

Innovazione e sviluppo del prodotto

Il settore farmaceutico (1)

Paolo Barbanti Ph.D., MBA

pbarbanti@liuc.it

Delivering transformative innovation



- Advancing research and development of new therapies in many disease areas
- Building new technology platforms
 - cell and gene therapies
 - radioligand therapies
- Integrating data science and digital technologies into research and development

Pioneering breakthrough approaches in multiple disease areas



**Preventing
Alzheimer's**



Curing cancer



Treating asthma



**Eliminating
malaria**



Access to biologics



**Fighting liver
disease**



**Conquering heart
failure**



**Restoring
sight**



A golden age for medical science



Accelerating innovation

+46%

**The rise in the average annual
number
of US approvals for new molecules
in 2012-2016 vs. 2007-2011**

Source: US FDA website “Drugs/NDA and BLA Calendar Year Approvals”
<https://www.fda.gov/drugs/nda-and-bla-approvals/nda-and-bla-calendar-year-approvals>



Demographic trends are changing healthcare



Growing populations

+1bn by **2030**

About 8.5 billion people are expected to inhabit the planet by the year 2030

Source: UN "World Population Prospects 2019" brochure
https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf



Demographic trends are changing healthcare



Rapid aging

+500mn over **60**
by **2030**

About 1.4 billion people worldwide are projected to be 60 or older by the year 2030, fueling a rise in chronic illness

Source: UN "World Population Prospects 2019" brochure

https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf



Working to deliver better health outcomes for patients



Outcome-based pricing

Real-world evidence of effectiveness

Data and analytics

Digital health, “beyond the pill”

