# Cancer Real World - From Needs to Challenges

Milano, 24-25 Gennaio 2019

## Il Software diventa Terapia...

# Digital Therapeutics #DTx ed Innovazione

**Giuseppe Recchia, Vice Presidente**

**Fondazione Smith Kline**

# #Pharma2020… Paziente e Tecnologia


*FasterCures* is an action tank that works to speed and improve the medical research system.

**10,000 diseases. 500 treatments. We have work to do.**

10.000 malattie

- 7.000 rare
- 500 trattamenti adeguati
- 9.500 malattie in attesa di trattamento adeguato

**<u>in questa generazione…</u>**

***#CuresNow***

***#FasterCures***

***Patients Can't Wait***

# 21^ Century Cures Act

## RESEARCH

- Remove barriers to research collaboration
- Invest in STEM education
- Provide new incentives for the development of rare disease drugs

## GETTING TREATMENTS TO PATIENTS MORE QUICKLY

- Foster coordination to find cures more quickly
- Modernize clinical trials to increase access to drugs and treatments
- Incorporate patient feedback in drug development and review process

## KEEPING JOBS HERE AT HOME

- Ensure U.S. remains a global leader in medical innovation, protecting and creating jobs at home
- Encourage development of new medical apps to save lives and create jobs

#CURESatOne

E&C

- **Removing regulatory uncertainty for the development of new medical apps.**

  Regulatory uncertainty has slowed the development of medical apps that generate real time patient data. These apps hold tremendous promise for improving healthcare—saving time, money, and lives. HR 6 provides more certainty for app developers, clarifying their regulatory path moving forward and will speed the creation and deployment of these innovative health tools.

# Perché Digital Therapeutics?

## Limiti Terapie Attuali

- Efficacia
- Tollerabilità
- Aderenza
- Costi

**Patient Support Programs / Digital**

## Nuove Terapie

- Farmaci
- Advanced Therapies
- Electroceuticals
- ***Digital Therapeutics***
- Altre

# Digital Therapeutics #DTx

- Che cosa sono?
- Come funzionano?
- Quali indicazioni terapeutiche?
- Come si scoprono e sviluppano?
- Come si valutano?
- Come si prescrivono?
- Come entrano nella pratica medica?
- Chi le paga?

Digital Therapeutics Alliance

# Che Cosa Sono?

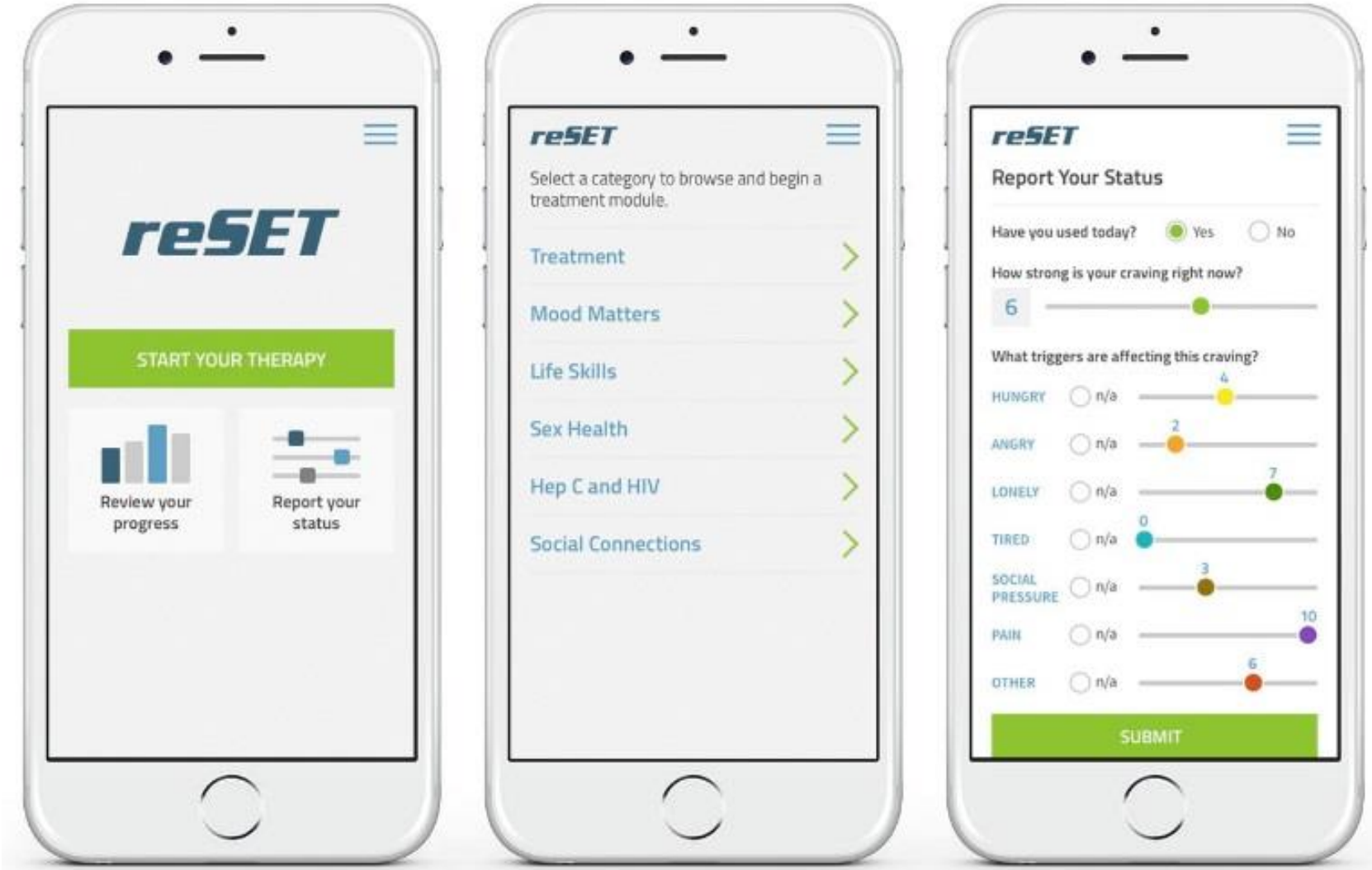
- Interventi Terapeutici*
- Software come *Principio Attivo*
- Sviluppati attraverso RCTs
- Autorizzati da enti regolatori
- Sottoposti a valutazione HTA
- Rimborsati da SSN / assicurazioni
- Prescritti dal medico

