



Scuola di Specializzazione in Farmacologia e Tossicologia Clinica



in collaborazione con **Fondazione Smith Kline**

Digital Therapy / Digital Therapeutics DTx

Terapia Digitale

Milano, 13 marzo 2019

Giuseppe Recchia, Vice Presidente



Fondazione Smith Kline

Digital Health

The expanding **digital health landscape** includes products such as:

Mobile Health (mHealth)

Examples include:

- Wellness, fitness trackers, and nutrition apps
- Consumer health information
- Medication adherence apps

Digital Therapeutics

Digital therapeutics deliver evidence-based therapeutic interventions to patients to prevent, manage, or treat a medical disorder or disease.

Examples provided on page 6.

Health Information Technology (HIT)

Examples include:

- Electronic medical record systems
- Electronic prescribing and order entry
- Consumer health IT applications

Devices, Sensors, and Wearables

Examples include:

- Wearable and wireless devices
- Biometric sensors
- Diagnostic products

Personalized Healthcare

Examples include:

- Patient reported outcomes
- Predictive analytics
- Clinical decision support

Telehealth

Examples include:

- Telemedicine virtual visits
- Remote patient monitoring
- Remote care programs

Sources provided on page 14.

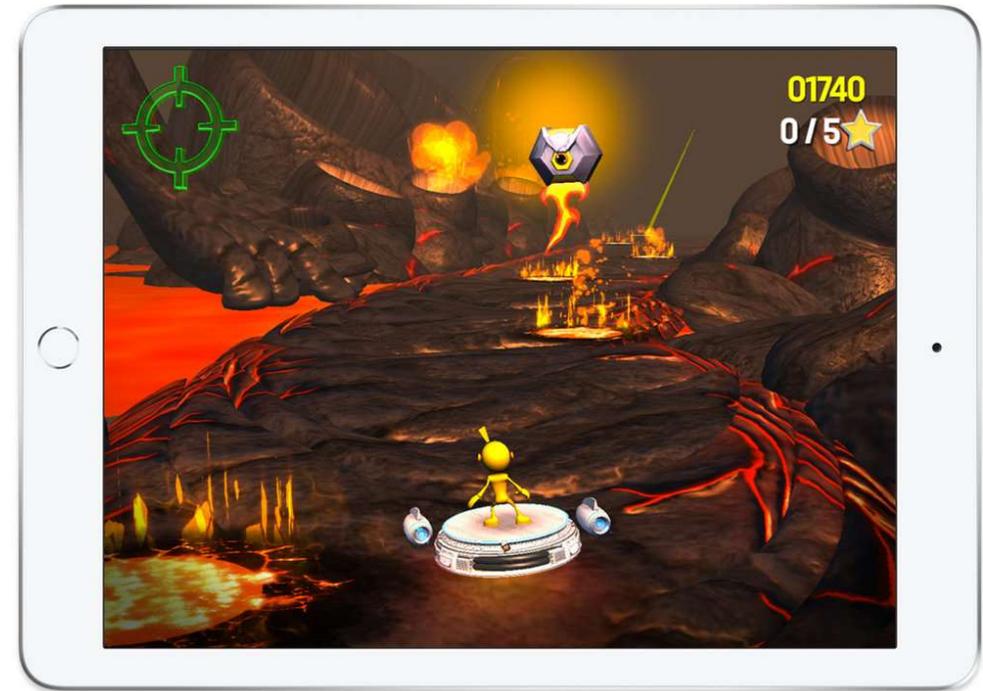
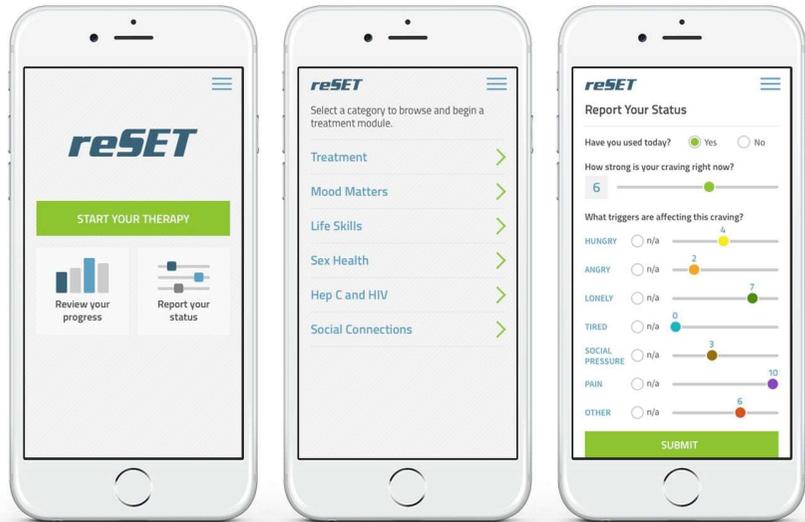
#DTx – Software è il «Principio Attivo»

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

**Digital
Therapeutics
Alliance**



#DTx – mApps, Games, Sensori....



gli «eccipienti»



#DTx – Come funzionano?

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*⁵
 - *Depressione*
 - *ADHD*
 - *Schizofrenia (Novartis)*



#DTx – Quali Indicazioni Terapeutiche?