Health system capacity building

We need to Reimagine Medicine



How we fight disease



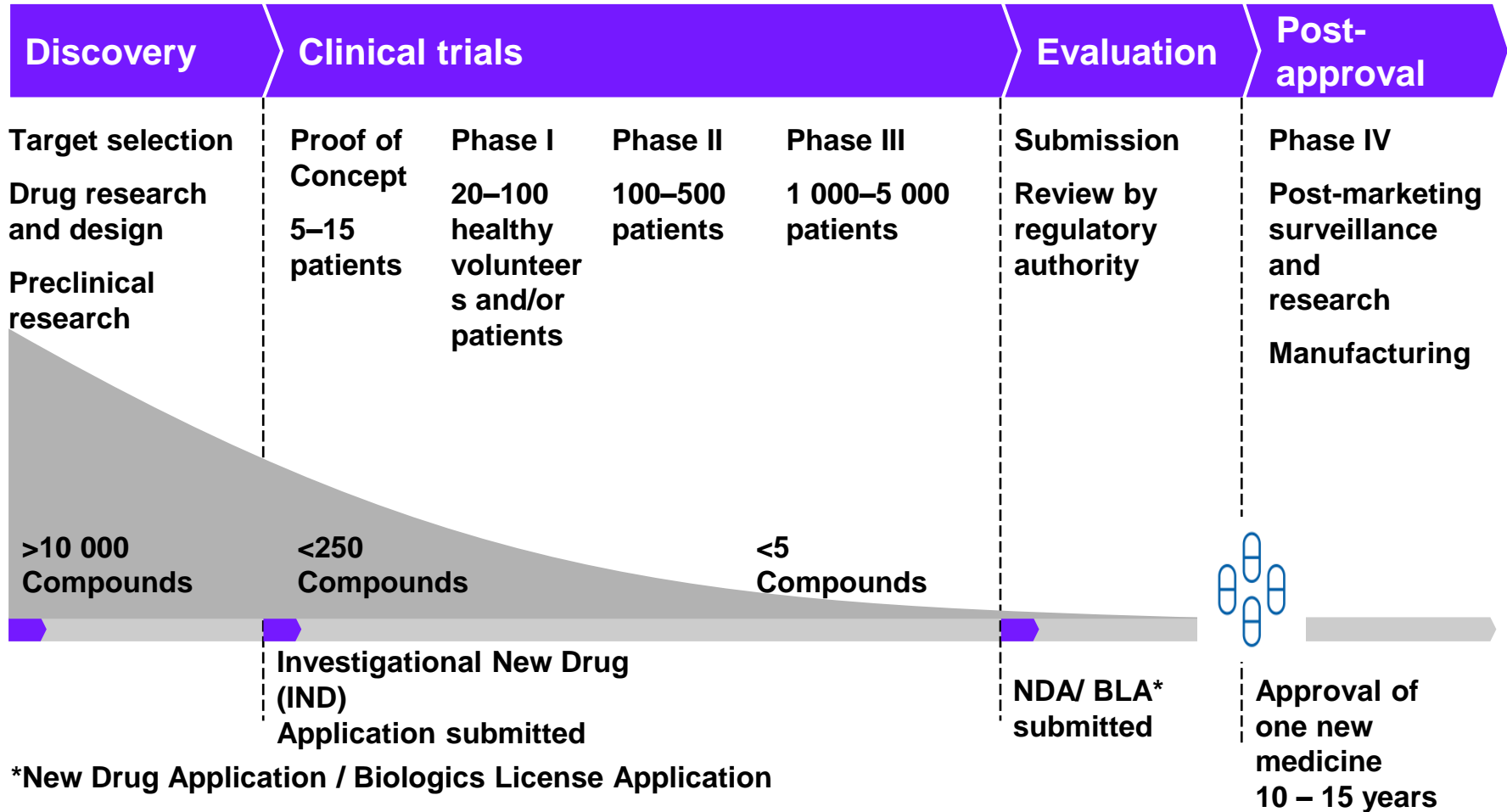
How we deliver treatments



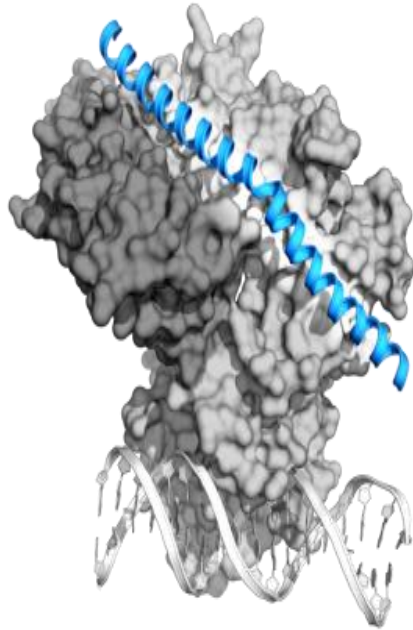
How we operate



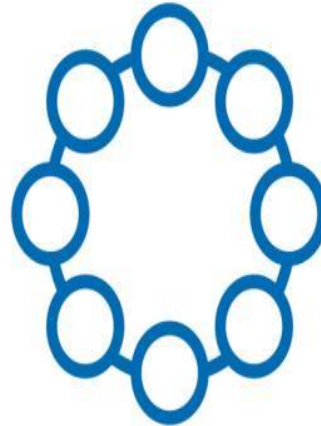
The path to a new medicine



On the forefront of the next generation of drug discovery



Innovate the new science of therapeutics



Promote connectedness to innovators beyond our walls



Tap digital technologies to transform drug discovery

Digital Transformation

Digital Transformation In The Music Business:



Alvaro Rebollo Ena [Follow](#)

Mar 24 · 7 min read

What Other Businesses Could Have Learnt From It, And The Convergence (or Not) of Spotify and Netflix



I stepped in the music business in the year 2000. I was really lucky to be able to experience the final days of the majors' golden age: A lot of CDs were sold, massive media campaigns were launched, piracy on the Internet was still inexistent, revenues were not that bad...