**recupero da condizioni patologiche*

Digital Therapeutics Alliance

# Software Principio Attivo

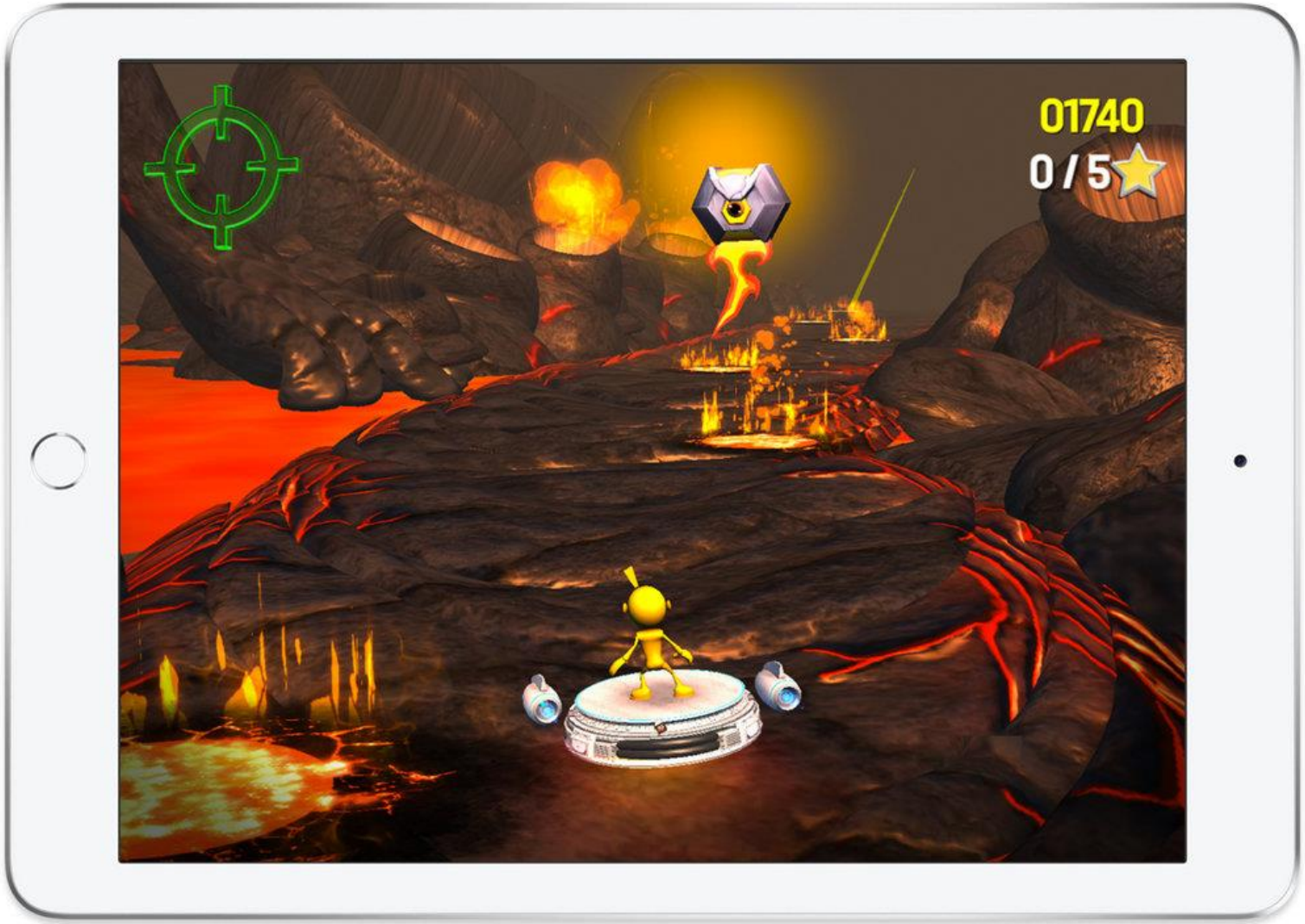
**mApp**




**«*Eccipiente*» Tecnologico**

# Software Principio Attivo

## Serious Game




## «*Eccipiente*» Tecnologico

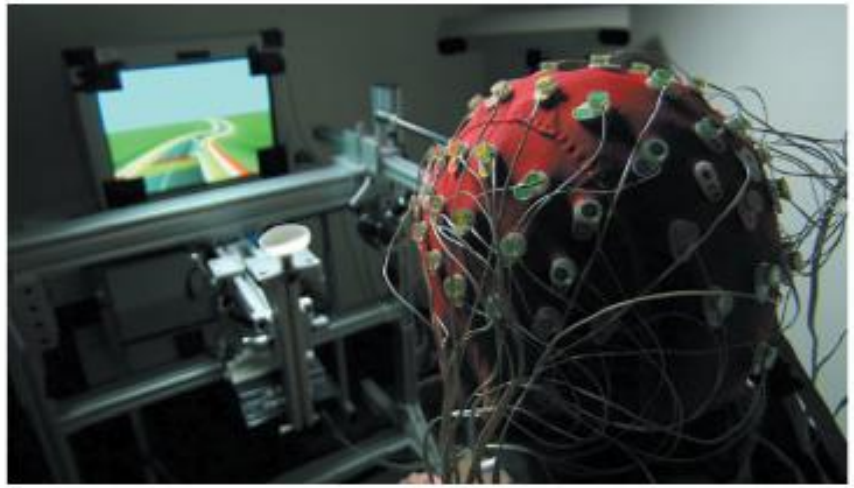
# Software Principio Attivo

## Device


## «*Eccipiente*» Tecnologico

# Come Funzionano? MoA

NEWS IN FOCUS



Improved mental skills that come from playing a video game are mirrored by increased brain activity.

NEUROSCIENCE

## Gaming improves multitasking skills

*Study reveals plasticity in age-related cognitive decline.*

BY ALISON ABBOTT

Sixty-five-year-old Ann Linsey was starting to worry about how easily she got distracted from whatever she was doing. "As you get older, it seems harder to do more things at once," she says. Then she enrolled in a study to test whether playing a game could

NeuroRacer is a three-dimensional video game in which players steer a car along a winding, hilly road with their left thumb, while keeping an eye out for signs that randomly pop up. If the sign is a particular shape and colour, players have to shoot it down using a finger on their right hand. This multitasking exercise, says Gazzaley, draws on a mix of cognitive skills

**Intervento cognitivo comportamentale**

## Explore the science and technology behind Akili's digital treatments

Developed through the collaboration of world-renowned cognitive neuroscientists and acclaimed entertainment and technology designers, Akili has created a proprietary technology platform that represents an entirely new category of medicine.

Built on extensive peer-reviewed research, Akili's products are designed to deliver sensory and motor stimuli to selectively target and activate specific cognitive neural systems in the brain. The proprietary technology is engineered to directly generate physiological changes in the brain to improve cognitive function.

# Quali Indicazioni Terapeutiche?

## Combinazione con il farmaco

**Terapia di Combinazione**

- Monitoraggio della aderenza alla terapia
- Raccomandazioni sul dosaggio del farmaco
- Raccomandazioni su gestione eventi avversi
- Proposta di intervento medico

