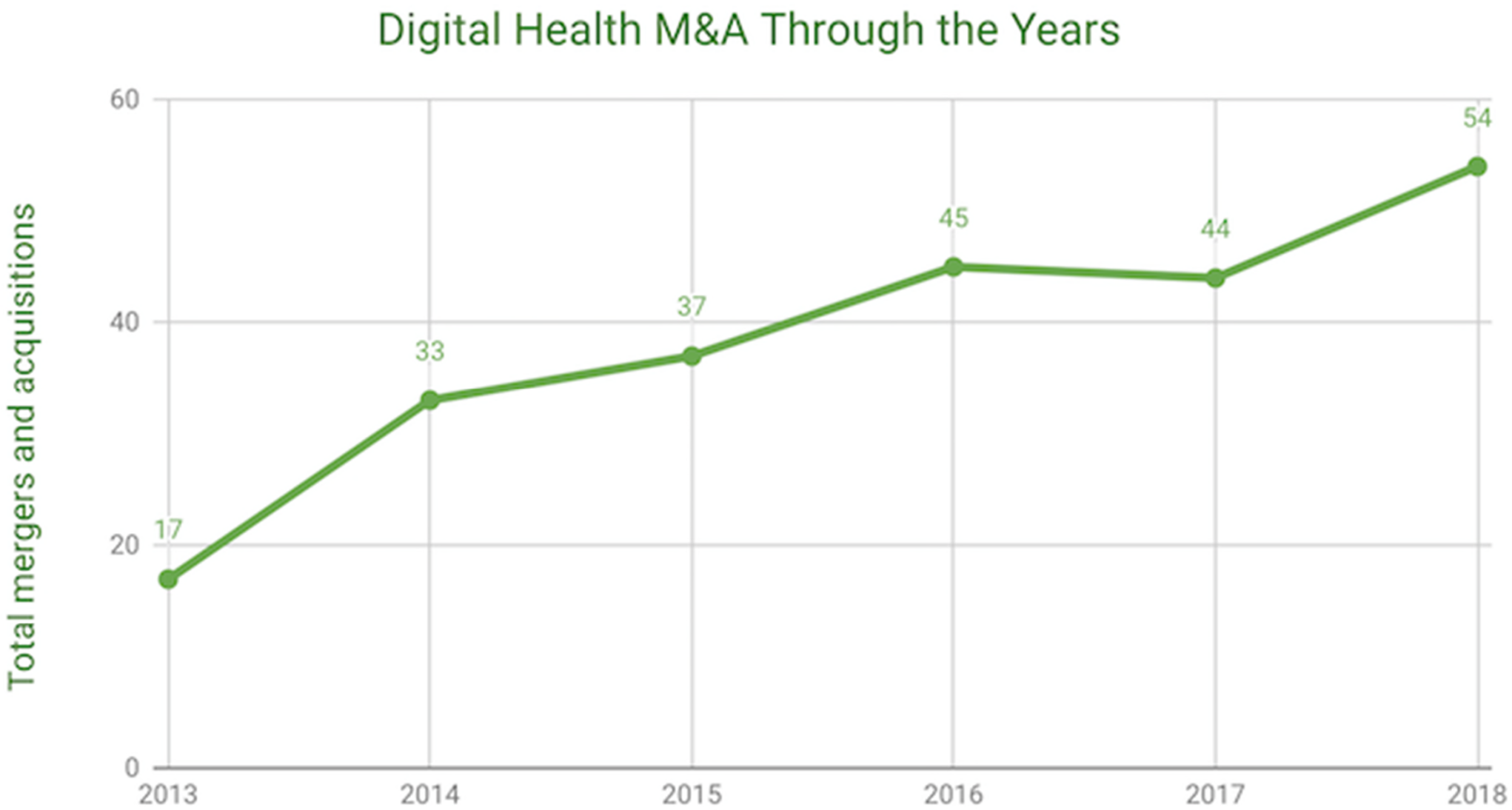
Lo sviluppo su larga scala

Obiettivo principale delle terapie digitali e' quello di fornire interventi terapeutici diretti. Ma le terapie digitali possono incorporare funzionalità aggiuntive consentendo di:

- integrarle nelle piattaforme mobili per la salute,
- fornire interventi complementari di natura diagnostica o di aderenza,
- accoppiarle con dispositivi medici, sensori o dispositivi indossabili,
- fornire interventi a distanza,
- integrarle in sistemi di prescrizione, dispensazione e raccolta di dati medici (cartelle cliniche).



https://www.mobihealthnews.com/content/56-digital-health-mergers-and-acquisitions-2018