1982



1999



2003



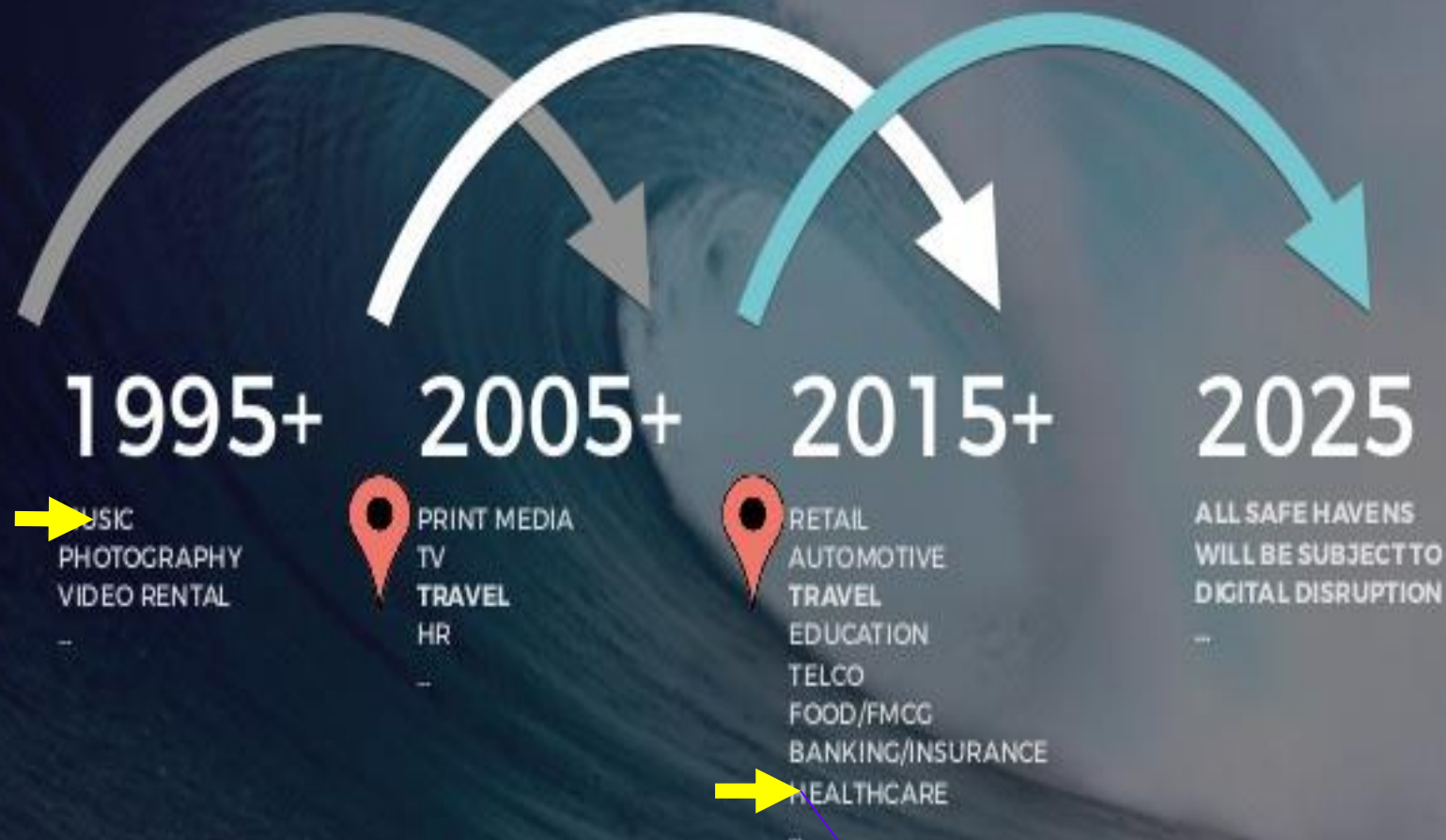
2006



Digital Transformation... It is its turn

duval union
consulting

WAVES OF *Disruption*



It is 2025...



Digital Therapeutics: pharma's threat or opportunity



Paul Simms
Chairman
eye for pharma



Jim O'Donoghue
President
S3 Connected Health

It is 2025 and digitally delivered therapies are now part of our regular healthcare experience. The smartphone, already our first port of call on health matters, has been elevated to the role of personal health mentor and condition management guide.

