



**Giuseppe Recchia**  
Vice Presidente Fondazione Smith Kline, Verona

# Digital Therapeutics

## Verso la Pratica Medica in Italia

**Giuseppe Recchia**

Vice Presidente, Fondazione Smith Kline - Verona

Co-founder & CEO, daVinci Digital Therapeutics – Milano

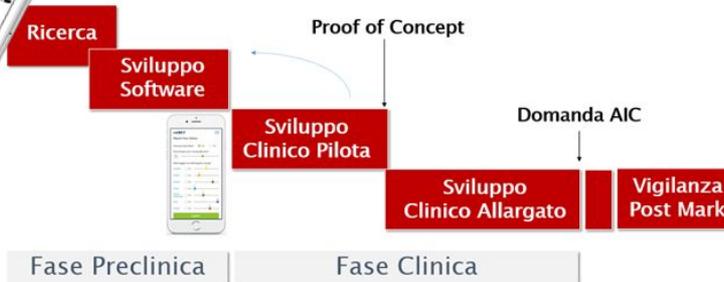


# DIGITAL THERAPEUTICS – CHE COSA SONO ...

- Tecnologie Sanitarie a finalità terapeutica
- Modifica dei comportamenti *disfunzionali*
- Sviluppate attraverso RCTs
- Autorizzate da enti regolatori
- Rimborsate da servizi sanitari
- Prescritte dal medico
- Principio Attivo è un **algoritmo**



Digital Therapeutic	Produttore	Fase	Indicazione Terapeutica
Deprexis	GAIA AG	Approvato 2009	Depressione
Sleepio	Big Health	Approvato 2013	Insomnia
Reset	Pear Therapeutics	Approvato 2017	Dipendenza da sostanza da abuso
Reset-O	Pear Therapeutics	Approvato 2018	Dipendenza da oppiacei
Oleena	Voluntis	Approvato 2019	Sintomi associati a neoplasia
Somryst	Pear Therapeutics	Approvato 2020	Insomnia cronica
Endeavor	Akili Laboratories	Approvato 2020	ADHD Bambino
CA Smoking Cessation	CureApp	Approvato 2020	Disassuefazione dal fumo
Hypertension	Cure App	Sviluppo	Ipertensione arteriosa
AKL-T02	Akili Laboratories	Sviluppo	Disturbi Spettro Autistico
PEAR-004	Pear Therapeutics	Sviluppo	Schizofrenia



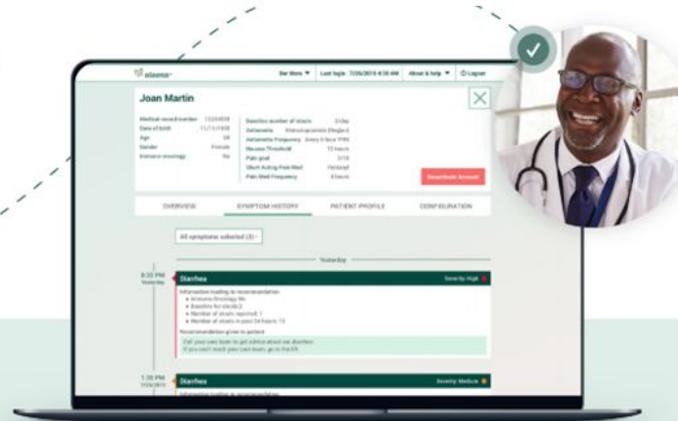


## Sono Efficaci?

Oleena is a prescription mobile app for cancer patients, designed to help them in the management of symptoms and enable remote monitoring by care teams



A prescription mobile app that provides personalized symptom recommendations.



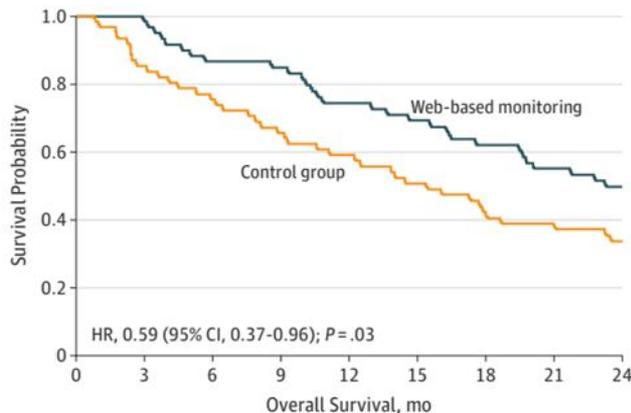
A dedicated interface to gain continuous insights on patients' symptoms.

# Sono Efficaci?

JAMA 22 Jan 2019, 321(3) ; Denis E et al.