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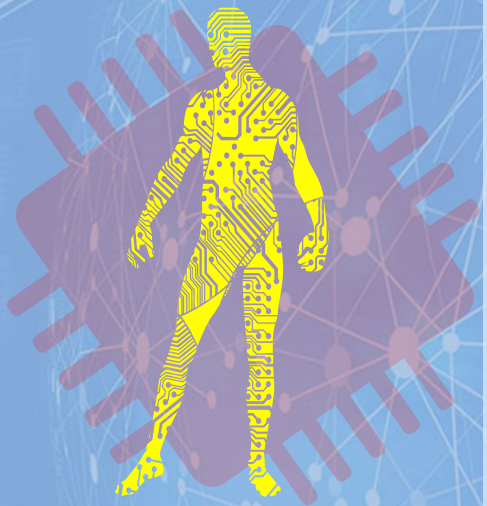
Quali le aree interessate delle DTx



- *prevenzione e gestione del diabete mellito di tipo 2,*
- *abuso di sostanze,*
- *asma,*
- *insonnia,*
- *schizofrenia,*
- *ADHD (disturbo da deficit di attenzione/iperattività), disturbo depressivo maggiore (MDD), disturbi dello spettro autistico (ASD),*
- *PTSD (disturbo da stress post-traumatico),*
- *malattie cardiovascolari.*

Prodotti sviluppati nell'ambito delle terapie digitali

omada

Programma di allenamento online per la prevenzione del diabete

Sleepio™ Clinic

App appositamente ideata per migliorare la qualità del sonno, che sostituisce completamente qualsiasi farmaco induttore del sonno

PEAR THERAPEUTICS

Terapia cognitivo comportamentale utilizzata in aggiunta alla terapia standard, per il trattamento di disturbi da sostanze d'abuso

reSET-O

Propeller

AKILI ...

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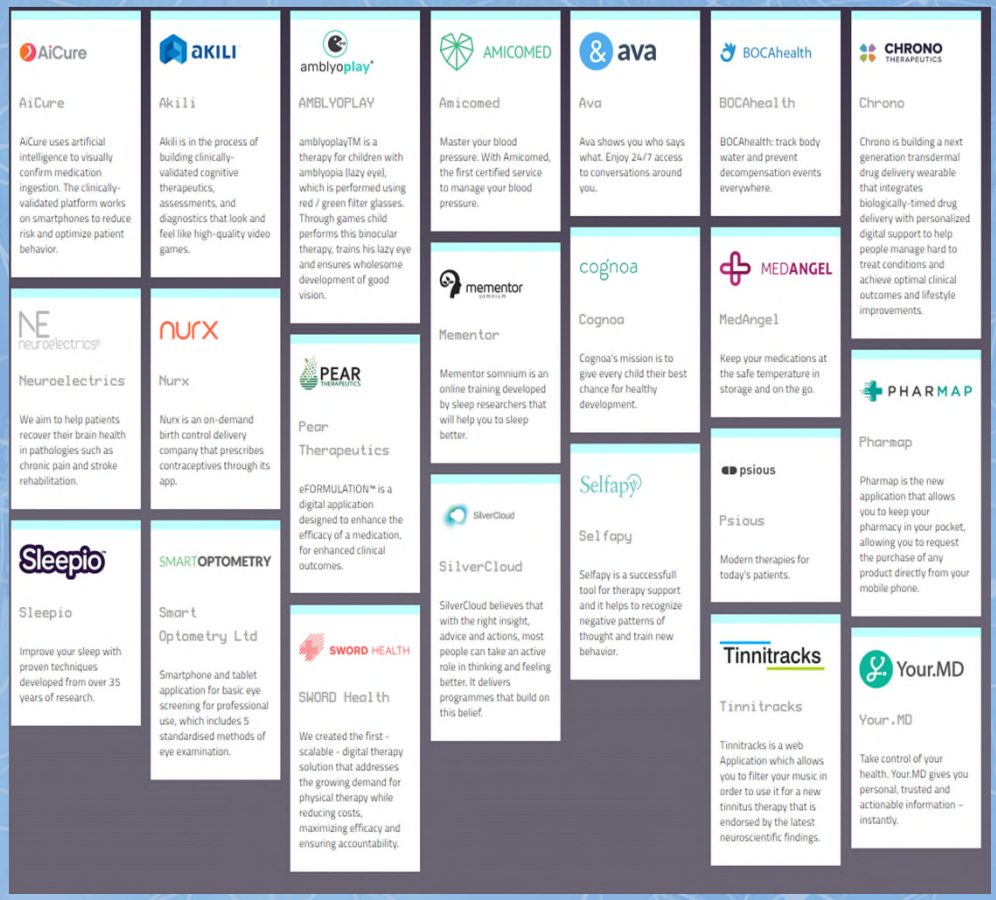
Prodotti sviluppati nell'ambito delle terapie digitali



