



XIX
CONGRESSO
NAZIONALE DELLA
PNEUMOLOGIA

SAVE
THE
DATE



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VENEZIA LIDO

Are we ready for take-off?

Digital Therapeutics In Respiratory Medicine

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Introduction 1

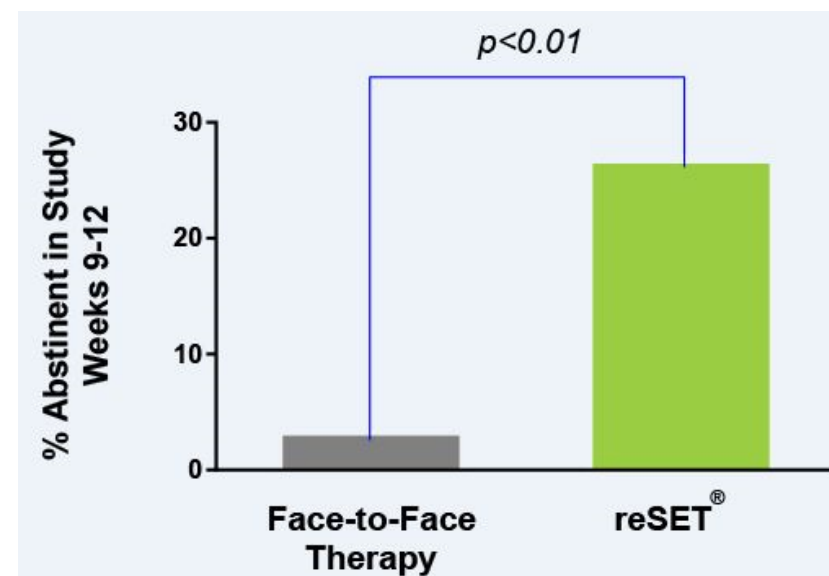
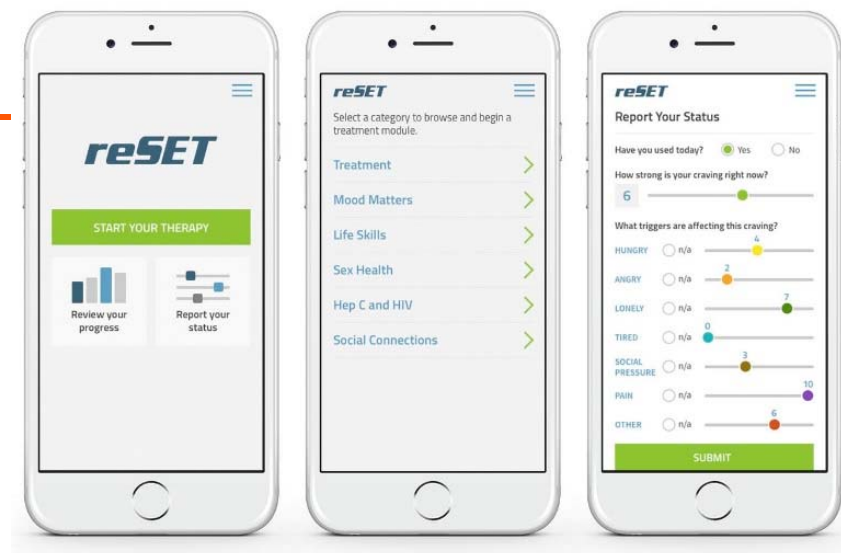
Bio – Digital convergence



Digital Therapeutics [#DTx]

