

Progetto «Terapie Digitali per Italia»

Incontro con le imprese – Milano, 20 febbraio 2020

R&D of Digital Therapeutics #DTx

a new generation of evidence-based prescription interventions

Giuseppe Recchia

Vice President Smith Kline Foundation

Co-founder and CEO daVinci Digital Therapeutics



5th European Conference on Clinical Research

10 - 11 February 2020, Amsterdam, The Netherlands



Digital Transformation in Healthcare – Why?

Aging

Chronic Diseases



Patient

Digital Technologies

We need more than just drugs...



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7 Nov 2019

Digital Health

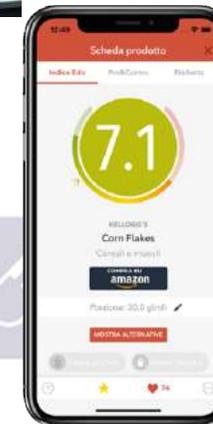


Digital health includes technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.

Typically do not require clinical evidence



Digital Technologies



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Digital Health



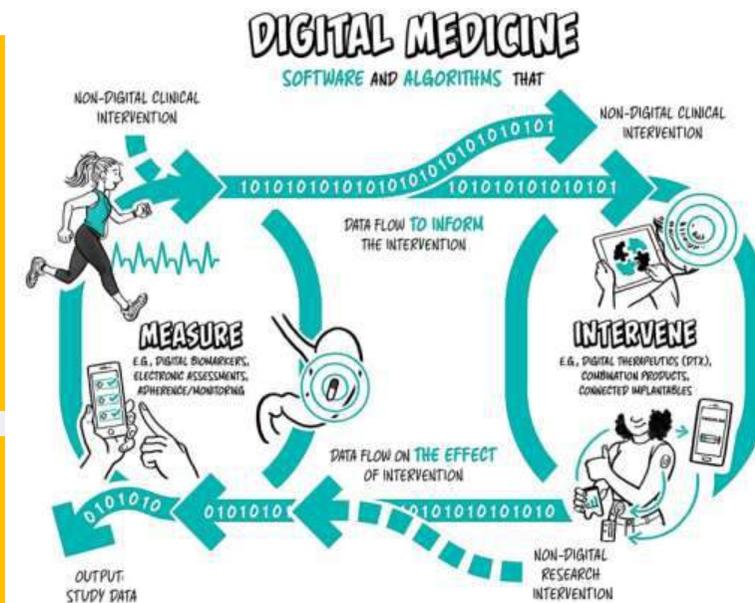
Digital Medicine

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Clinical evidence is required for all digital medicine products.



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Digital Therapeutics

Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease

Clinical evidence and real world outcomes are required for all products

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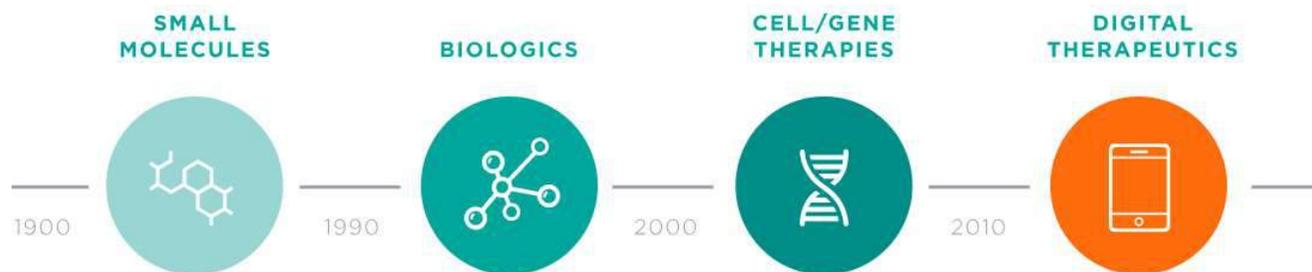
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2 DTx



VISION

«Digital Therapeutics – standalone, addon or combo – are the first therapeutic option offered by physicians to patients with chronic diseases or dependence»



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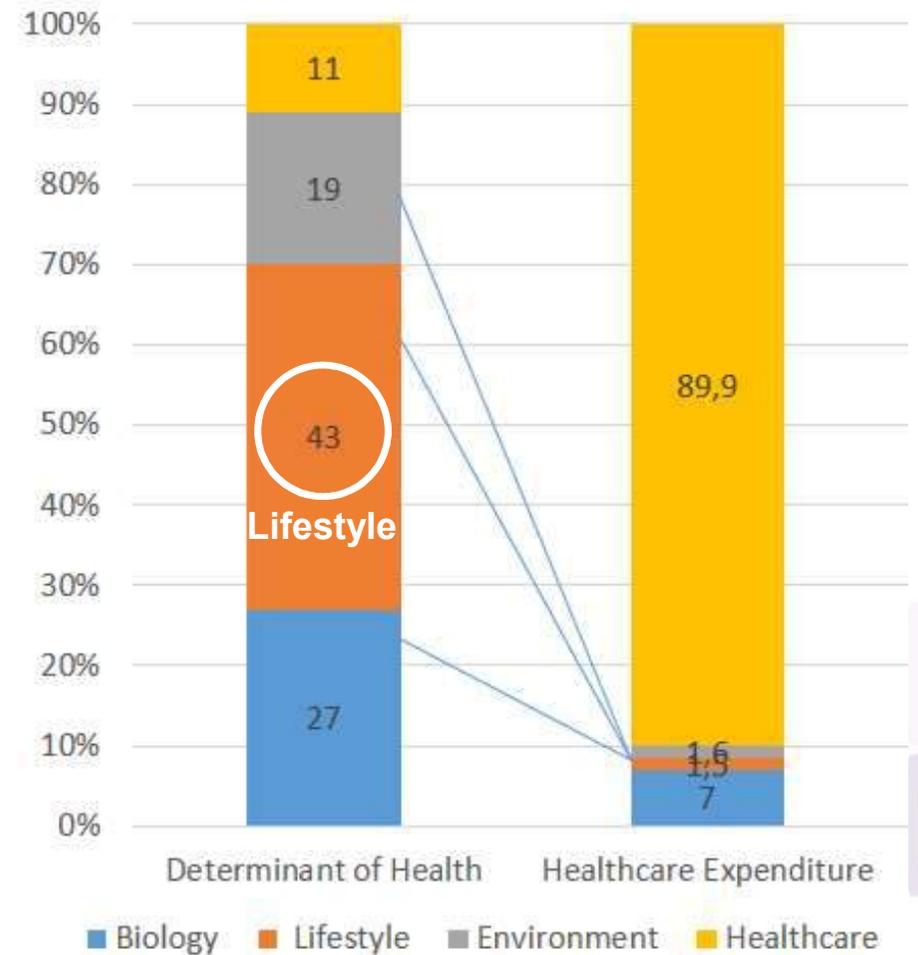
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2009