170+ Aziende di *DTx*

DigitalHealth storymap

www.digitalhealthstorymap.com

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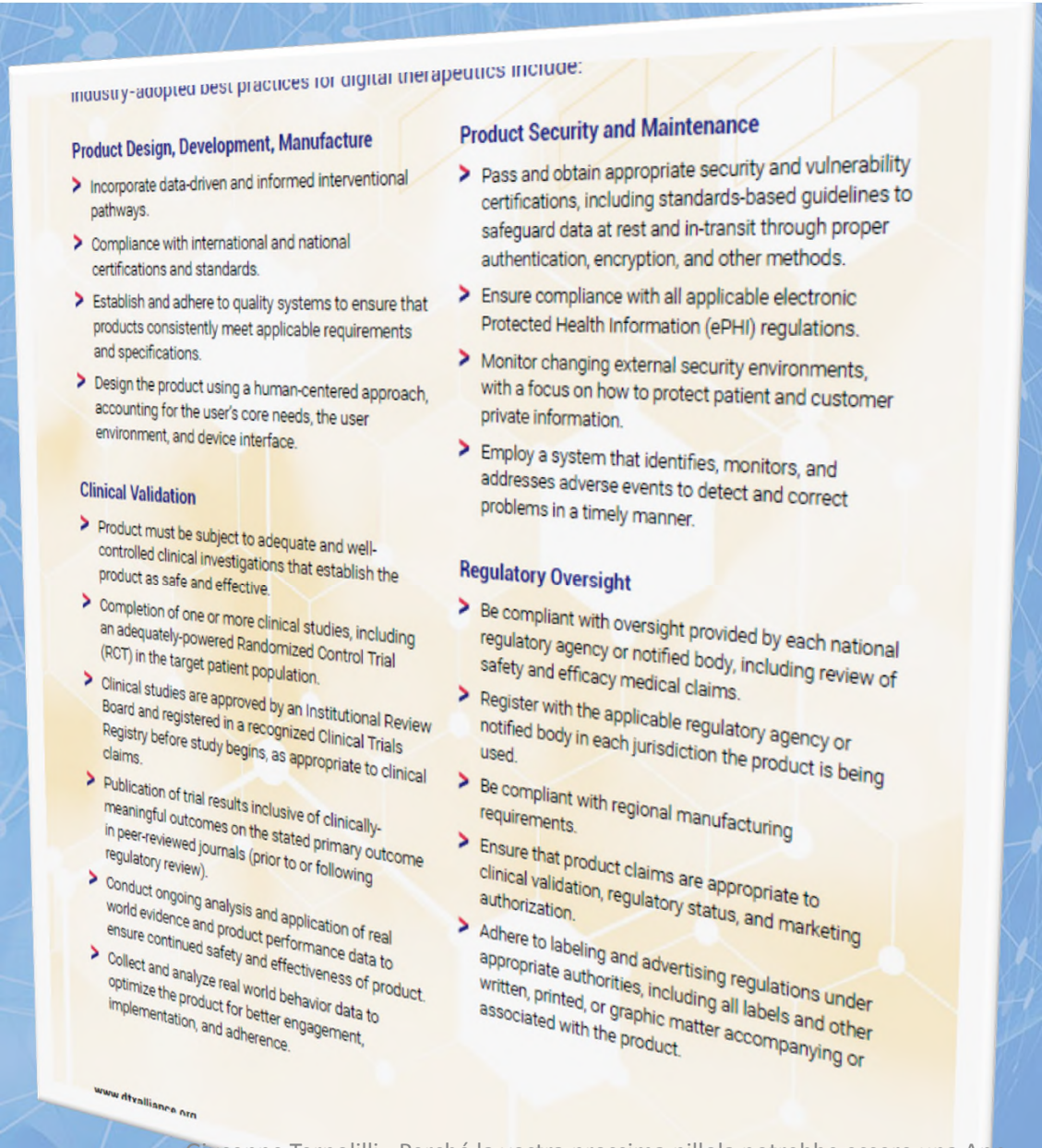
DTx: Best Practices

- ✓ **Progettazione**
  - ***Approccio incentrato sull'uomo***
- ✓ **Produzione**
  - ***Conformità agli standard di qualità***
- ✓ **Convalida Clinica**
  - ***Studi Clinici (almeno un RCT)***
  - ***Pubblicazione risultati clinicamente significativi***
  - ***Studi post market in real-life***
- ✓ **Regolamentazione**
  - ***In accordo alle normative locali***



Industry-adopted best practices for digital therapeutics include:

Product Design, Development, Manufacture

- Incorporate data-driven and informed interventional pathways.
- Compliance with international and national certifications and standards.
- Establish and adhere to quality systems to ensure that products consistently meet applicable requirements and specifications.
- Design the product using a human-centered approach, accounting for the user's core needs, the user environment, and device interface.

Clinical Validation

- Product must be subject to adequate and well-controlled clinical investigations that establish the product as safe and effective.
- Completion of one or more clinical studies, including an adequately-powered Randomized Control Trial (RCT) in the target patient population.
- Clinical studies are approved by an Institutional Review Board and registered in a recognized Clinical Trials Registry before study begins, as appropriate to clinical claims.
- Publication of trial results inclusive of clinically-meaningful outcomes on the stated primary outcome in peer-reviewed journals (prior to or following regulatory review).
- Conduct ongoing analysis and application of real world evidence and product performance data to ensure continued safety and effectiveness of product.
- Collect and analyze real world behavior data to optimize the product for better engagement, implementation, and adherence.