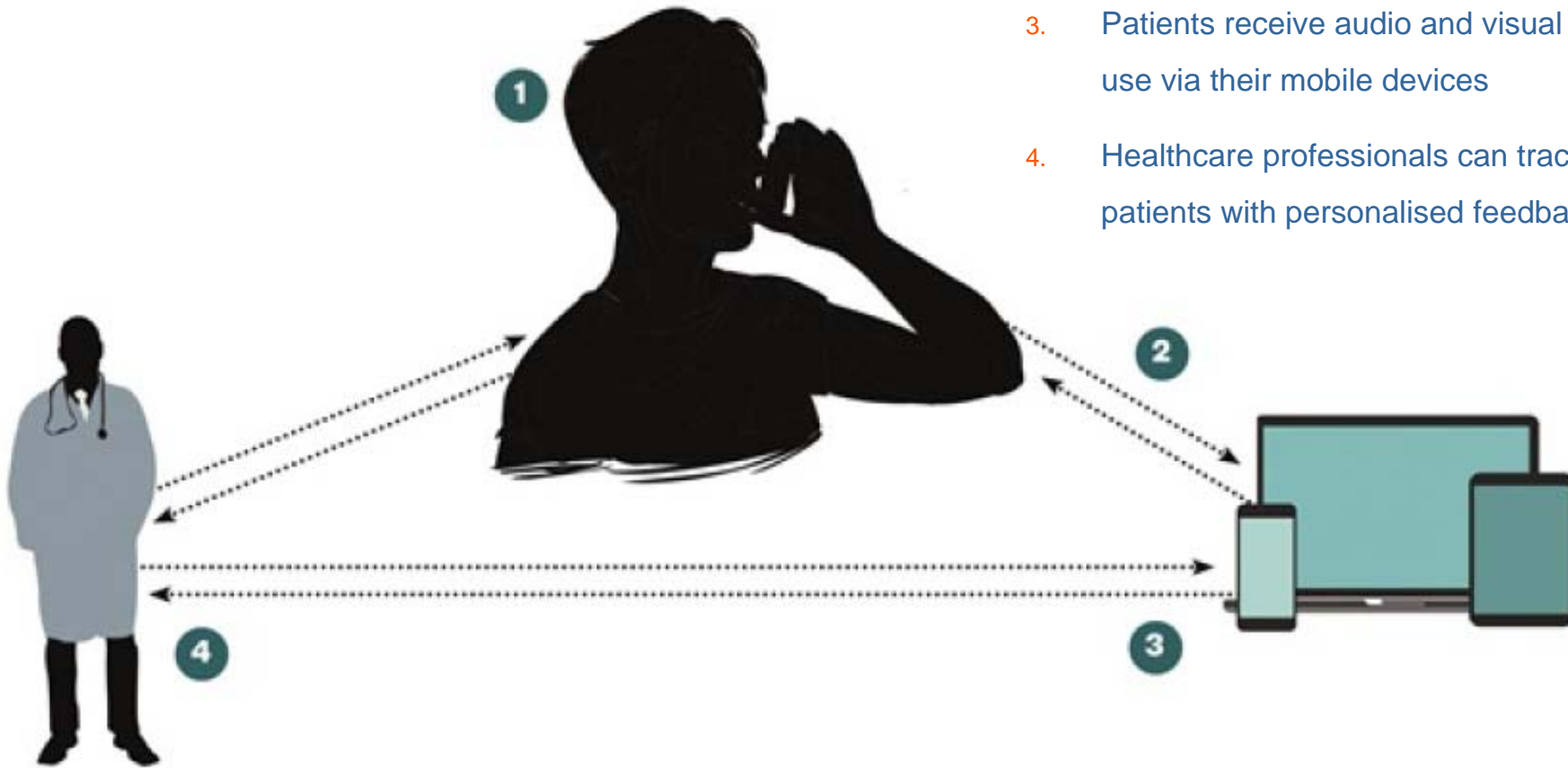
Introduction 2 – Digital Therapy

1. Software is the active ingredient
2. Developed with RCTs
3. Authorized by Regulatory bodies
4. Marketed by Pharma / Tech companies
5. HTA
6. Reimbursed by NHS / insurances
7. Prescribed by a Physician



Introduction 3 – Respiratoria Digital Therapy

1. Smart inhalers have sensors that record inhaler use
2. Data are communicated to a mobile app or desktop computer, and are stored in the cloud
3. Patients receive audio and visual reminders about inhaler use via their mobile devices
4. Healthcare professionals can track inhaler use and provide patients with personalised feedback and education



Rational for the Study



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

Tuesday, 24 April 2018

#DHLCOLLABORATE
#DigitalHealthLondon

Digital Health London

IQVIA **NHS England** **DIGITAL THERAPEUTICS ALLIANCE** **hin** **Health Innovation Network** **IMPERIAL COLLEGE HEALTH PARTNERS** **UCLPartners** **Academic Health Science Partnership** **MEDCITY**

Global Smart Inhaler Technology



The collage consists of four images: top-left shows a surgical room with a patient on a table and medical monitors; top-right shows dental equipment with a green protective cover; bottom-left shows a globe with several white and yellow capsules scattered around it; bottom-right shows a person in blue scrubs using a tablet computer.