170+ Digital therapeutics companies

<p>Mental Health</p>	<p>Brain Fitness</p>	<p>Addiction</p>	
<p>Sleep</p>	<p>DIGITALHEALTH.NETWORK Insights-Introductions-Investments</p>	<p>Alzheimers</p>	<p>Respiratory</p>
<p>Pain</p>	<p>Female Health</p>	<p>Hearing</p>	<p>Vision</p>
<p>Chronic Disease</p>	<p>Diabetes</p>	<p>Rehabilitation</p>	
<p>Cardiovascular</p>	<p>RX Infrastructure «Digital Pharmacy»</p>		

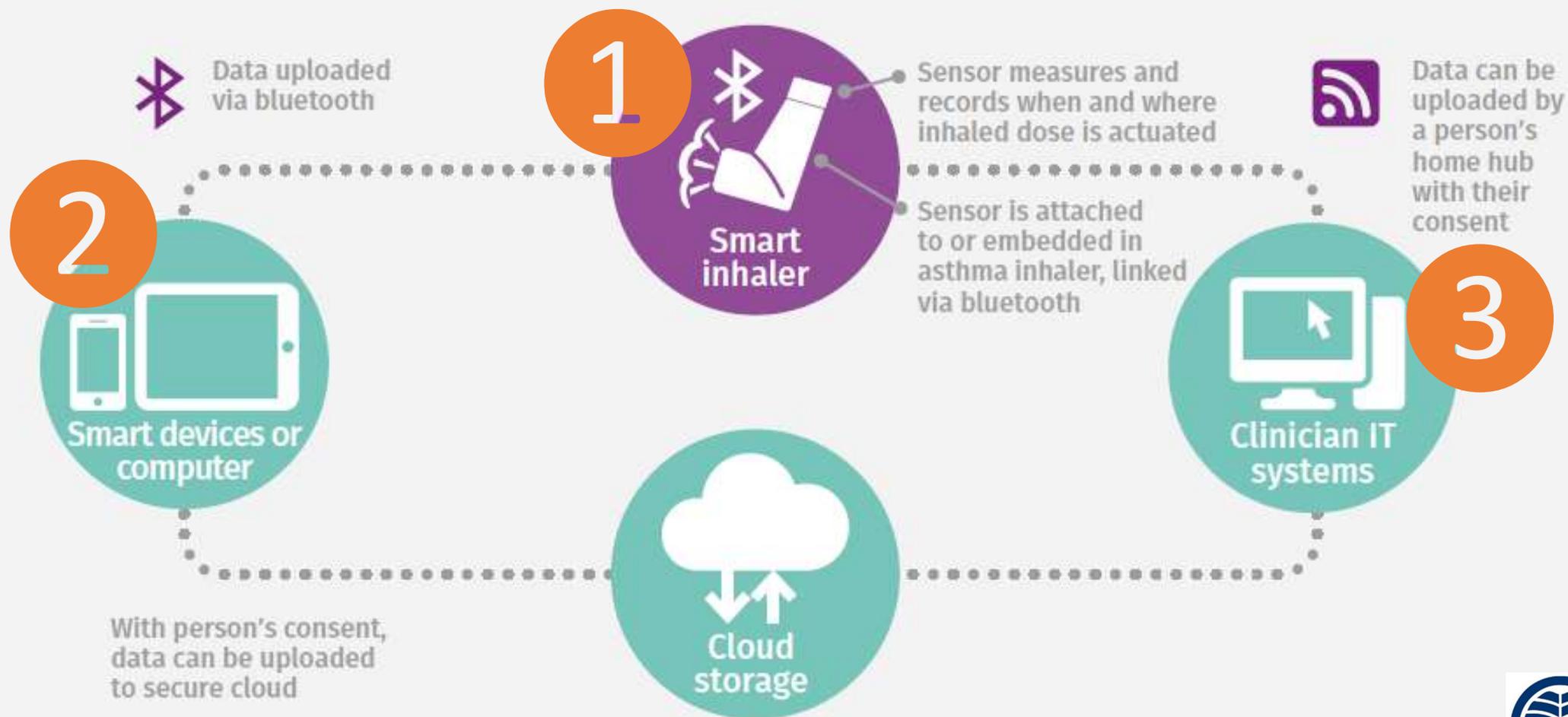


DTx - Software (e qualche volta Hardware)