DTx – What are they?

- Therapeutic interventions
- Designed to modify behaviours
- Developed through RCTs
- Approved by regulatory bodies
- Reimbursed by NHS / insurance
- Prescribed by a Physician
- Active Ingredient

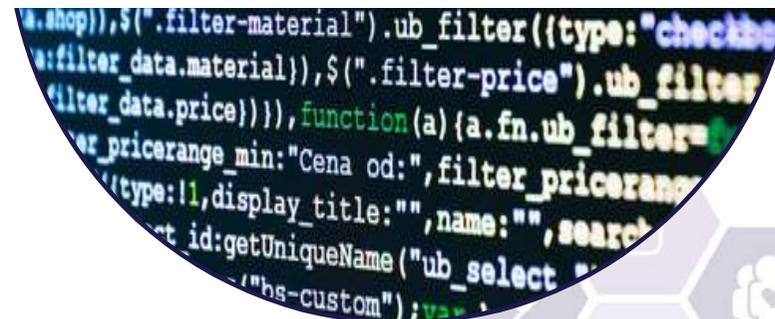


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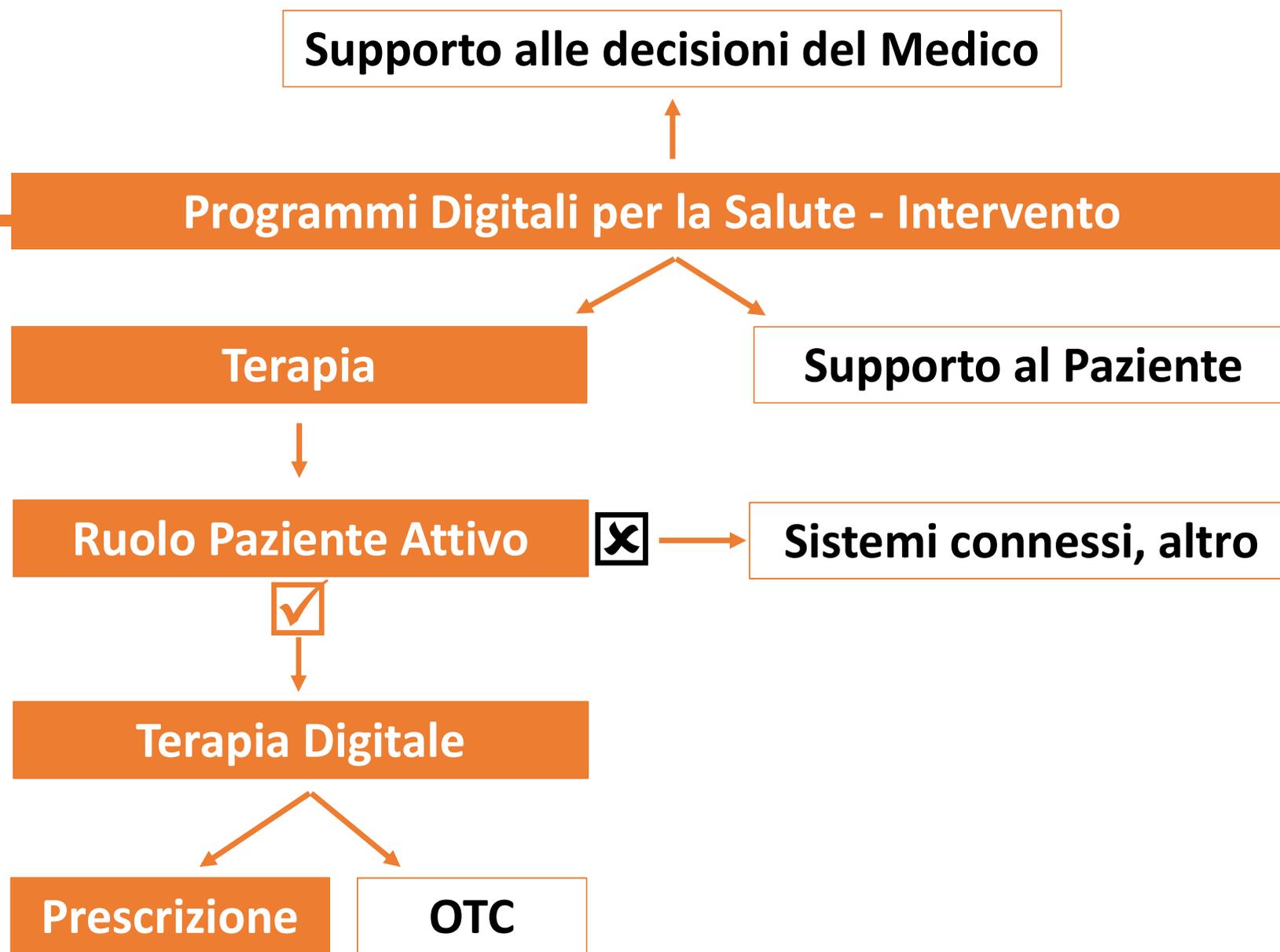
Programmable Medicines