Global Smart Inhaler Technology
Market 2018 - 2022

Objectives of the Study

- Situation assessment about the development of DTx for respiratory diseases
- Proposals for the development of Research and Development of Digital Therapy for the treatment of respiratory diseases in Italy

Methodology

- Analysis of scientific literature
- Analysis of published documentation
- Analysis of the status of clinical trials
 - clinicaltrials.gov
 - clinicaltrialsregister.eu
- Structured interviews with experts in the disciplines involved in the research, development, approval, marketing and prescription of DTx in the respiratory field

Results 1 – Respiratory Digital Therapies

- Respiratory Digital Therapeutics (RDT)
- Respiratory Digital Medicines (RDM)
- Smart Inhalers (SI)
- Connected Inhaler Systems (CIS)
- Remote Inhaler Monitoring Device (RIMD)
- Inhalers' Use and Adherence Monitoring Tools (IUAMT)
- Electronic Monitoring Devices (EMD)
- Adherence Monitoring Device (AMD)
- AI – Powered Sensors

Respiratory Digital Therapeutics [R - DTx]

#R-DTx

Results 2 – Respiratory Digital Therapies in Development

- | | |
|------------------------------------|-------------|
| ■ Propeller Health | marketed |
| ■ Hailie by Adherium | marketed |
| ■ BreatheSmart by Cohero Health | marketed |
| ■ Respiro by Amiko | development |
| ■ CareTRx by Teva | development |
| ■ Intelligent Control Inhaler 3M * | development |
| ■ INCA * | development |
| ■ Connected Breezhaler * | development |

* Smart inhaler - not a DTx

at 10.2018



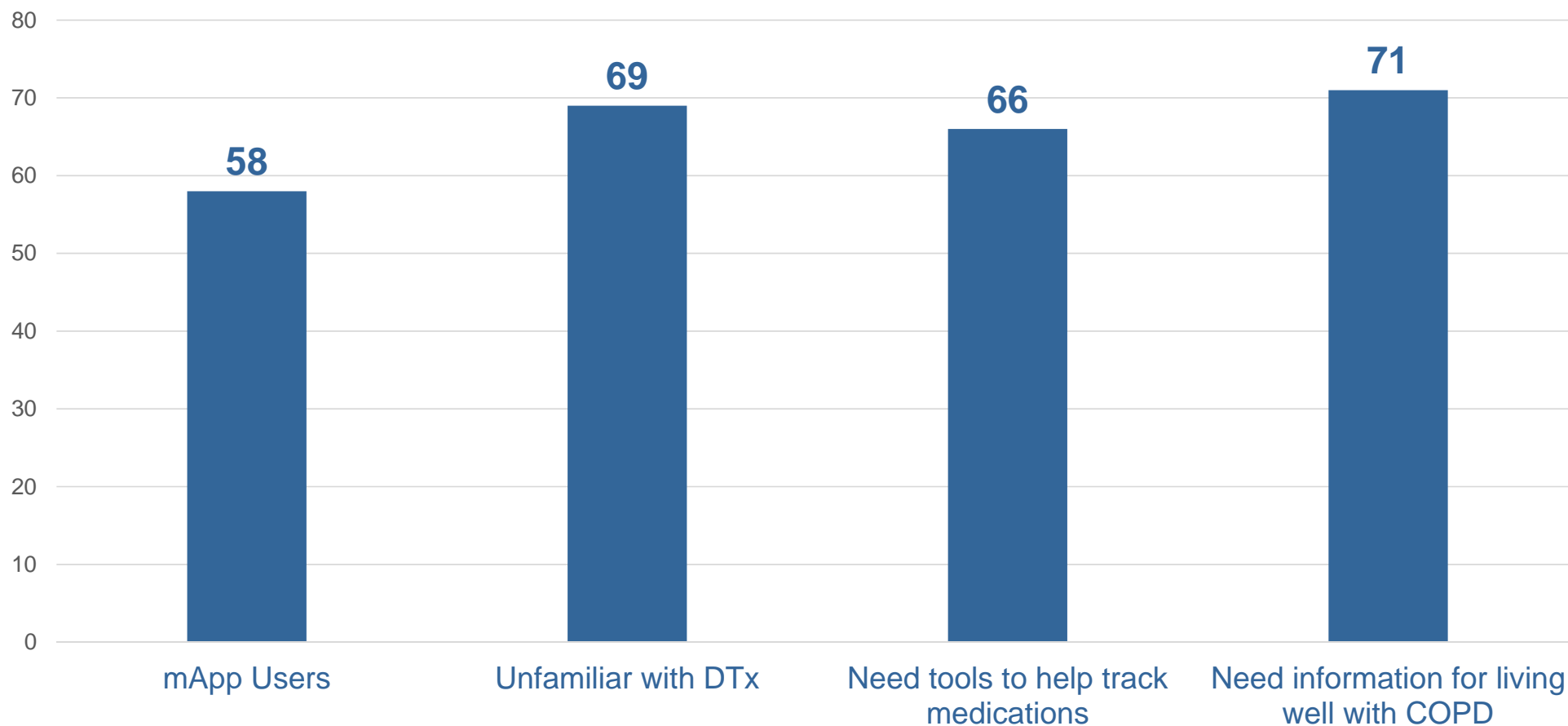
Results 3 – Respiratory Digital Therapies