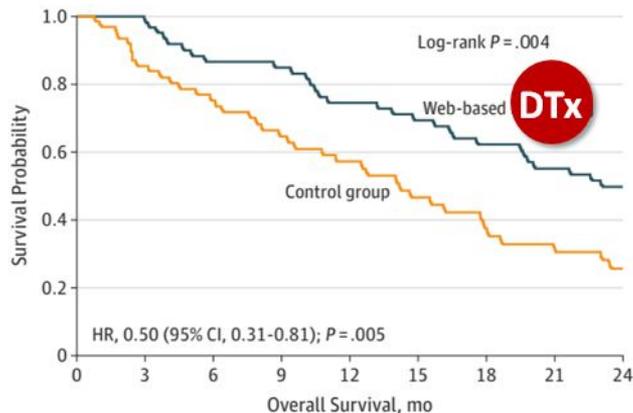
Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer

**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

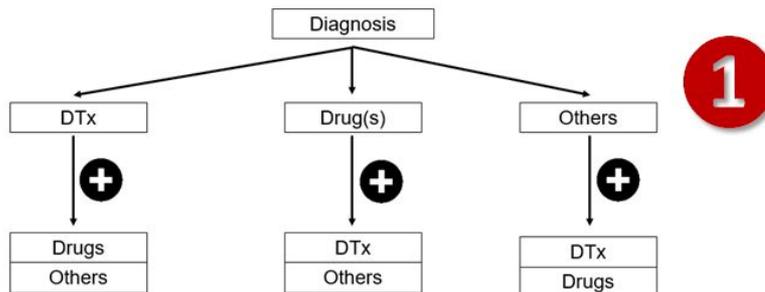


Source	Median OS	12-mo OS, %	24-mo OS, %
Web-based monitoring	22.5 mo	75	50
Control	13.5 mo	53	26

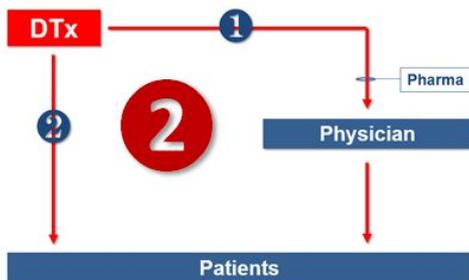
Symptom monitoring via weekly web-based PROs following treatment for lung cancer was associated with increased survival compared with standard imaging surveillance. A potential mechanism of action is that symptoms suggesting adverse events or recurrence were detected earlier

# DIGITAL THERAPEUTICS – AREE GRIGIE

1. Place in Therapy
2. Ruolo del medico
3. Rapporto con il farmaco
  - a. Sostituzione
  - b. Aggiunta
  - c. Combinazione

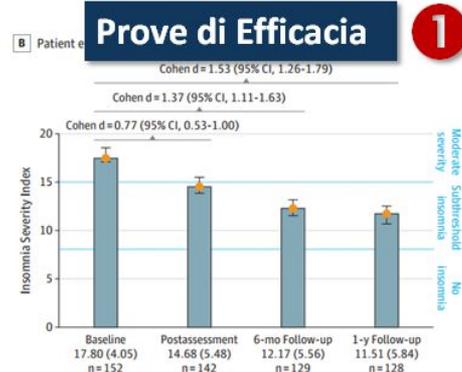
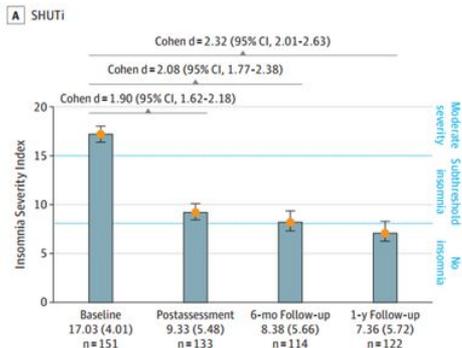


- Migliorare gli esiti di salute del paziente
- Aumentare il valore terapeutico del farmaco
- Estendere il ciclo di vita del farmaco
- Accedere a dati Real World / Real Time
- Personalizzare la terapia
- Completare l'offerta terapeutica
- Entrare in nuove aree terapeutiche





## Aree di Criticità



1

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

Tuesday, 24 April 2018

#DHLCOLLABORATE  
#DigitalHealthLondon

**Rimborso**

- I medici possono prescrivere le app.
- Migliore accesso ai dati dei pazienti per ricerca.
- La comunicazione medico e pazienti e la prescrizione si sposta su canali digitali.
- Every insured member will have access to an electronic health record.
- Health insurers will be allowed to offer online member sign ups.
- Pharmacies, HCPs and hospitals are forced to connect to secure communication network.
- Il teleconsulto diventa la norma.
- Health innovation is financially supported. 200 Mio EUR p.a.

**Moovcare® becomes the first digital therapy reimbursed in France!**

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## Decentralized Clinical Trial

3



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

## DIGITAL THERAPEUTICS ITALIA – QUANDO?

2020

- 12.2020 - «DTxItaly» Book to be published;
- 4Q2020 - «DTxItaly» Book to be promoted to institutions, pharma, insurance comp., scientific societies, patient organization
- 4Q2020 - «DCTxITA» **Decentralized Clinical Trials** Project for Italy to start;

2021

- 1Q2021 - «DTxItaly» paper published on int'l journal, broadening the **debate** on access, reimbursement and clinical develop.
- 2Q2021 – Discussion on DTx access and reimbursement in Italy with **Ministry of Health (Fondazione RES – SK – Altri)**
- 1H2021 – Clinical development of anti **obesity** DTx to start in Italy; avvio **formazione** di Medici e Pazienti attraverso **Unitelma Sapienza**
- 2H2021 – Controlled clinical use of a **antidepressant? / anti ADHD?** DTx in Italy

2022

- 1H2022 - Definition of a DTx **reimbursement model** by Ministry of Health and Italian Drug Agency
- 1H2022 – **Antidepressant? / ADHD?** DTx conditional reimbursement agreement with Ministry of Health
- 1H2022 - Clinical development of DTx to treat **chronic insomnia** to start in Italy
- 2H2022 – A regulatory document on DTx; end of controlled DTx introduction in Italy

Ott. 2022. Forse prima...