*- Diabete (Roche, Sanofi)*

*- Oncologia (AZ, Roche)*

*- Malattie Respiratorie (GSK, AZ, Novartis, Teva)*

## Alternativa al farmaco

**Monoterapia**

- Interventi cognitivo – comportamentali

*- Dipendenze (Novartis)*

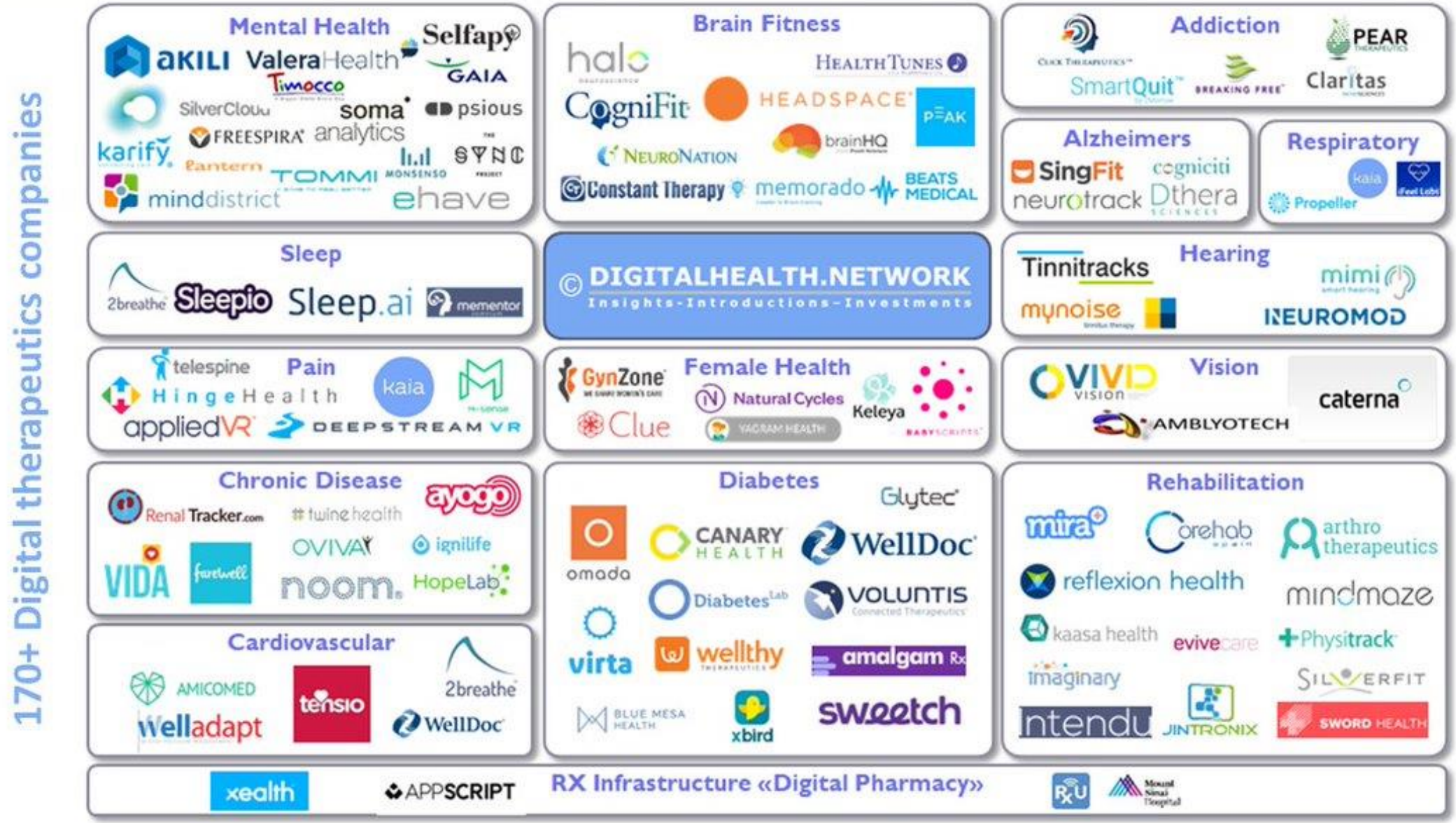
*- Insonnia*

*- Depressione*

*- ADHD*

*- Schizofrenia (Novartis)*

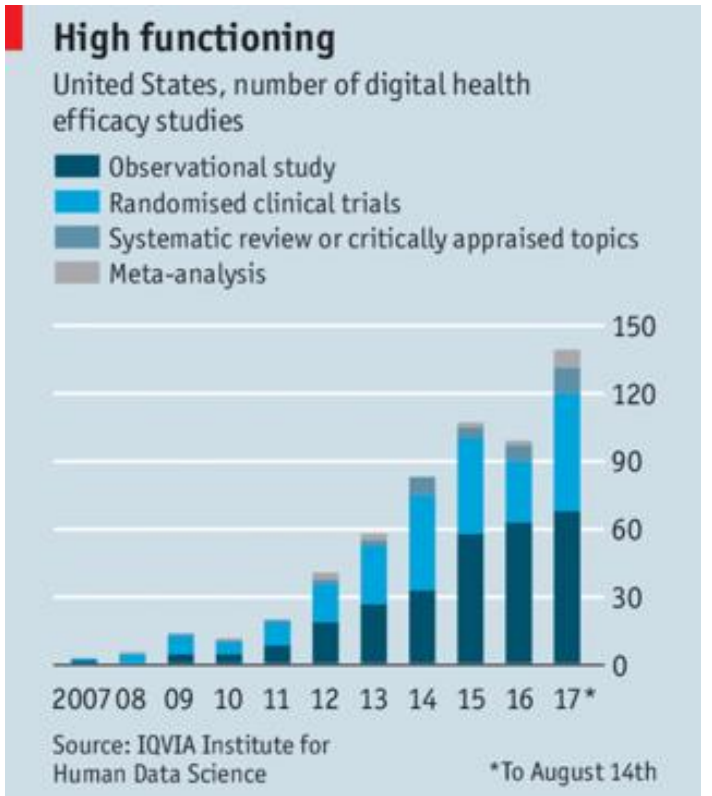
# Quali Indicazioni Terapeutiche?



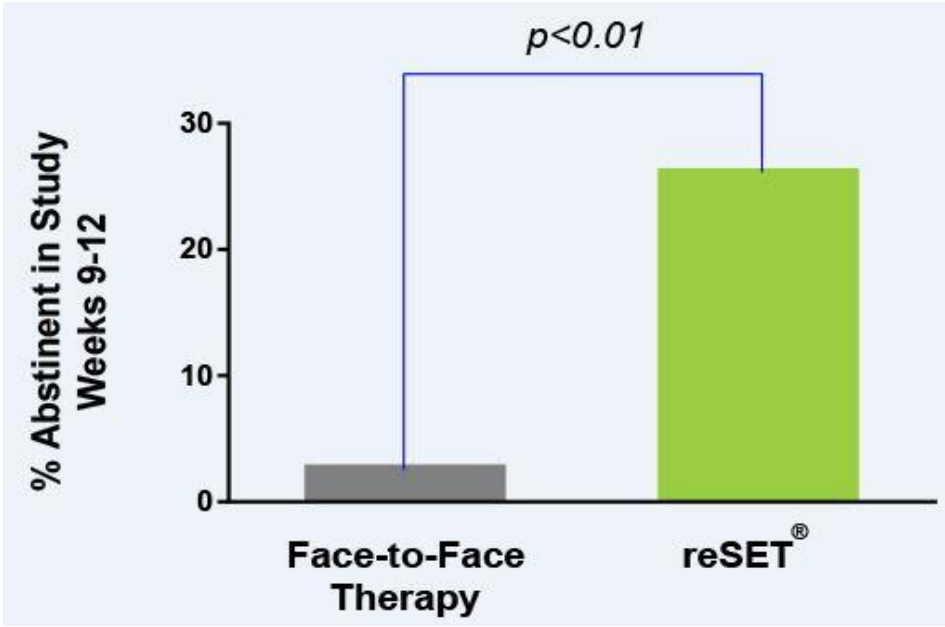
# Quale Ricerca & Sviluppo?