Product Security and Maintenance

- Pass and obtain appropriate security and vulnerability certifications, including standards-based guidelines to safeguard data at rest and in-transit through proper authentication, encryption, and other methods.
- Ensure compliance with all applicable electronic Protected Health Information (ePHI) regulations.
- Monitor changing external security environments, with a focus on how to protect patient and customer private information.
- Employ a system that identifies, monitors, and addresses adverse events to detect and correct problems in a timely manner.

Regulatory Oversight

- Be compliant with oversight provided by each national regulatory agency or notified body, including review of safety and efficacy medical claims.
- Register with the applicable regulatory agency or notified body in each jurisdiction the product is being used.
- Be compliant with regional manufacturing requirements.
- Ensure that product claims are appropriate to clinical validation, regulatory status, and marketing authorization.
- Adhere to labeling and advertising regulations under appropriate authorities, including all labels and other written, printed, or graphic matter accompanying or associated with the product.

www.dtxalliance.org

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Limiti dell'approccio regolatorio
Da dove si e' partiti?

International Medical Device Regulators Forum (IMDRF) / Software as a Medical Device:

"software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

https://www.fda.gov/medicaldevices/digitalhealth/softwareasamedicaldevice/default.htm

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21st Century Cures Act

La *Cures Act* deriva dalla volontà da parte della americana *Food and Drug Administration* (*FDA*) di integrare il punto di vista dei pazienti nello sviluppo dei farmaci, prodotti biologici e dispositivi medici, nei processi decisionali della stessa autorità.

https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/21stcenturycuresact/default.htm

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"This outlines FDA's approach for assuring that all Americans, including patients, consumers and other health care customers have timely access to high-quality, safe and effective digital health products".

Home/Drugs/ Development & Approval Process (Drugs)

"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."

Innovation

FDA recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products.

Approach

FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development ..for software-based medical technologies..

American people

For the American people to see the full potential of digital health technologies, FDA must lean forward and adapt our processes.

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Approccio NICE (UK)

Evidence standards framework for digital health technologies: user guide

«Digital health technologies comprise a wide range of products used in the health and care system including apps, software and online platforms that are intended to benefit people or the wider health and care system.

They may be standalone or combined with other products such as medical devices or diagnostic tests".

Pipeline di sviluppo di prodotti DT di Pear Therapeutics e Novartis/Sandoz.

PRODUCT/ CANDIDATE	THERAPUTIC AREA	STAGE						ACADEMIC PARTNER	COMMERCIAL PARTNER
		DISCOVERY	POC	FDA PRESUB	PIVOTAL STUDIES	FDA SUBMISSION	FDA AUTHORIZATION		
reSET	Substance Use Disorder						■	DARTMOUTH	SANDOZ
reSET-O	Opioid Use Disorder						■	DARTMOUTH	SANDOZ
PEAR-003	Insomnia/ Depression				■				
PEAR-004	Schizophrenia (Pos Sx)				■				NOVARTIS
DISCOVERY	Cognition		■					UCSF	
DISCOVERY	Epilepsy		■						
reCALL™	PTSD		■					USC	
PEAR-007	Pain		■						
DISCOVERY	Movement Disorders	■							
PEAR-006	Multiple Sclerosis	■							NOVARTIS
DISCOVERY	Migraine	■							
DISCOVERY	Autism Spectrum Disorder	■						SickKids	
DISCOVERY	Oncology, Inflammation, CV, GI, Respiratory	■							

■ PARTNERED ■ INTERNAL

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Recent landmarks in DTx

2016

- Department of Health and Human Services agrees to reimburse Diabetes Prevention Program DTx (Omada Health, Canary Health, and Blue Mesa Health)
- Sanofi and Alphabet subsidiary Verily Life Sciences launch $500m Onduo diabetes JV

2017

- US Food and Drug Administration (FDA) approves the first mobile medical application (Pear Therapeutics' reSET for substance use disorders)
- Roche acquires mySugr to form a platform for digital diabetes management
- FDA pre-certifies 9 companies for digital health fast-track pilots
- Akili Interactive posts positive clinical trial data on digital treatment for ADHD
- Digital Therapeutics Alliance formed
- The first fully integrated digital medicine, the Proteus/Otsuka Abilify MyCite, is approved by the FDA

2018

- Apple Health Records brings together hospital and clinical records into the existing Apple Health app
- Novartis & Pear agree MS and schizophrenia DTx collaboration
- Q1&2 200 digital health deals total $3.4bn
- Several major pharma companies make strategic investments in 'pure' DTx companies, such as Sanofi spending $17m for Click Therapeutics
- UK launches Evidence for Effectiveness to develop DTx guidance and standards
- FDA plans Centre of Excellence in digital health
- FDA issues guidance offering clearer and faster routes to market in DTx
- Big Health's insomnia treatment Sleepio becomes available on the NHS
- Sandoz and Pear's commercial launch of reSET-O for opioid use disorder
- ResMed acquires digital therapeutics company Propeller Health for $225m