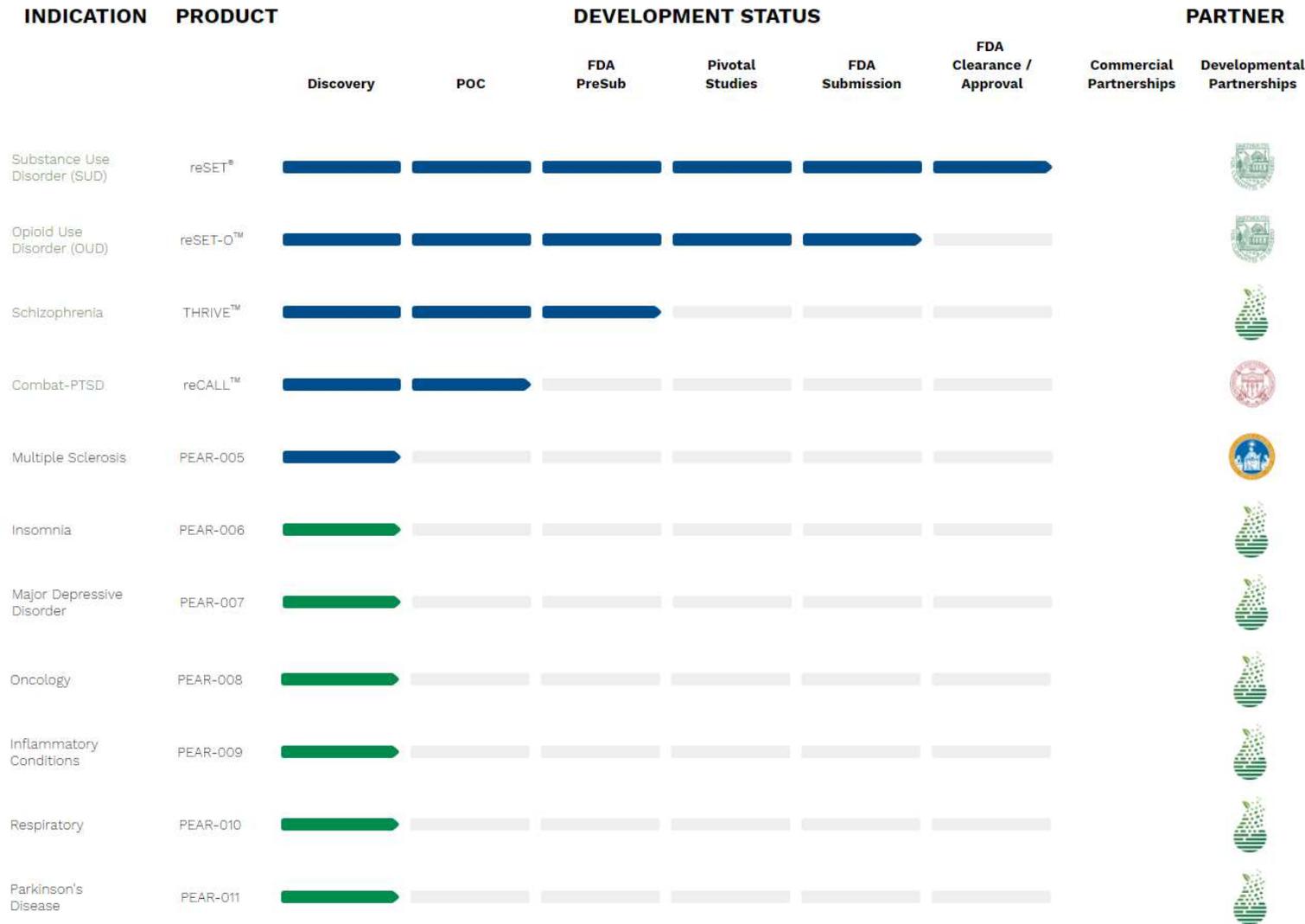


1. Registra se / quando /come il paziente usa l'inalatore, avvisa quando usare l'inalatore
2. Riceve informazioni dal sensore, fornisce supporto personalizzato
3. Mostra le tendenze individuali e di gruppo nel tempo, consente il monitoraggio da remoto, consente l'interazione con il paziente

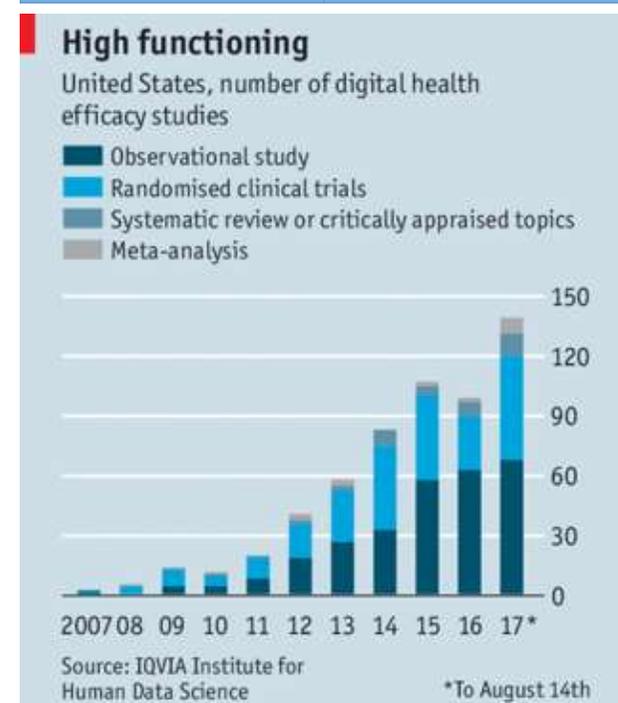
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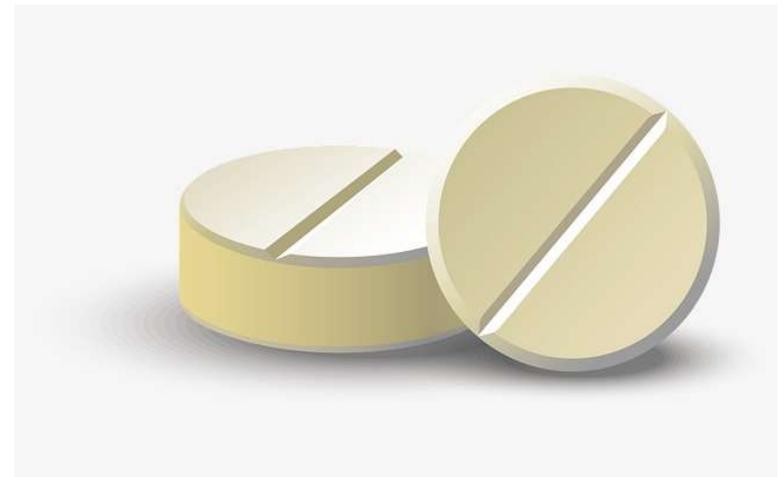
Quale Ricerca & Sviluppo?