| INDICATION | PRODUCT | DEVELOPMENT STATUS: Discovery | POC | FDA PreSub | Pivotal Studies | FDA Submission | FDA Clearance / Approval | Commercial Partnerships | PARTNER: Developmental Partnerships |
|---|---|---|---|---|---|---|---|---|---|
| Substance Use Disorder (SUD) | reSET® | ■ | ■ | ■ | ■ | ■ | ■ | | |
| Opioid Use Disorder (OUD) | reSET-O™ | ■ | ■ | ■ | ■ | ■ | | | |
| Schizophrenia | THRIVE™ | ■ | ■ | ■ | | | | | |
| Combat-PTSD | reCALL™ | ■ | ■ | | | | | | |
| Multiple Sclerosis | PEAR-005 | ■ | | | | | | | |
| Insomnia | PEAR-006 | ■ | | | | | | | |
| Major Depressive Disorder | PEAR-007 | ■ | | | | | | | |
| Oncology | PEAR-008 | ■ | | | | | | | |
| Inflammatory Conditions | PEAR-009 | ■ | | | | | | | |
| Respiratory | PEAR-010 | ■ | | | | | | | |
| Parkinson's Disease | PEAR-011 | ■ | | | | | | | |

| Malattia | Salute |
|---|---|
| **Farmaco** | *Integratore* |
| **Digital Therapy** | *Wellness App* |
| **RCT +** | *RCT -* |



# Quali Prove di Efficacia e Sicurezza?




**DE NOVO CLASSIFICATION REQUEST FOR RESET**

**REGULATORY INFORMATION**

FDA identifies this generic type of device as:

**Computerized behavioral therapy device for psychiatric disorders**.

A computerized behavioral therapy device for psychiatric disorders is a *prescription device* intended to provide a computerized version of condition-specific behavioral *therapy* as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions.

The *digital therapy* is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes.

# Quali Prove di Efficacia e Sicurezza?

## INDICATIONS FOR USE

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for *patients 18 years of age and older* who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as *a 12 week (90 days) prescription-only treatment* for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse. It is intended to:

- increase abstinence from a patient's substances of abuse during treatment, and
- increase retention in the outpatient treatment program


## LIMITATIONS

- *For prescription use only.*
- The reSET device is not intended to be used as a stand-alone treatment device or to be used as a substitute for medication
- *The benefit of treatment with reSET on abstinence was not evaluated beyond 12 weeks of treatment.*

# Quali Prove di Efficacia e Sicurezza?

**Objective** *sindrome da deficit di attenzione e iperattività*

Pharmacological and behavioral therapies have limited impact on the distinct neurocognitive impairments associated with ADHD, and existing cognitive training programs have shown limited efficacy. This proof-of-concept study assessed treatment acceptability and explored outcomes for a novel digital treatment targeting cognitive processes implicated in ADHD.

**Method**

Participants included 40 children with ADHD and 40 children without ADHD. Following psychiatric screening, ADHD ratings, and baseline neuropsychological measures, participants completed 28-days of at-home treatment. Neuropsychological assessment was repeated at end-of-study along with treatment satisfaction measures.

**Results**

Eighty-four percent of treatment sessions were completed and ratings showed strong intervention appeal. Significant improvements were observed on a computerized attention task for the ADHD group and a highly impaired ADHD High Severity subgroup. There was no change for the non-ADHD group. Spatial working memory also improved for the ADHD group and the ADHD High Severity subgroup.

**Conclusion**

Findings provide preliminary support that this treatment may improve attention, working memory, and inhibition in children with ADHD. Future research requires larger-scale randomized controlled trials that also evaluate treatment impact on functional impairments.

ELSEVIER

Journal of the American Academy of Child & Adolescent Psychiatry

Volume 57, Issue 10, Supplement, October 2018, Page S172

## 2.40 A Multicenter, Randomized, Active-Control Registration Trial of Software Treatment for Actively Reducing Severity of ADHD (Stars-Adhd) to Assess the Efficacy and Safety of a Novel, Home-Based, Digital Treatment for Pediatric ADHD

Scott H. Kollins PhD ✉, Jeffrey Bower PhD, Robert L. Findling MD, MBA, Richard Keefe PhD, Jeffrey Epstein PhD, Andrew J. Cutler MD, Roseann White, Laura Aberle, Denton DeLoss, Stephen V. Faraone PhD

AKILI

**Akili Interactive plans to seek FDA approval for its 'digital medicine' after its tablet-based video game passed a pivotal trial in attention-deficit/hyperactivity disorder (ADHD).**

The US firm's AKL-T01 game has just completed a randomised, controlled trial of 348 children and adolescents with ADHD in which it improved attention scores.