2019

- reSET-O launches
- Otsuka America & Click Therapeutics collaborate to develop and commercialize a prescription digital therapeutic for Major Depressive Disorder (MDD) in a deal that could be worth more than $300m for Click

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Opportunita’ e rischi per la terapia digitale

Bisogni medici insoddisfatti come le malattie rare o patologie croniche, altamente debilitanti e/o progressivamente disabilitanti (es. diabete mellito, morbo di Alzheimer, morbo di Parkinson, asma e ADHD) hanno reso sempre più crescente la necessità di migliorare le terapie esistenti piuttosto che sollecitare la produzione di nuove e favorirne disponibilità ed accessibilità ai pazienti.

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Opportunita’ e rischi per la terapia digitale

Affinchè le terapie digitali possano essere autorizzate dagli enti regolatori, è fondamentale inquadrare queste terapia da un punto di vista regolatorio, quindi distinguerle dal più ampio campo delle app per salute e benessere.

Partendo dal presupposto che queste tecnologie debbano svolgere un effetto terapeutico, per consentirne la commercializzazione è obbligatorio ottenere delle evidenze cliniche di efficacia e sicurezza.

Per fare ciò è necessario definire sempre da un punto di vista regolatorio la tipologia di *DT*, quindi quali e quanti studi clinici saranno necessari per rendere disponibile sul mercato tale terapia.

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THE LANCET VOLUME 392, ISSUE 10165, P2665-2667, DECEMBER 22, 2018

What is an appropriate level of evidence for a digital health intervention?

Greaves F, Joshi I, Campbell M, Roberts S, Patel N, Powell J.

"Le tecnologie digitali ... hanno il potenziale per supportare un sistema sanitario basato sulla tecnologia, in cui le interazioni assistenziali sono allontanate dai contesti formali e i cittadini sono incoraggiati a gestire la propria salute e la propria malattia.

La scalabilità e spesso il basso costo marginale degli interventi digitali suggeriscono che essi potrebbero fornire benefici in termini di costi a servizi estesi che devono far fronte alle esigenze di una popolazione che invecchia e che vive più a lungo con livelli più elevati di malattie croniche.

Allo stesso tempo, un sistema sanitario finanziato con fondi pubblici ha ragioni sia finanziarie che morali per spendere il denaro in modo coscienzioso e giudizioso per fornire ai suoi cittadini un'assistenza efficace e basata su prove di efficacia".

PLOS ONE

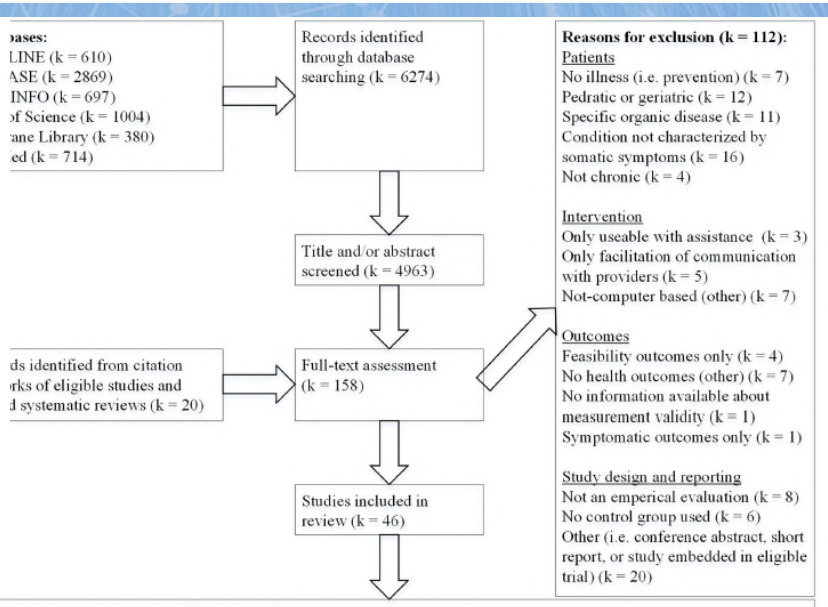
RESEARCH ARTICLE

The effectiveness of various computer-based interventions for patients with chronic pain or functional somatic syndromes: A systematic review and meta-analysis

Miel A. P. Vugts[1]*, Margot C. W. Joosen[1], Jessica E. van der Geer[2], Aglaia M. E. E. Zedlitz[2], Hubertus J. M. Vrijhoef[3,4,5]

1 Tranzo Scientific Center for Care and Welfare, Tilburg School of Social and Behavioral Sciences, Tilburg University, Tilburg, the Netherlands, **2** Department of Health Medical and Neuropsychology, Leiden University, Leiden, the Netherlands, **3** Department of Patient & Care, Maastricht University Medical Center, Maastricht, the Netherlands, **4** Department of Family Medicine and Chronic Care, Vrije Universiteit Brussel, Brussels, Belgium, **5** Panaxea B.V., Amsterdam, the Netherlands