- Genes
- Cells
- Software



DTxITA – Quale Perimetro ?



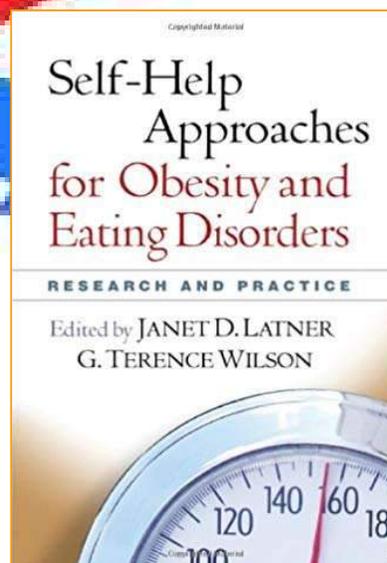
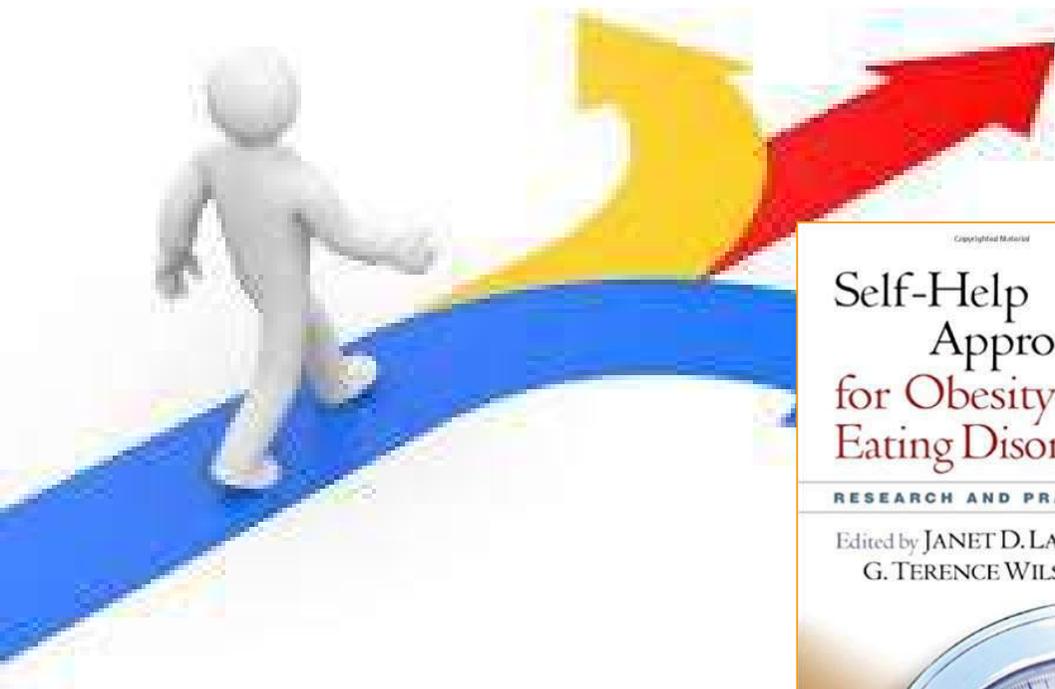
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How Do DTx Modify Behaviours?

- Information
- Motivation



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Are DTx “Apps” ?



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Do DTx Depend on Drugs?

Therapeutics Plug-in

- Management of adverse events
 - *Oncology (AZ, Novartis)*

Standalone

- Cognitive Behavioural Therapy
- Psychoeducation
 - *Dependence*
 - *Depression / MDD*
 - *Obesity*
 - *ADHD*

Clinical Outcome

Do DTx Depend on Drugs?

1. Replacement

2. Add-on

3. Combination

Standalone

- Cognitive Behavioural Therapy
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Clinical Outcome

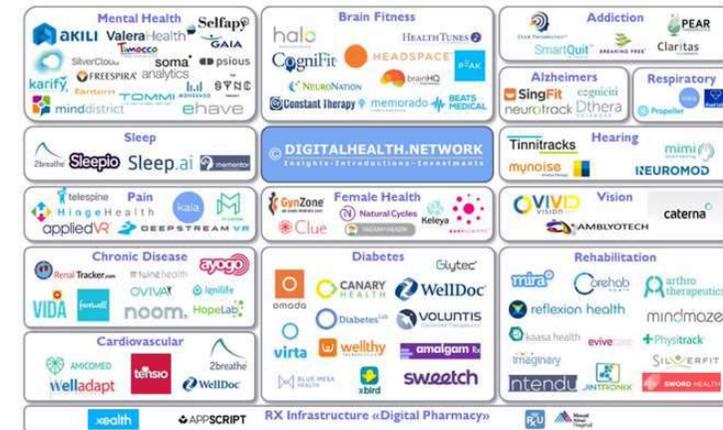
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What Are Therapeutic Indications?