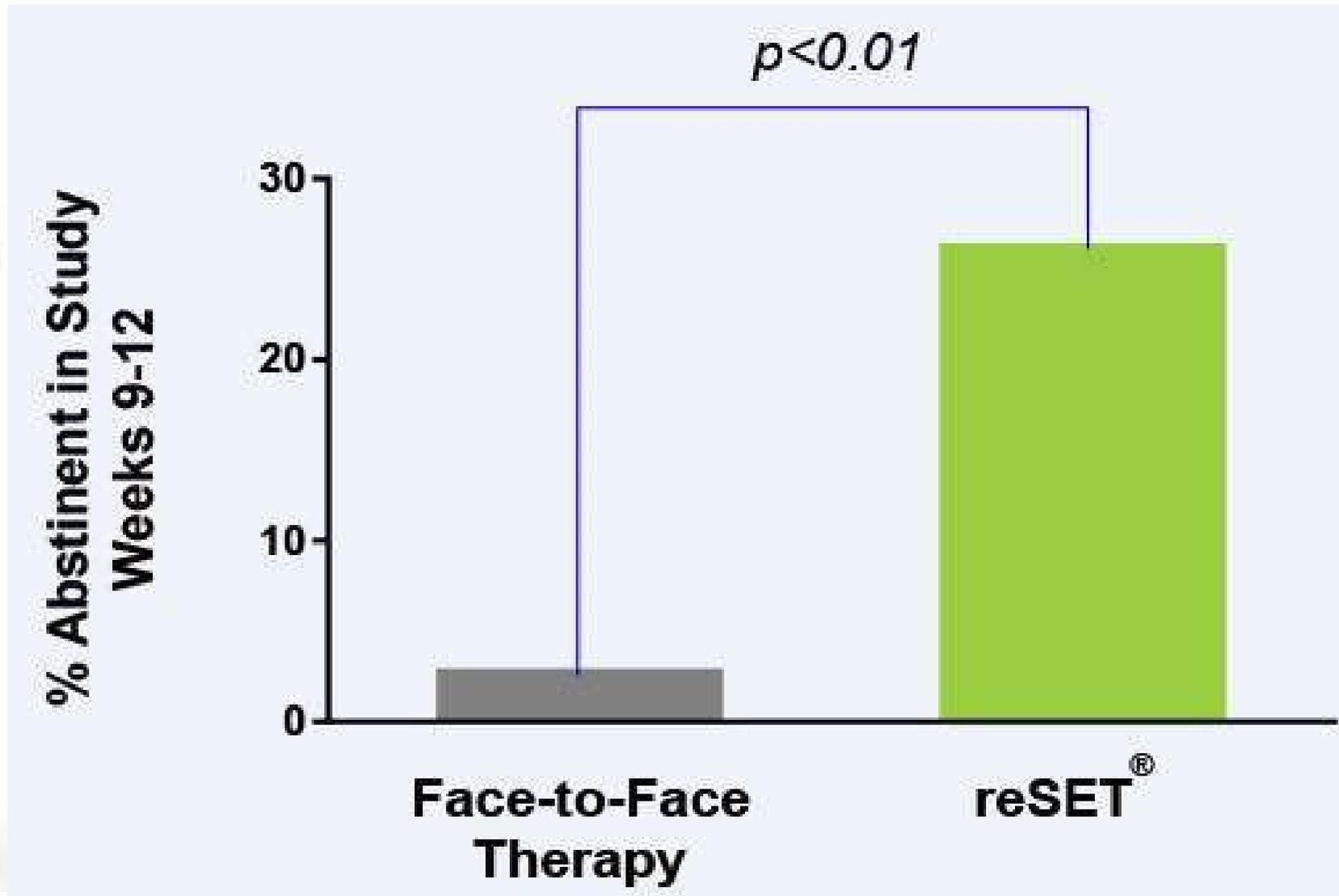
Malattia	Salute
Farmaco	Integratore
Digital Therapy	Wellness App
RCT +	RCT -