Check for updates



Studies and participants included in calculations of (pooled) standardized mean differences:

Outcome	1. CBI versus passive controls (k=35)		2. CBI versus active controls (k=15)	
	Post	Follow-up	Post	Follow-up
Somatic symptoms	1.1 k = 29, n = 3284	1.6 k = 4, n = 1015	2.1 k = 11, n = 1292	2.6 k = 5, n = 683
Health-related quality of life	1.2 k = 14, n = 1408	1.7 k = 1, n = 651	2.2 k = 6, n = 761	2.7 k = 3, n = 461
Functional interference	1.3 k = 30, n = 3387	1.8 k = 4, n = 1015	2.3 k = 10, n = 1097	2.8 k = 6, n = 672
Catastrophizing	1.4 k = 24, n = 2900	1.9 k = 4, n = 1015	2.4 k = 10, n = 946	2.9 k = 5, n = 432
Depression	1.5 k = 24, n = 2221	1.10 k = 4, n = 416	2.5 k = 8, n = 646	2.10 k = 6, n = 517

Fig 1. PRISMA flow-diagram of studies. Abbreviations and symbols: k = number of studies, *n* = number of study participants, OC = outcome, SS = Somatic Symptoms, HRQOL = Health Related Quality Of Life, FI = Functional Interference, CAT = Catastrophizing, DEP = Depression.

To conclude, there is a minority of good quality evidence for small positive average effects of computer-based (cognitive) behavior change interventions, similar to traditional modes.
These effects may be sustainable. Indications were found as of which interventions work better or more consistently across outcomes for which patients.
Future process analyses are recommended in the aim of better understanding individual chances of clinically relevant outcomes.

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Original Paper

The Potential of Mobile Apps for Improving Asthma Self-Management: A Review of Publicly Available and Well-Adopted Asthma Apps

Peter Tinschert[1], MSc; Robert Jakob[2], MSc; Filipe Barata[3], MSc; Jan-N

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[2]Operations & Supply Chain Management, School of Management, Technical University of
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Figure 1. Systematic search and exclusion criteria.

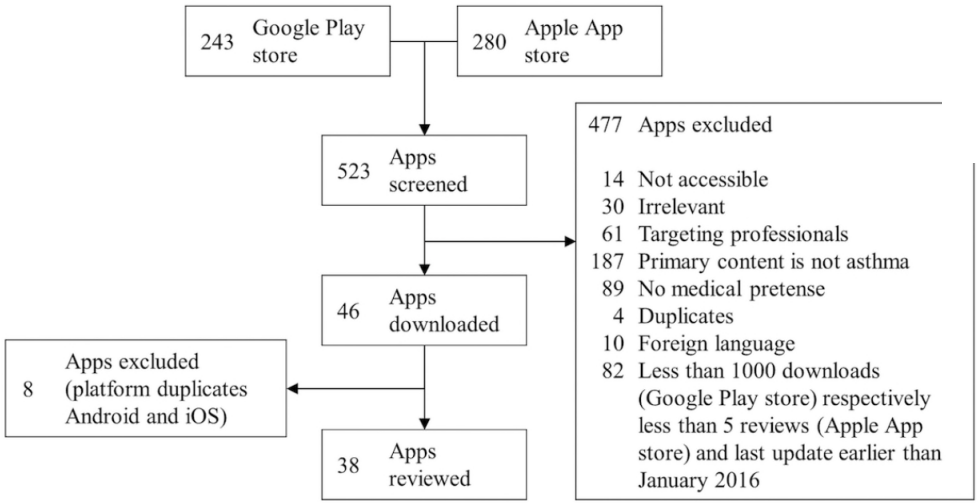
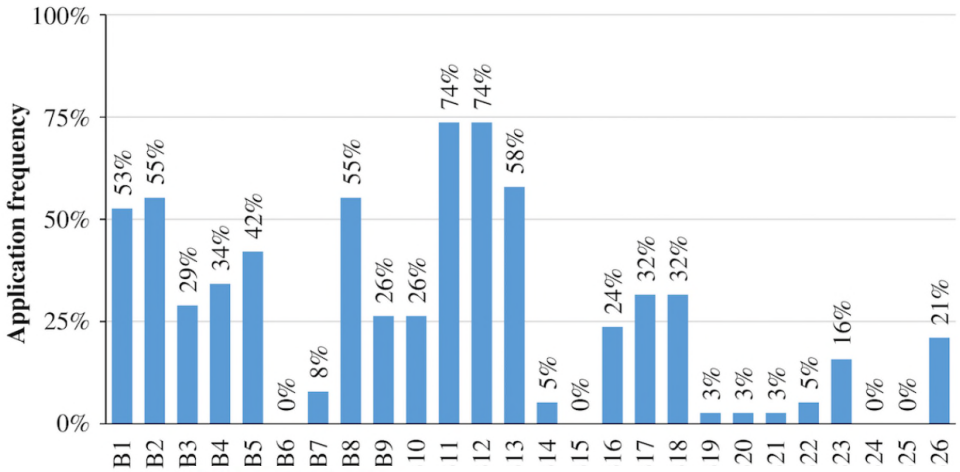


Figure 2. Percentage of asthma apps fully applying the corresponding behavior change technique (B1-B26; N=38).