- Major Depressive Disorder
- Generalized Anxiety Disorder
- Insomnia
- *ADHD Children / Adult*
- Autism Spectrum Disorder
- Eating Disorders
- Schizophrenia
- Dependence
- *Smoking Cessation*
- Type 2 Diabetes
- Obesity
- Oncology



Startup

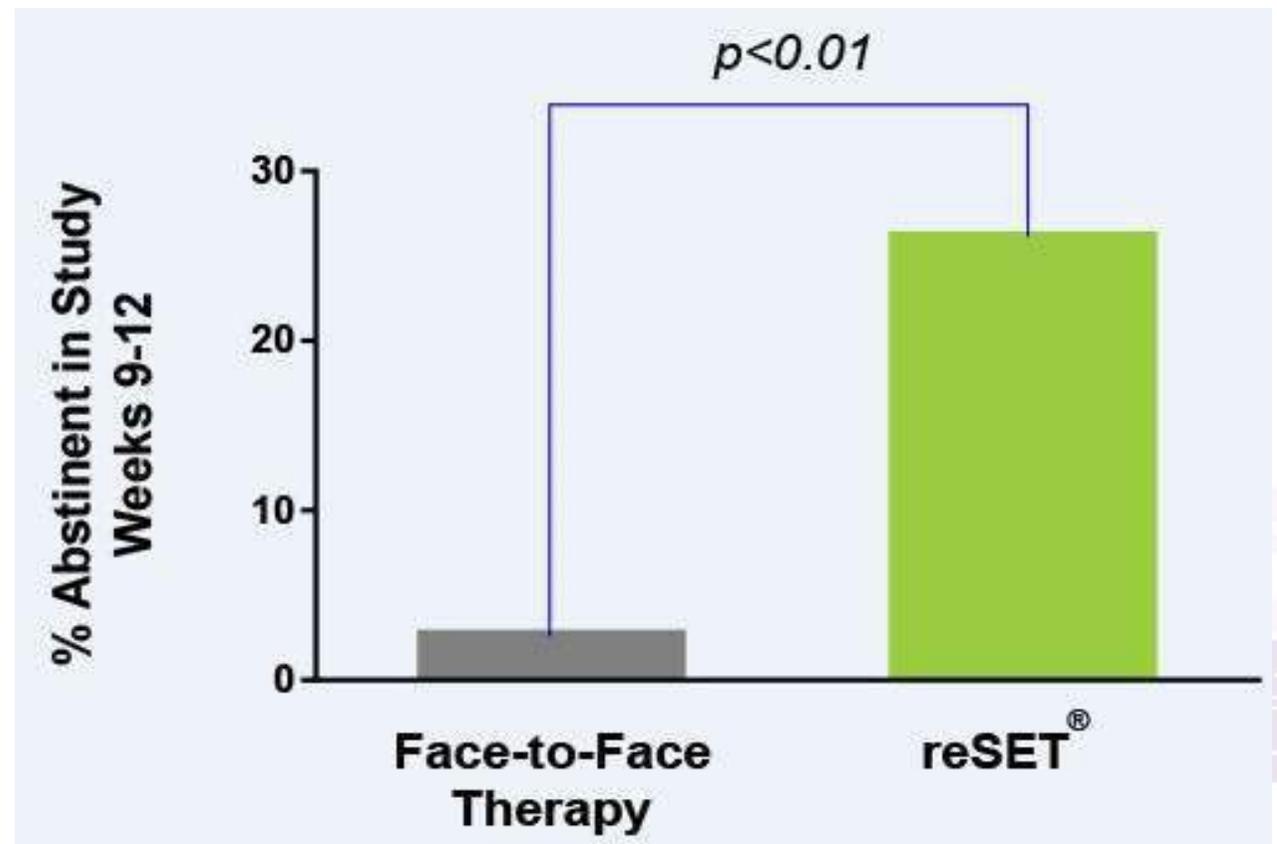
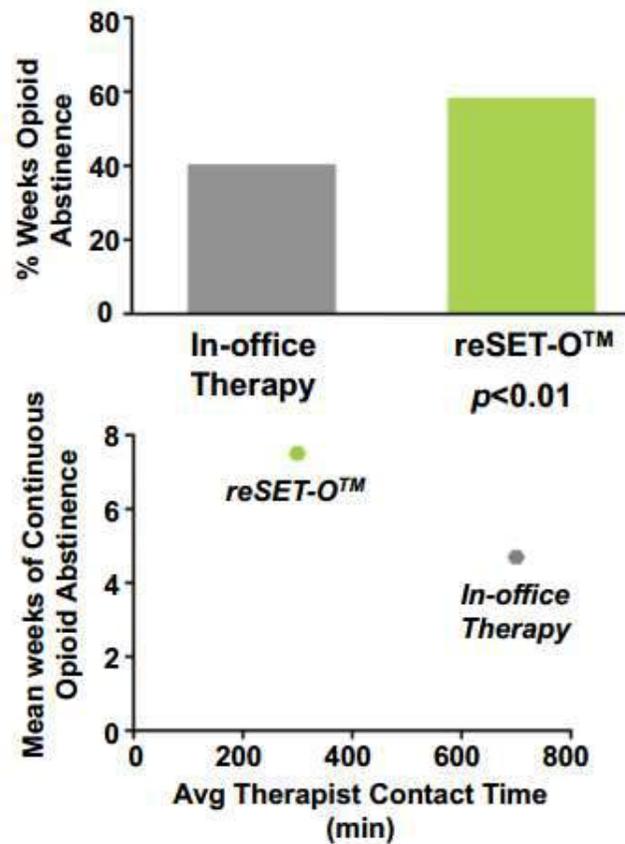
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What Qualifies Software as Therapy?