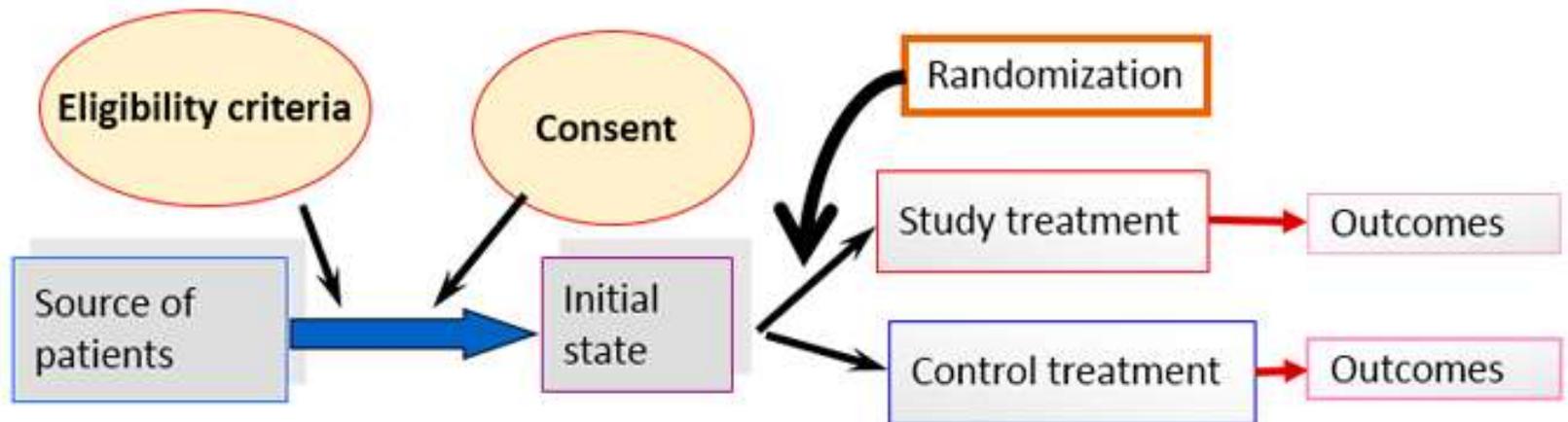
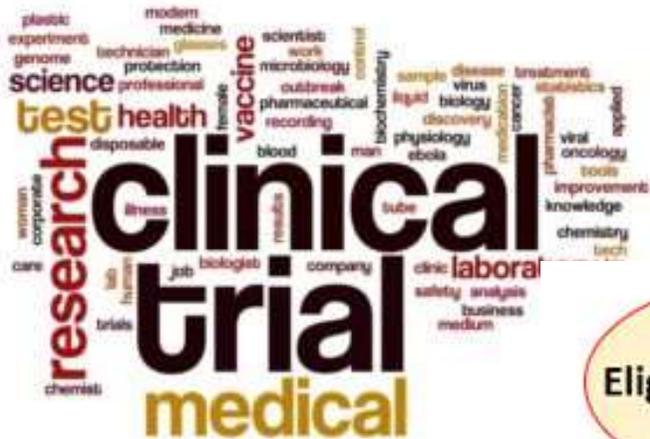
#DTx – Prove di Efficacia e Sicurezza?



#DTx – Prove di Efficacia e Sicurezza?



DTx – RCTs e Outcomes



Study Treatment

Standard + Digital

Control Treatment

Standard

Biases	Susceptibility	Performance	Detection follow-up
Design	Random allocation	Concurrent comparison	Objective observation

#DTx – 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



#DTx Respiratory – Clinical Trials

NIH U.S. National Library of Medicine

ClinicalTrials.gov

- Find Studies ▼
- About Studies ▼
- Submit Studies ▼
- Resources ▼
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Trial record **1 of 2** for: [ellipta connected](#) | Asthma

[Previous Study](#) | [Return to List](#) | [Next Study](#)

A Clinical Study to Evaluate the Effect of the Connected Inhaler System (CIS) on Adherence to Maintenance Therapy in Poorly Controlled Asthmatic Subjects

- 432 patients randomized 1:1:1:1:1
 - Maintenance therapy and rescue therapy
 - ✓ Feedback to patients
 - ✓ Feedback to patients / physician
 - ✓ No Feedback
- 432 patients
 - 6 months treatment
 - 4.2019