Conclusions

In conclusion, this review has found that the potential of asthma apps for improving asthma self-management varies considerably between apps. Physicians and asthmatics should therefore carefully read app reviews before deciding which app to recommend or to use. Additionally, currently available asthma apps do not take full advantage of today's technology. Developers should address the research-practice gaps outlined in the discussion.

Come siamo organizzati

c/o POLIHUB, Politecnico di Milano

daVinci Digital Therapeutics srli
Mission: lo sviluppo di terapie digitali (pazienti cronici, dipendenze, depressione lieve e moderata)

Alfa Technologies International srl
Sviluppo prodotti informatici: eHealth/mHealth, telemedicina

Advice Pharma Group srl
tCRO (Technology Clinical Research Organization)

Open access Protocol

BMJ Open

Lung Cancer App (LuCApp) study protocol: a randomised controlled trial to evaluate a mobile supportive care app for patients with metastatic lung cancer

Oriana Ciani,[1,2] Maria Cuccinello,[1,3] Francesco Petracca,[1] Giovanni Apolone,[4] Giampaolo Merlini,[5] Silvia Novello,[6] Paolo Pedrazzoli,[5] Nicoletta Zilembo,[4] Chiara Broglia,[5] Enrica Capelletto,[6] Marina Garassino,[4] Elena Nicod,[1] Rosanna Tarricone[1,3]

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ABSTRACT

Introduction Mobile health technologies may enhance patient empowerment and data integration along the whole care continuum. However, these interventions pose relatively new regulatory, organisational and technological challenges that limit appropriate evaluation. Lung Cancer App (LuCApp) is a mobile application developed by researchers and clinicians to promote real-time monitoring and management of patients' symptoms. This protocol illustrates a clinical trial designed to evaluate the usability, effectiveness and cost-effectiveness of LuCApp versus standard of care.

Methods and analysis This is a 24-week two-arm non-blinded multicentre parallel randomised controlled trial. A total of 120 adult patients diagnosed with small or non-small cell lung cancer and eligible for pharmaceutical treatments will be allocated 1:1 to receiving either standard care or LuCApp in addition to standard care at three oncology sites in Northern Italy. During the treatment period, LuCApp allows daily monitoring and grading of a list of symptoms, which trigger alerts to the physicians in case predefined severity thresholds are met. Patients will complete a baseline assessment and a set of valid and reliable patient-reported outcome measures every 3±1 weeks, and up to 24 weeks. The primary outcome is the change in the score of the Trial Outcome Index in the Functional Assessment of Cancer Therapy (Lung) questionnaire from baseline to 12 weeks. Secondary outcomes are the Lung Cancer Subscale, the EuroQoL 5D-5L questionnaire, the Hospital Anxiety and Depression Scale, the Supportive Care Needs Survey Short Form, the app usability questionnaire and the Zarit Burden Interview for the main caregiver.

Ethics and dissemination The trial received ethical approval from the three clinical sites. Trial results will be disseminated through peer-reviewed publications and conference presentations.

Conclusions This trial makes a timely contribution to test a mobile application designed to improve the quality of life and delivery of care for patients with lung cancer.

Trial registration number NCT03512015; Pre-results.

Strengths and limitations of this study

- Lung Cancer App (LuCApp) has been designed by a multidisciplinary team and developed through iterative sessions to improve patients' real-time monitoring of symptoms and side effects during pharmacological therapies for lung cancer.
- The impact of LuCApp on health-related quality of life, cancer supportive care needs, burden for caregivers and resource consumption will be tested in a parallel randomised controlled trial.
- Sources of bias may include the different levels of ease of participants when using mobile technologies, the impossibility to blind them and different modes of questionnaires administration (app-based vs paper/phone-based).

INTRODUCTION

The substantial progress made in the diagnosis and treatment of cancer entails it can be managed as other chronic diseases, where long-term active monitoring is needed. In order to enhance patients' quality of life, the traditional paternalistic model where the patient-provider relationship tends to be unilateral and the patient has little say in his/her care pathway might need to be outclassed by new models of care.[1]

To this end, self-management interventions can help patients and their families care for themselves along the cancer care continuum. Self-management is here defined as 'the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition'.[2] With respect to cancer care, patient involvement also aims at enhancing symptom management. Although recent advances in cancer therapies have led to better clinical outcomes,[3]

LuCApp RCT protocol

Primary Outcome

To determine whether LuCApp can lead to increased HRQoL scores as measured by the Functional Assessment of Cancer Therapy- Lung (FACT-L) questionnaire from the start of the pharmacological treatment for lung cancer and up to 12 and 24 weeks follow-up..