Offering us therapies and advice, both consciously and subconsciously, our device acts as our general healthcare concierge too, knowing when we've taken our medicine, showing us ways to optimize our desired lifestyle and determining medication dosages, and inviting us to visit specialists when they detect anomalous data. We are even seeing the emergence of the digital twin, a virtual version of yourself which can 'trial' treatments on your behalf before being adopted in your real body.

And clinicians, in a different role from the past, now rely on the data from your device too. They sanction or suggest technology-enabled patient services offering treatments that in many cases do not involve a chemical or biological intervention, but a digital one.

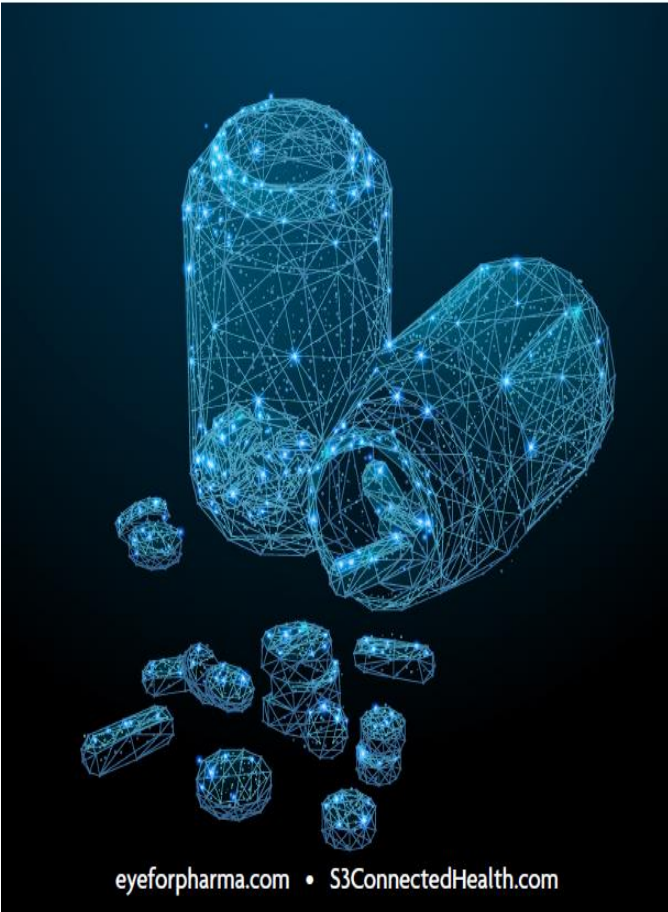
These therapies now routinely generate data in real time for deep-learning AI to interpret, enabling care providers to automate routine aspects of care, for example through alerts and 'bot' consultations, which give patients much of the information they need to stay compliant with their care plans.

Digital technologies act as a force multiplier for clinicians at all levels from consultants to nurses, who are now able to focus their time on the patients in most need and with the most complex ailments. Where necessary, the AI alerts a clinician to the need to intervene and assists them in making rapid decisions on the best and most appropriate course of action.

Meanwhile, payers rely on the rich real-world dataset that is now generated from these technologies and are used as an integral part of outcome based contracting without adding excessive burden to health systems. Digital therapeutics (DTx) are now a core part of the payer's arsenal of care delivery tools, having in many cases proven their worth in driving better care alongside analog medicines or, where they replace chemical alternatives, they do so often at a far lower cost. DTx revenues have ballooned as payers and HTAs see the value of recommending and prescribing them outright.

And in general, we now have a more proactive, voluntary health system where citizens actively prevent rather than simply manage their exposure to chronic diseases, moving the dial on population health at a global level whilst driving down costs. Healthcare systems under ever-increasing pressure from ageing populations can now do more with less. Patients are enjoying more quality years of wellness than they would have expected a decade before.