# Quali Prove di Efficacia e Sicurezza?

NIH U.S. National Library of Medicine

ClinicalTrials.gov

## Study Design

Go to

| | |
|---|---|
| Study Type: | Interventional (Clinical Trial) |
| Estimated Enrollment: | 195 participants |
| Allocation: | Randomized |
| Intervention Model: | Parallel Assignment |
| Masking: | Double (Participant, Investigator) |
| Primary Purpose: | **Treatment** |
| Official Title: | Clinical Trial of an Innovative **Digital Therapeutic** for Smoking Cessation With Biochemical Verification |
| Estimated Study Start Date: | October 2018 |
| Estimated Primary Completion Date: | May 31, 2019 |
| Estimated Study Completion Date: | June 30, 2019 |

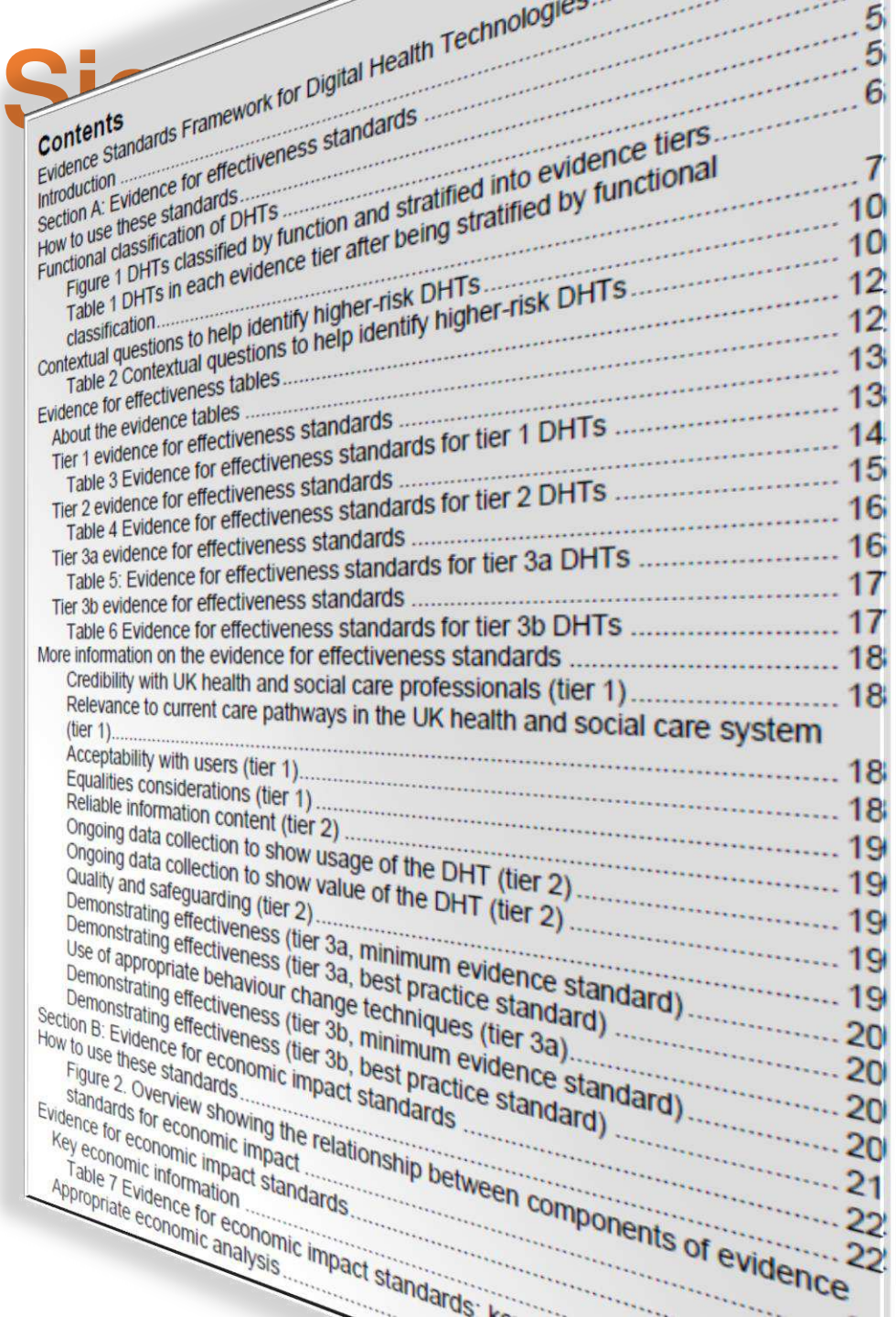
# Quali Prove di Efficacia e Si

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NHS England · NICE · Public Health England · MEDCITY · Digital Health. London

## EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

**December 2018**



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**Studio clinico pilota**

**Convalida SW medicale**

**Sperimentazione clinica allargata**

**Marcatura CE**
**FDA Certification**

**Introduzione nella Pratica Medica**

**Aggiornamento della Marcatura**

**Sorveglianza post market**

npj | Digital Medicine

www.nature.com/npjdigitalmed

PERSPECTIVE OPEN

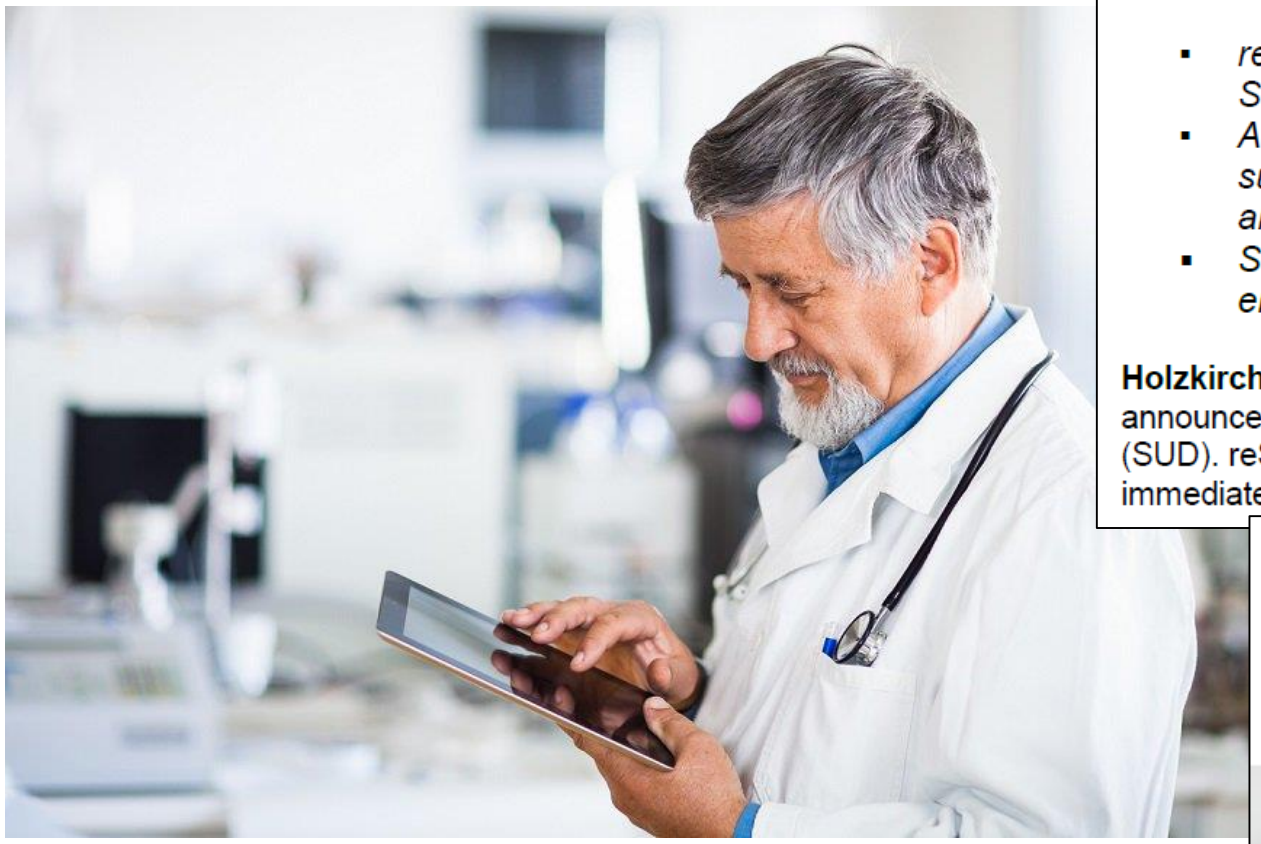
## Agile research to complement agile development: a proposal for an mHealth research lifecycle

Kumanan Wilson[1,2], Cameron Bell[2], Lindsay Wilson[2] and Holly Witteman[3]

Mobile health (mHealth) technology is increasingly being used, but academic evaluations supporting its use are not keeping pace. This is partly due to the disconnect between the traditional pharmaceutical approach to product evaluation, with its incremental approach, and the flexible way in which mHealth products are developed. An important step to addressing these problems lies in establishing agile research methods that complement the agile development methodologies used to create modern digital health applications. We describe an mHealth research model that mirrors traditional clinical research methods in its attention to safety and efficacy, while also accommodating the rapid and iterative development and evaluation required to produce effective, evidence-based, and sustainable digital products. This approach consists of a project identification stage followed by four phases of clinical evaluation: Phase 1: User Experience Design, Development, & Alpha Testing; Phase 2: Beta testing; Phase 3: Clinical Trial Evaluation; and Phase 4: Post-Market Surveillance. These phases include sample gating questions and are adapted to accommodate the unique nature of digital product development.

*npj Digital Medicine* (2018)1:46 ; doi:10.1038/s41746-018-0053-1

# Chi le prescrive?



**Sandoz and Pear Therapeutics announce launch of reSET® for treatment of patients with Substance Use Disorder**

- *reSET® is the first and only FDA-authorized prescription digital therapeutic for Substance Use Disorder (SUD)*
- *Adding reSET to outpatient therapy significantly improved abstinence in substances of abuse and treatment retention compared to standard of care alone*
- *Sandoz and Novartis continue to embrace digital technologies to enhance R&D and deliver better outcomes for patients*

**Holzkirchen, November 19, 2018** – Sandoz, a Novartis division, and Pear Therapeutics, Inc., announced today the commercial launch of reSET® for patients with Substance Use Disorder (SUD). reSET, the first and only FDA-authorized prescription digital therapeutic, is immediately available.


# Come entrano nella pratica medica?

# Chi le paga?

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

25 Jul 2018

Generali Welion and Amicomed unite to deliver a digital service against hypertension


NHS England · DIGITAL THERAPEUTICS ALLIANCE · hin Health Innovation Network · IMPERIAL COLLEGE HEALTH PARTNERS · UCLPartners · MEDCITY

# #DTx Oncologia

**Our digital therapeutic moves mountains**


Theraxium
ONCOLOGY

## Enable personalized symptom management

Theraxium Oncology helps empower patients to self-manage their symptoms.

Our technology combines a prescription app for patients with a web app for health care teams.