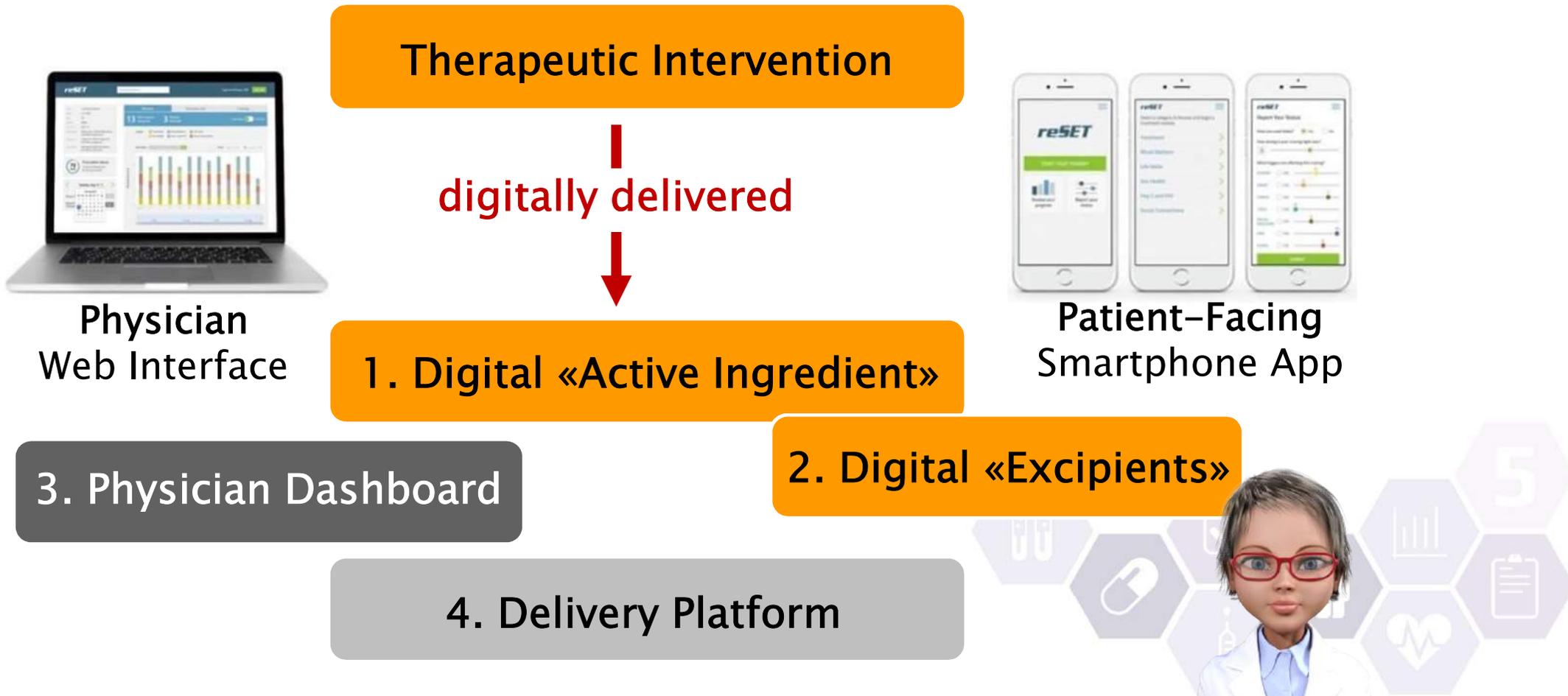
Substance Use Disorder



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3 R&D



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Therapeutic Intervention

A randomized-controlled trial of cognitive-behavioral therapy for depression with integrated techniques from emotion-focused and exposure therapies

Martin Grosse Holtforth ✉, Tobias Krieger, Johannes Zimmermann, David Altenstein-Yamanaka, Nadja Dörig.

Background: Emotional processing (EP) is hypothesized to be a key mechanism of change in psychotherapy that may enhance its long-term efficacy. To study the effects of fostering EP in psychotherapy for depression, this randomized-controlled clinical trial compares the efficacy and pattern of change of a cognitive-behavioral therapy that integrates emotion-focused techniques within an exposure framework (Exposure-Based Cognitive Therapy for depression; EBCT-R) to a standard cognitive-behavioral therapy (CBT). **Methods:** One hundred and forty-nine depressed outpatients were randomized to a maximum of 22 sessions of manualized EBCT-R ($N=77$) or CBT ($N=72$). Primary outcomes were self-reported and clinician-rated depressive symptoms at posttreatment and 12-month follow-up. Secondary outcomes were self-esteem, interpersonal problems, and avoidance thoughts and behaviors. **Results:** Depressive symptoms improved significantly over therapy in both treatments, with large within-group effect sizes for CBT ($d=-1.95$) and EBCT-R ($d=-1.77$). The pattern of depression change during treatment did not differ between treatments. Symptom relief lasted over 12 months and did not differ between EBCT-R and CBT. **Conclusions:** Results suggest that both treatments produced significant short- and long-term improvement in depression symptoms, but the integration of emotion-focused techniques within an exposure framework did not have added benefit.