Welcome



Digital Transformation in Healthcare

Perspective

Page 1 of 8

Digital health is a cultural transformation of traditional healthcare



The Journey to 2025 – Driving Forces

Aging

Cancer

**Chronic
Diseases**

**Patient
Impatient
Empowered**

**Personalized
Medicine**

**Digital
Revolution**

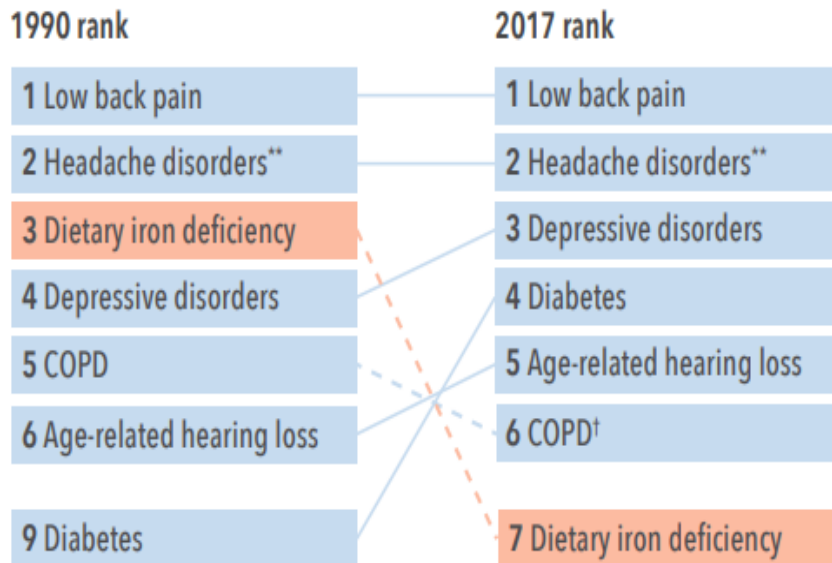


The biggest challenge to health and healthcare

Chronic

Leading causes of disability, 1990 and 2017

Global all-age YLDs



Communicable, maternal, neonatal, and nutritional diseases

Non-communicable diseases

**Headache disorders mainly include migraine.

†Chronic obstructive pulmonary disease

Drugs are not enough!

- Support
- Education
- Monitoring
- Adherence



we need something more...



Patients - What do they want?

- Take control of their health
- Empowerment
- De-centralization
- Home Testing for Chronic Diseases



Patient



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

**CTTI Recommendations:
Decentralized Clinical Trials**

September 2018



What do patients want?



Patient

Theme 2

Empowered patients – access to data, more control

While digitally supported healthcare professionals will play an important role in changing the way that healthcare is delivered, understanding **how technology can have a positive impact on the patient experience** is just as significant.

The general population is looking for information and more control over almost all aspects of their lives. Giving an individual access to their own health data makes them more likely to engage with it in a way that will improve the quality of care they receive and their overall healthcare experience.

What do patients want?



Patient

Diagnose Yourself, Anywhere

At rHEALTH®, we develop technologies that fundamentally change how people access analytical and diagnostic information*.

Combining portable diagnostic and monitoring capabilities will enable delivery of better and more timely health information. From this, we can begin to shift away from existing standards of curative medicine to future predictive, preemptive, and personalized medicine.

*rHEALTH devices are limited by FDA regulation for research or investigational purposes only.

What do patients prefer?



Patient

At-Home Health Testing

imaware™ provides awareness of life-altering diseases to empower patients to engage in personalized healthcare



New Players in healthcare



Patient

Amazon has explored getting into consumer health diagnostics – testing for disease at home

PUBLISHED FRI, DEC 14 2018 • 3:54 PM EST | UPDATED FRI, DEC 14 2018 • 4:10 PM EST



Christina Farr
@CHRISSEYFARR



Eugene Kim
@EUGENEKIM222

SHARE



KEY POINTS

- Amazon looked at buying a start-up developing at-home health tests called Confer Health, but talks broke down a few months ago.
- As recently as this summer, it had a team dedicated to diagnostics within its moonshots group “Grand Challenge.” It is unknown whether the group is still active.
- A move into the home health-testing space would be a signal of Amazon’s ambitions to remake the entire health care supply chain, and could compete with testing giants Quest and LabCorp.