- *Patients report symptom data in the smartphone app to receive immediate actionable recommendations that are personalized to their profile and current condition.*
- *Care teams can follow the progress of their entire patient population from their desks thanks to their web app, no download needed.*

# #DTx Oncologia

| | |
|---|---|
| **Date** | 10 September 2017 |
| **Event** | ESMO 2017 Congress |
| **Session** | Poster display session |
| **Topics** | **Anticancer Agents**<br>**Ovarian Cancer**<br>**Supportive Measures**<br>**Gynaecological Malignancies**<br>**Supportive and Palliative Care**<br>**Therapy**<br>**Biological Therapy** |
| **Presenter** | Joyce Liu |
| **Citation** | Annals of Oncology (2017) 28 (su<br>10.1093/annonc/mdx388 |
| **Authors** | J. Liu[1], C. Whalen[1], S. Morrissey<br>N. Houston[2], R.M. Wenham[3], D.M<br>R. Phillips[6], K. Mari[7], S.P. Ivy[8], B.<br>**Author Affiliations** |

*eCediranib / Olaparib*

## Voluntis Extends Partnership with AstraZeneca in Digital Therapeutics for Oncology

August 30, 2018 12:00 PM Eastern Daylight Time

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Regulatory News:

Voluntis (Paris:VTX), a digital biotech specialized in digital therapeutics, has announced the extension of its collaboration with AstraZeneca (NYSE: AZN) in the field of oncology. As part of the renewed agreement, the partners will implement a new phase of clinical evaluation of their digital therapeutic designed to support platinum resistant ovarian cancer patients treated with a combination of Cediranib plus Olaparib.

The eCO (eCediranib/Olaparib) solution will be tested in the GY005 randomized phase III clinical trial sponsored by the National Cancer Institute (NCI), which will evaluate if the digital therapeutic can complement treatment by determining whether it enables better management of side effects and thereby improves patient outcomes. Women and their clinicians will be given eCO in conjunction with their Cediranib and Olaparib treatment to help manage symptoms of hypertension and diarrhea sometimes associated with their therapy to enable them to stay longer on treatment. Patients will access eCO through a smartphone app in which they can record their symptoms to receive real-time recommendations. Clinicians will be able to use a corresponding web portal to track their patient population remotely and adjust symptom management plans as necessary.

# #DTx Oncologia

**A Study to Assess the Feasibility of an E-Health System (ZEMY) Designed to Manage Symptoms in Participants With Breast Cancer Under Anti-Cancer Treatment (ZEMY)**

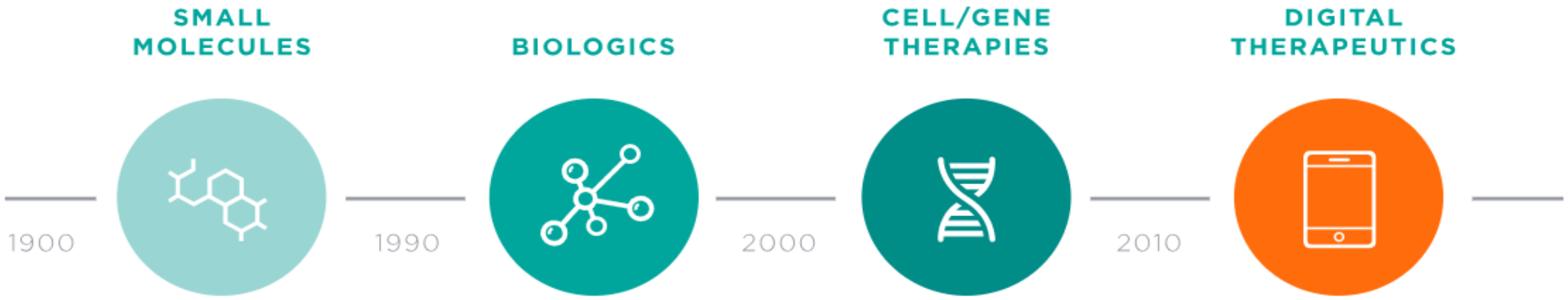
## Voluntis and Roche Pharma France reinvent cancer patient support with digital therapeutics

VOLUNTIS

NEWS PROVIDED BY
**Voluntis →**
Mar 26, 2018, 05:42 ET

PARIS, March 26, 2018 /PRNewswire/ -- Today, Voluntis and Roche Pharma France announced that important milestones have been reached in the development of ZEMY, a digital therapeutic developed by Roche Pharma France in partnership with Voluntis since 2015. ZEMY aims to improve care support for breast cancer patients. Its co-construction with various stakeholders (patients, healthcare professionals, etc.) has been critical in developing its medical algorithms and validating its ease of use.

# Che cosa fare in Italia?




# Che cosa fare in Italia?

## ❶ Chiarire Aree Incertezza

- Entità e natura delle prove di efficacia
  - ✓ Sperimentazione Clinica Randomizzata e Controllata (RCT)
  - ✓ Contesto naturale (Real World)
- Valutazione Tecnologica e modelli di rimborso
- Introduzione nella pratica medica e sanitaria

## ❷ Creare Condizioni Abilitanti

- Informazione e Formazione degli Operatori Sanitari
- Consapevolezza nei pazienti / cittadini
- Scientific Advice esperto
- Qualità della valutazione
- Accesso al paziente / Rimborso
- Network di sperimentazione clinica

SOCIETÀ ITALIANA DI PNEUMOLOGIA

XIX CONGRESSO NAZIONALE DELLA PNEUMOLOGIA

SAVE THE DATE

Venezia 13-15 Ottobre 2018 VENEZIA LIDO

**Siamo preparati al decollo?**

# Digital Therapeutics In Medicina Respiratoria

*Roberta Bodini[1], Martijn Grinovero[2], Claudio Micheletto[3], Franco Del Zotti[4], Angelo Corsico[5], Giuseppe Recchia[1], Salvatore D'Antonio[6], Fulvio Braido[7]*

# Digital Therapeutics Italia #DTxITA

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@GGRecchia

# Grazie