Supporto attività del farmaco

Attività Fisica

Alimentazione

Intervento Cognitivo Comportamentale

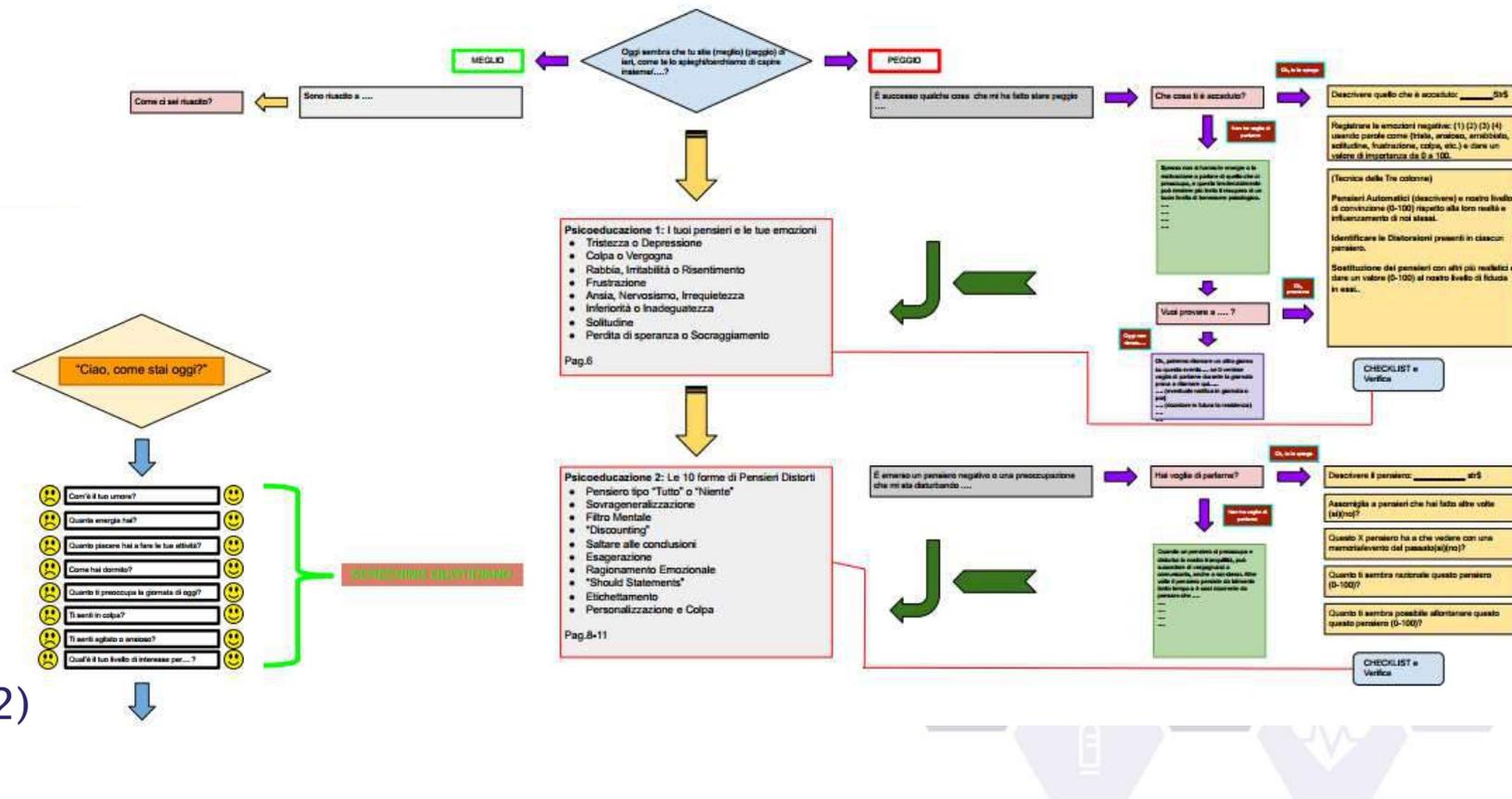
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Therapeutic Intervention

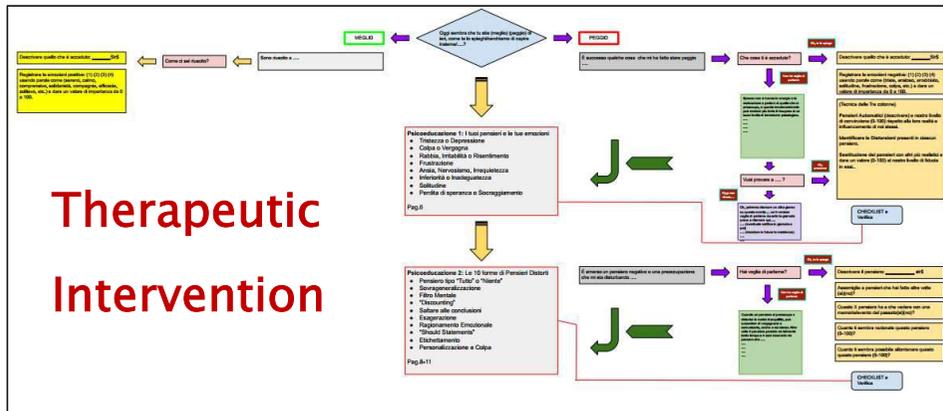
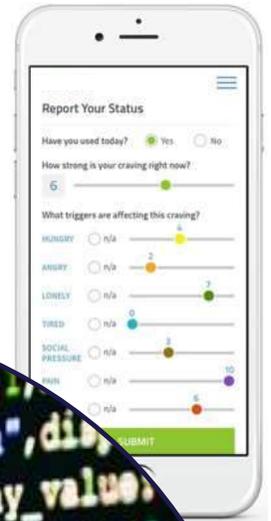
- a. Patients (2)
- b. Caregivers
- c. Expert Patient (1)
- d. Specialists (2)
- e. GPs (1)
- f. Engineers (2)
- g. UX-UI Specialist (2)