- Asthma: R-DTx improves adherence to treatments (1)
- Asthma: R-DTx improves symptom control (2)
- Asthma: 79% patients satisfied with the use of R-DTx (3)
- Asthma: R-DTx increases treatment adherence, reduce hospitalization, reduce exacerbations and lost school days (4)
- COPD: 64% patients satisfied with the use of R-DTx (5)
- COPD: R-DTx provides clinical and economic benefits (6)

1 AH Chan et al. Lancet Respiratory Medicine 2015; 2 RK Merchant. JACIP 2016; 3 RK Merchant et al. JMIR Mhealth Uhealth 2018; 4 RW Morton et al, Thorax 2017; 5 K Sumino et al. JAMPDD 2017 6 Van Boven et al, Primary Care Respiratory Medicine

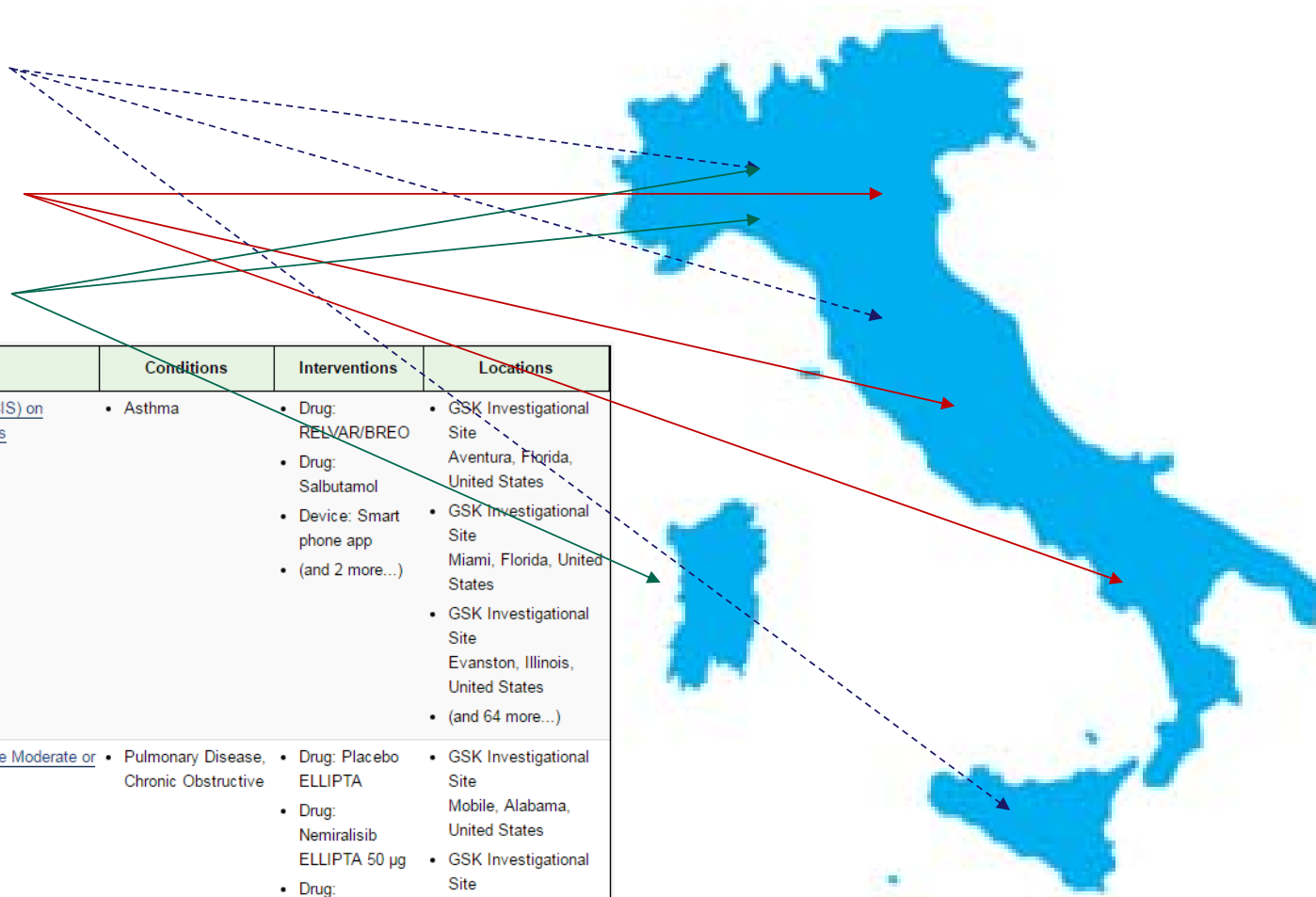
Results 4 – Patients and DTx for COPD

COPD Patient Survey – COPD Foundation (%)



Results 5 – Respiratory Digital Therapies in Development - Italy

- Propeller Health
- Hailie by Adherium
- Respiro by Amiko



situazione a 10.2018

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	A Clinical Study to Evaluate the Effect of the Connected Inhaler System (CIS) on Adherence to Maintenance Therapy in Poorly Controlled Asthmatic Subjects	<ul style="list-style-type: none"> Asthma 	<ul style="list-style-type: none"> Drug: RELVAR/BREO Drug: Salbutamol Device: Smart phone app (and 2 more...) 	<ul style="list-style-type: none"> GSK Investigational Site Aventura, Florida, United States GSK Investigational Site Miami, Florida, United States GSK Investigational Site Evanston, Illinois, United States (and 64 more...)
2	<input type="checkbox"/>	Active, not recruiting	Dose Finding Study of Nemiralisib (GSK2269557) in Subjects With an Acute Moderate or Severe Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)	<ul style="list-style-type: none"> Pulmonary Disease, Chronic Obstructive 	<ul style="list-style-type: none"> Drug: Placebo ELLIPTA Drug: Nemiralisib ELLIPTA 50 µg Drug: Nemiralisib ELLIPTA 100 µg (and 5 more...) 	<ul style="list-style-type: none"> GSK Investigational Site Mobile, Alabama, United States GSK Investigational Site Huntington Beach, California, United States GSK Investigational Site

Results 6 – Respiratory Digital Therapies in Development - Italy

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 and physician
- ✓ No Feedback