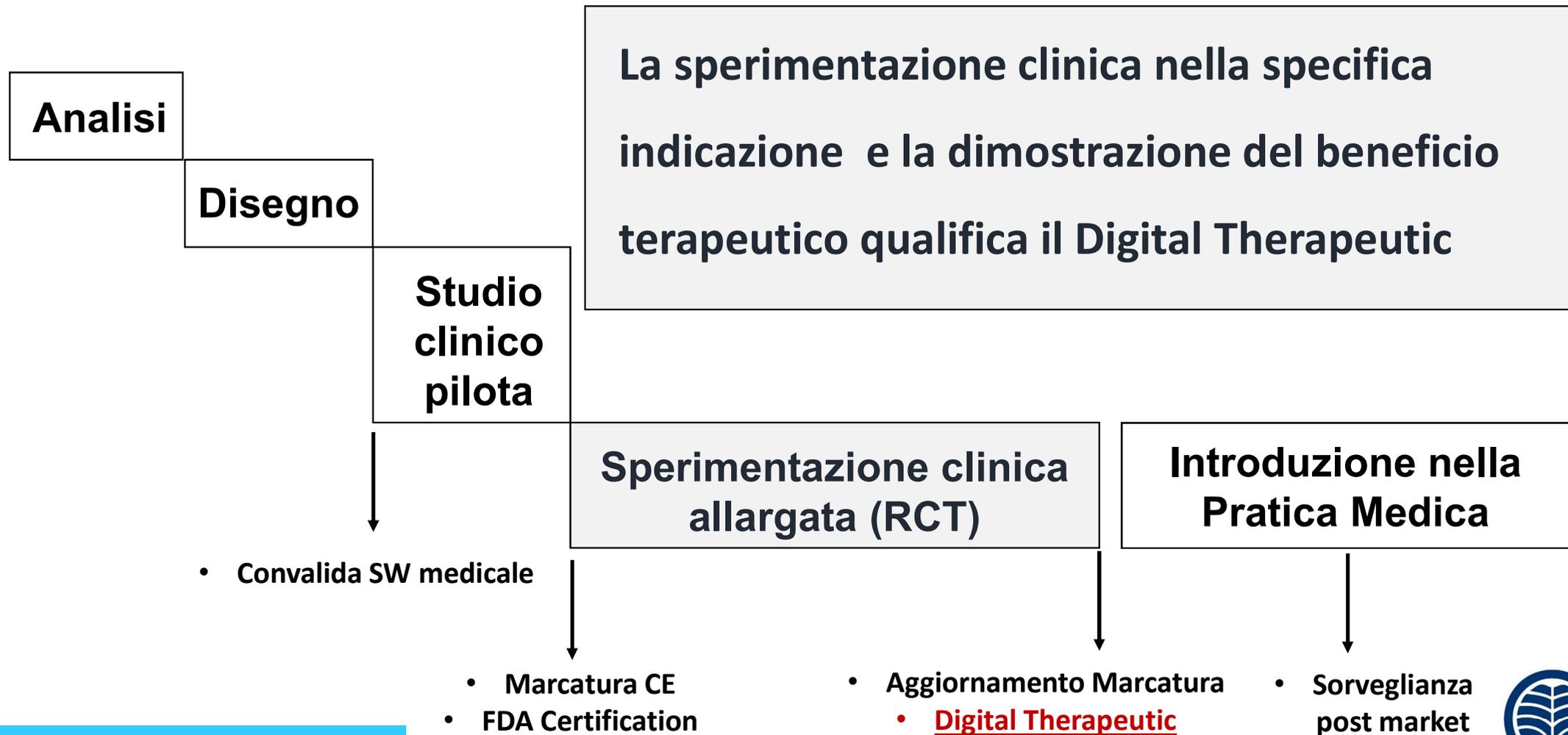
Primary Outcome Measure

1. % of doses taken between months 4 and 6

Secondary Outcome Measure

1. % of doses taken between months 1 and 3
2. % of doses taken between months 1 and 6
3. % of rescue free days
4. Total rescue medication use
5. Change from Baseline in ACT total score
6. % of subjects with an increase from Baseline ≥ 3 in ACT total score

#DTx – Come si Ricercano & Sviluppano?

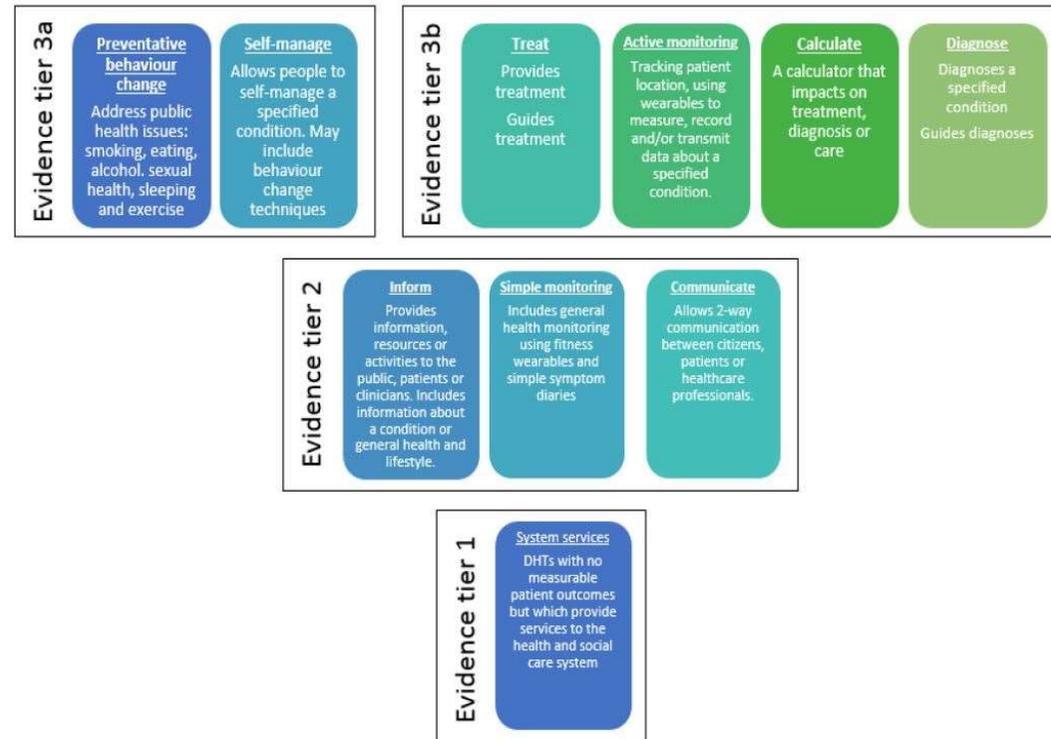


Quali Prove di Efficacia e Sicurezza?