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Software Development



Therapeutic Intervention

Active Ingredient

Excipients

- Reminders
- Rewarding
- Gamification
- Goal Setting
- Action Planning
- Chat Bot
- Commitment
- Feedback
- Social Support
- Social Reward
- Social Comparison



- Data Privacy
- Data Security
- Cyber Security

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Pilot Clinical Development



1. Clinical Test – Usability and Acceptability

- ✓ *50 volunteers with / without the disease (Ph1 like)*

2. Pilot Clinical Study to Assess Efficacy and Safety

- ✓ *PoC Study*
- ✓ *100 patients, with mild to moderate depression*
- ✓ *Randomized, controlled*
- ✓ *Endpoint : Patient Health Questionnaire-9 (PHQ-9) at day 30 (vs basal)*



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Confirmatory Clinical Trial Design



1. Combo Development DTx + Drug

DTx + Drug > Drug

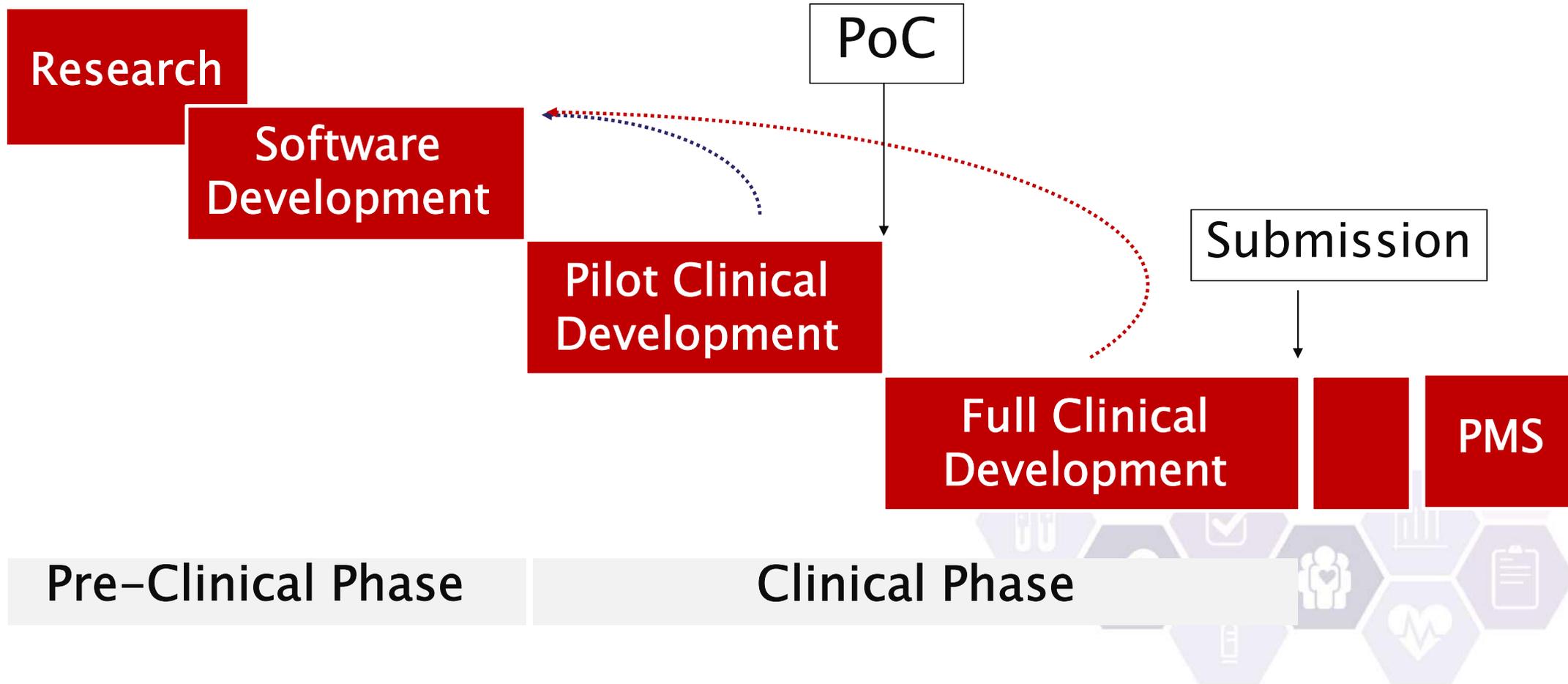
2. DTx Standalone Development / Add-on to Therapy As Usual (TAU)