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

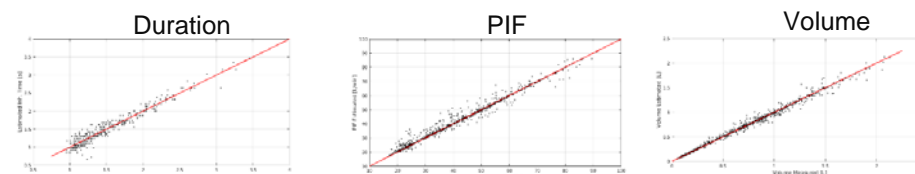
Results 7 – Respiratory Digital Therapies in Development - Italy

A new tool for inhalers' use and adherence monitoring: the Amiko® validation trial

Investigators: Braido F.1, Canonica W.1, Ponti L. 2, Paa F.2

1Ospedale S.Martino, Genova, 2, Amiko Digital Health, Milano

- Study type: Laboratory testing
- Tested with Ellipta, NEXThaler, Spiromax



Can we improve inhaler technique in COPD patients with a digital medicines use review?

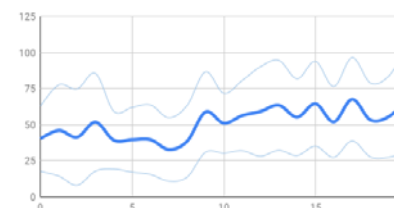
Investigators: Braido F.1, Canonica W.2

in progress

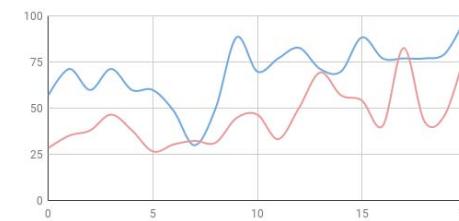
1Ospedale S.Martino, Genova, 2Ospedale Humanitas, Milano

- Chronic Obstructive Pulmonary Disease, 60 patients

Respiro True



Respiro True in + and - CAT groups



Towards improved asthma control through inhaler feedback and personalised MUR

Investigators: Koffijberg E.1, Floris N.2

in progress

1UTwente, Enschede, 2Sifac, Sassari

- Asthma, 140 patients, Patients receive an active digital sensor for use in conjunction with their pharmacotherapy. Routine digital MUR target improved adherence, correct inhaler technique and optimal asthma control

Primary Outcome

- Asthma Control

Secondary Outcome

- True Adherence
- Quality of Life
- Medical consumption

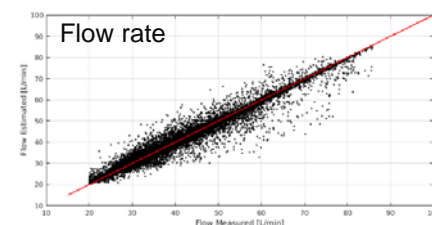
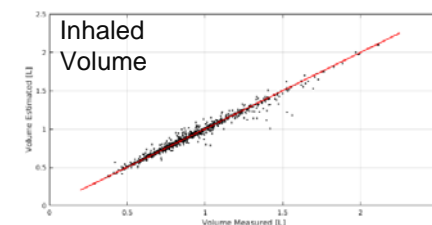
Results 8 – Respiratory Digital Therapies and Artificial Intelligence



Smart inhaler with Machine Learning

Real-time machine learning to recognize the patient's inhalations

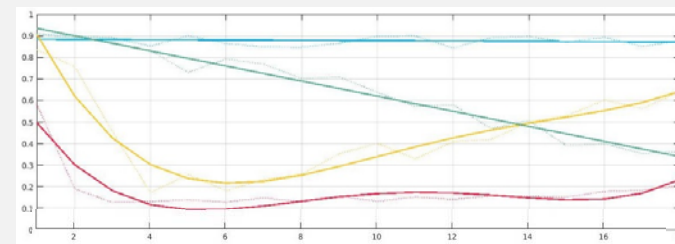
- Advanced data
- Low-cost
- External to drug delivery pathway
- Add-on and integrated



AI Platform

- 1y flagging of poorly adherent / uncontrolled patients
- DSS enables therapy optimization and exacerbation prevention
- Personalized interventions to identify, predict and improve medication use

Prediction of medication use behaviours



Digital tools for HCPs and patients