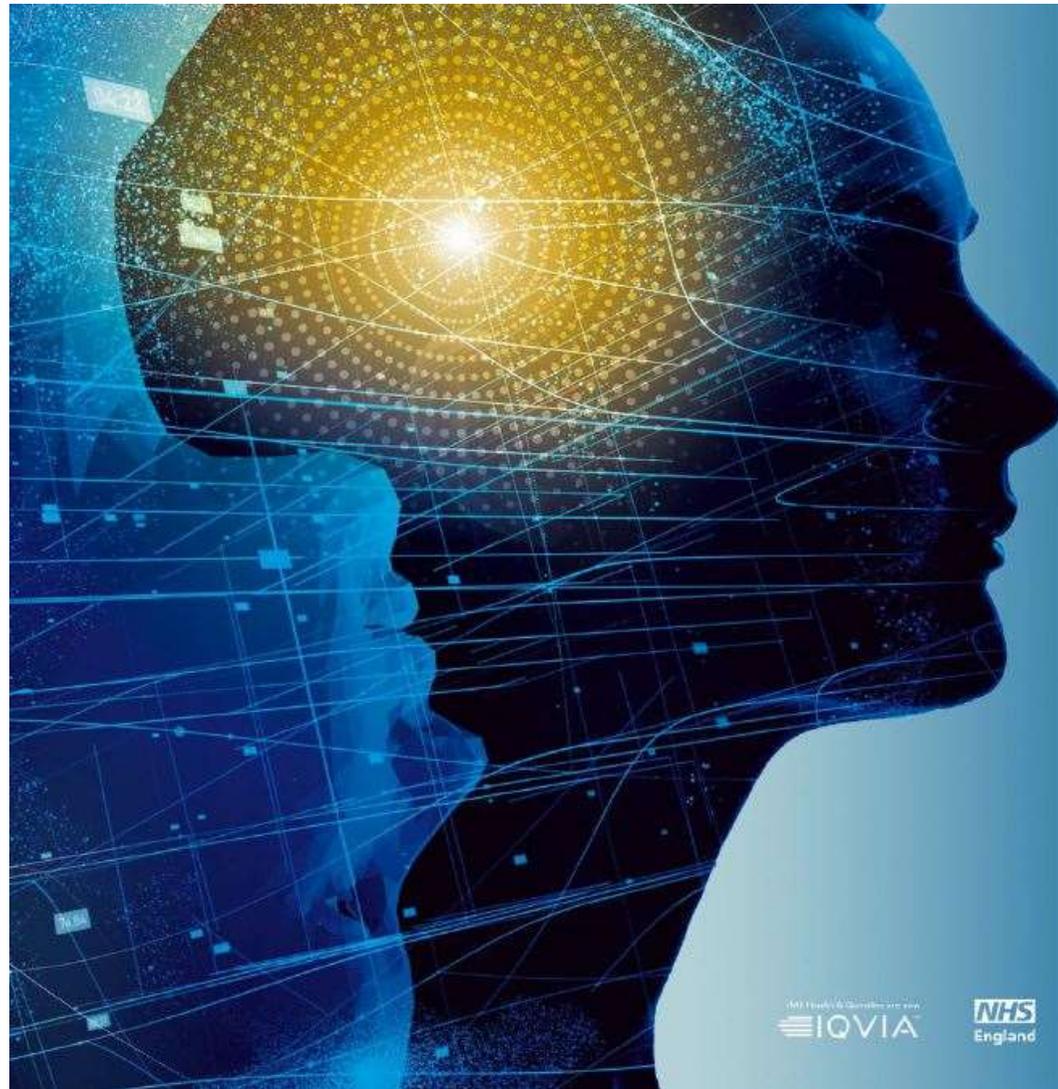
NATIONAL INSTITUTE FOR HEALTH
AND CARE EXCELLENCE

EVIDENCE STANDARDS
FRAMEWORK FOR DIGITAL
HEALTH TECHNOLOGIES

December 2018



#DTx – Chi le paga?