DTx + TAU > Digital Placebo + TAU

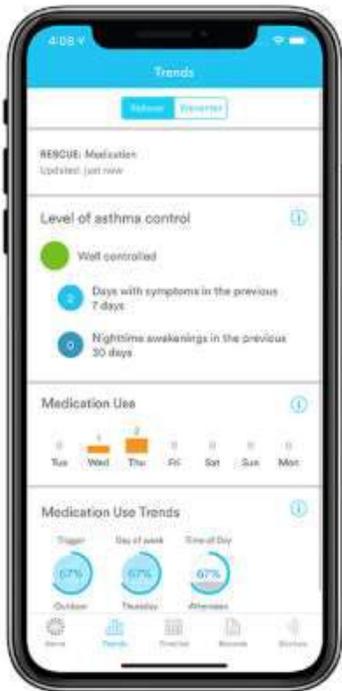


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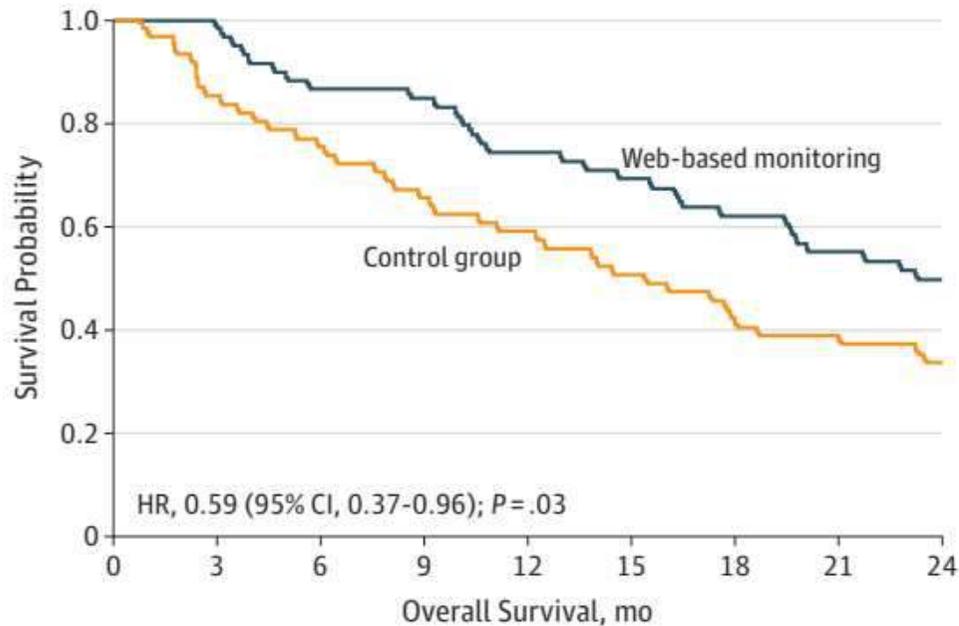
Respiratory : DTx?



**asthma and COPD
medication adherence
solution**

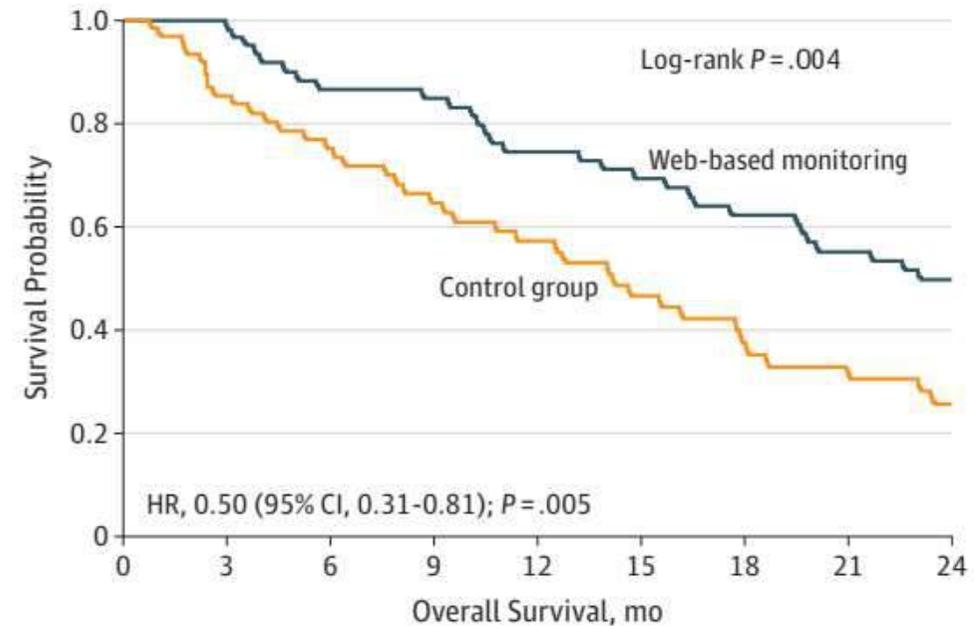
DTx Oncologia

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

Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer

DTx Oncologia



HOW WE HELP

Voluntis Announces Market Authorization for Oleena™, First Digital Therapeutic in Oncology

31 luglio 2019, 18:11 CEST

Reinvent symptom management.

Oleena™ is the first digital therapeutic in oncology for patients and their care teams.

This site is intended for use by US residents only.



DTx ADHD

The FDA is for ADHD

Dane Finley Jan 23, 2020, 5:35 PM

The talks have been ongoing since mid-2018, and it's unclear when the agency will make a decision — highlighting the complex path DTx firms must navigate when seeing a new medical treatment through to market.

Akili's video game treatment is designed to stimulate patients' prefrontal cortices via game-based sensory stimuli — and could replace the use of traditional pharmaceuticals in treating children with ADHD.

Should Akili's prescription video game receive the FDA go-ahead, the startup could be looking at an opportunity to transform a massive market.



Business Insider Intelligence

video game