Other secondary objectives

To evaluate the impact of LuCApp up to 12 and 24 weeks follow-up for:

1. Improved HRQoL, EuroQol-5-Dimensions-5 Level (EQ-5D-5L).
2. Reduced anxiety and depression as measured by Hospital Anxiety and Depression Scale (HADS)
3. Impact on patients' cancer supportive care, measured by the Supportive Care Needs Survey Short Form (SCNSSF34).
4. Impact on caregiver measured by the Zarit Burden Interview (ZBI).
5. Acceptable cost-effectiveness profile of LuCApp versus standard care, based on resource use data collected throughout the study and quality-adjusted life-years (QALY) calculated through EQ-5D-5L.
6. Good usability and user satisfaction with LuCApp, as assessed by a modified Computer System Usability Questionnaire (CSUQ).

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Open access Protocol

BMJ Open

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LuCApp

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LuCApp allows daily monitoring and grading of a list of symptoms, which trigger alerts to the physicians in case predefined severity thresholds are met.

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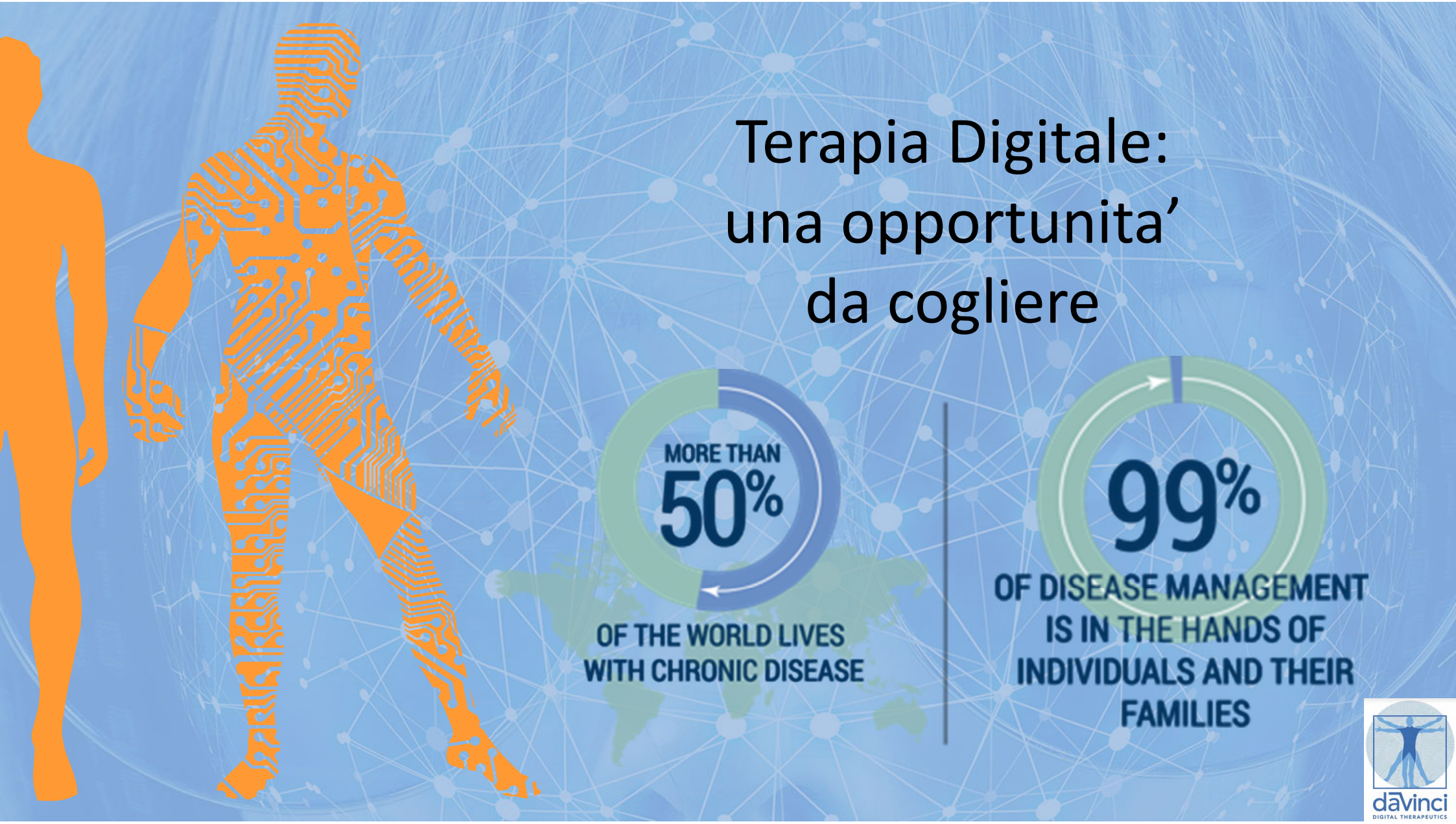
Terapia Digitale: una opportunita' da cogliere



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Thank You

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