Digital Therapeutics in the NHS:

The rise of digital therapies
& the evidence that proves
they work

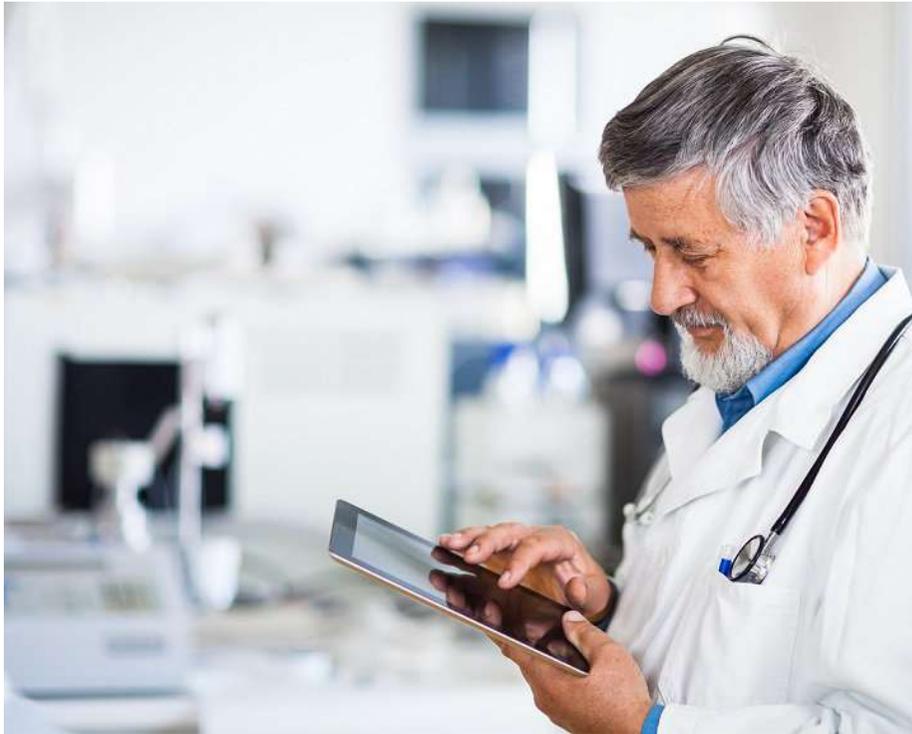
Tuesday, 24 April 2018

#DHLCOLLABORATE

#DigitalHealthLondon



#DTx – Chi le prescrive?



Global Initiative for Asthma (GINA) What's new in GINA 2017?



GINA Global Strategy for Asthma Management and Prevention

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Come entrano nella pratica medica?

#DTx – A che punto siamo?

Three of the most prominent DTx companies have shown great progress in validating across all four dimensions

	Discovery in areas of important unmet clinical need	Science & evidenced based design and development	Randomized controlled clinical trials	FDA clearance to <i>manage</i> or <i>treat</i> disorder	HEOR medical cost savings and improved QALYs	Payer contract for payment	Pharma sales support and detailing	Physician activation and adoption	Patient activation and adoption	Patient sustained engagement
	Efficacy		Regulatory			Commercial		Engagement		
PEAR	Inhouse third-parties Dartmouth Washington	Inhouse third-parties Dartmouth Washington	5 RCTs - Schizo 6 RCTs - SUD, OUD	reSET, reSET-O, others pre-sub	reSET, reSET-O	In process, none announced	Sandoz started	None	RCT data 1,212 SUD, OUD 1,200 schizo	None
AKILI	Inhouse From UCSF	Inhouse From UCSF	5 RCTs	None Pre-sub Completed	None	None	None, plans to go it alone	None	RCT date 600	None
CLICK	In-house and Univ New South Wales	In-house and Icahn School of Medicine	2 RCTs in MDD 1 RCT smoking	None Pre-sub completed	None	None for MDD Started smoking	Otsuka will start in 1-2 years	None	RCT data 416 smoking 300 MDD	None

■ Demonstrated
 ■ In process
 ■ Yet to be developed



Italia - DTxITA



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 Bodini¹, Martijn Grinovero², Claudio Micheletto³, Franco Del Zotti⁴, Angelo Corsico⁵,

Giuseppe Recchia¹, Salvatore D'Antonio⁶, Fulvio Braido⁷

¹Fondazione SmithKline, Verona; ²Amiko Digital Health, Londra; ³UOC Pneumologia Ospedale di Legnago; ⁴Medicina Generale, Azienda ULSS 9, Verona; ⁵Pneumologia, Fondazione IRCCS Policlinico San Matteo Pavia; ⁶Associazione Italiana Pazienti BPCO Onlus Roma; ⁷Clinica Malattie Respiratorie e Allergologia, Azienda Policlinico IRCCS San Martino di Genova





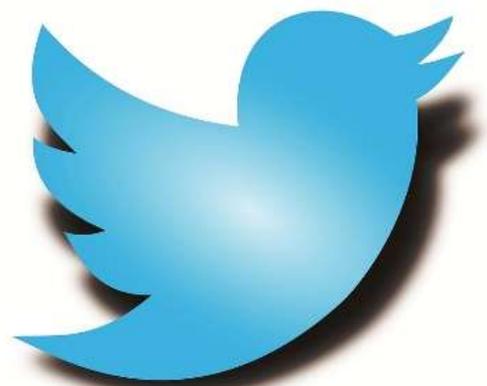
① Chiarire Aree Incertezza

1. Clinical development
2. Regulatory approval
3. reimbursement coverage
4. Integration into healthcare

② 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

Per sapere come andrà...



@GGRecchia

@fsk_it



grazie !