New Players in healthcare

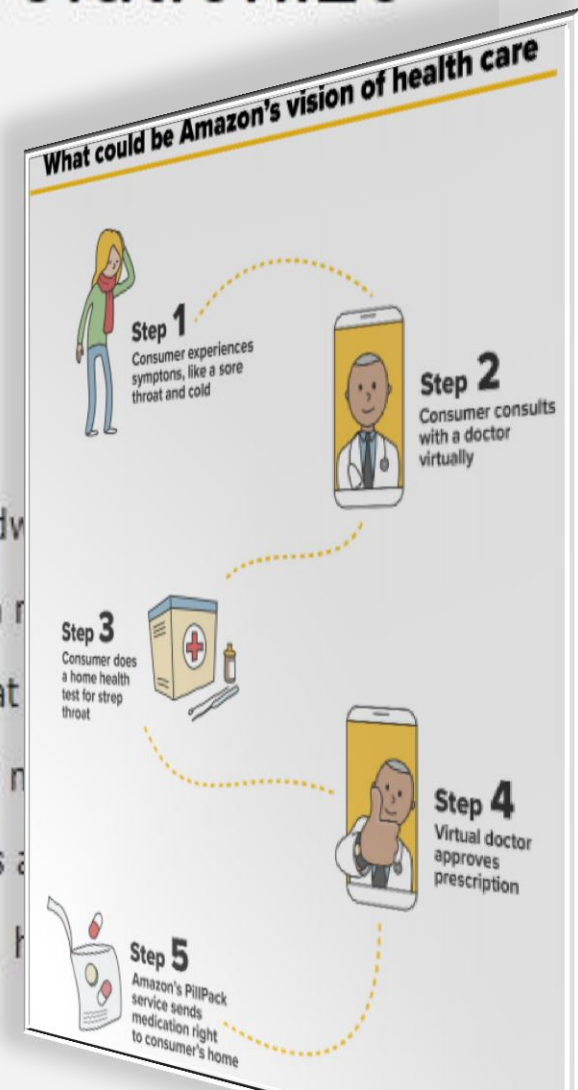
Amazon, Google, Apple To Revolutionize Consumer Health Tech

August 20, 2019



rising cost of healthcare...

With the proliferation of hardware
homes and hands, it's only a matter of
devices turn into sensors that
practitioners to continuously monitor
a very long time, the U.S. as a whole
those in the healthcare field, the



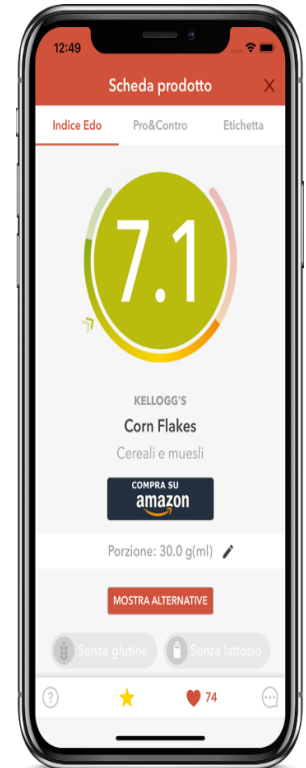
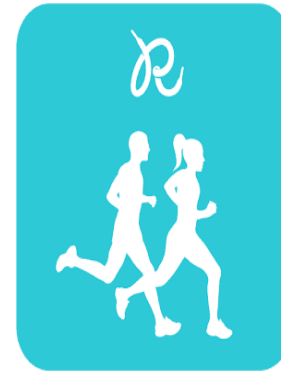
Digital Health

DIGITAL HEALTH

use of Digital Technologies to
(1) support and deliver healthcare (2) improve health and well-being of people

1

SMART HEALTH



Digital Health Technologies

Digital Medicine

Digital Health
Technologies
based on

DIGITAL HEALTH

DIGITAL
MEDICINE

- **measure**
- **intervention**

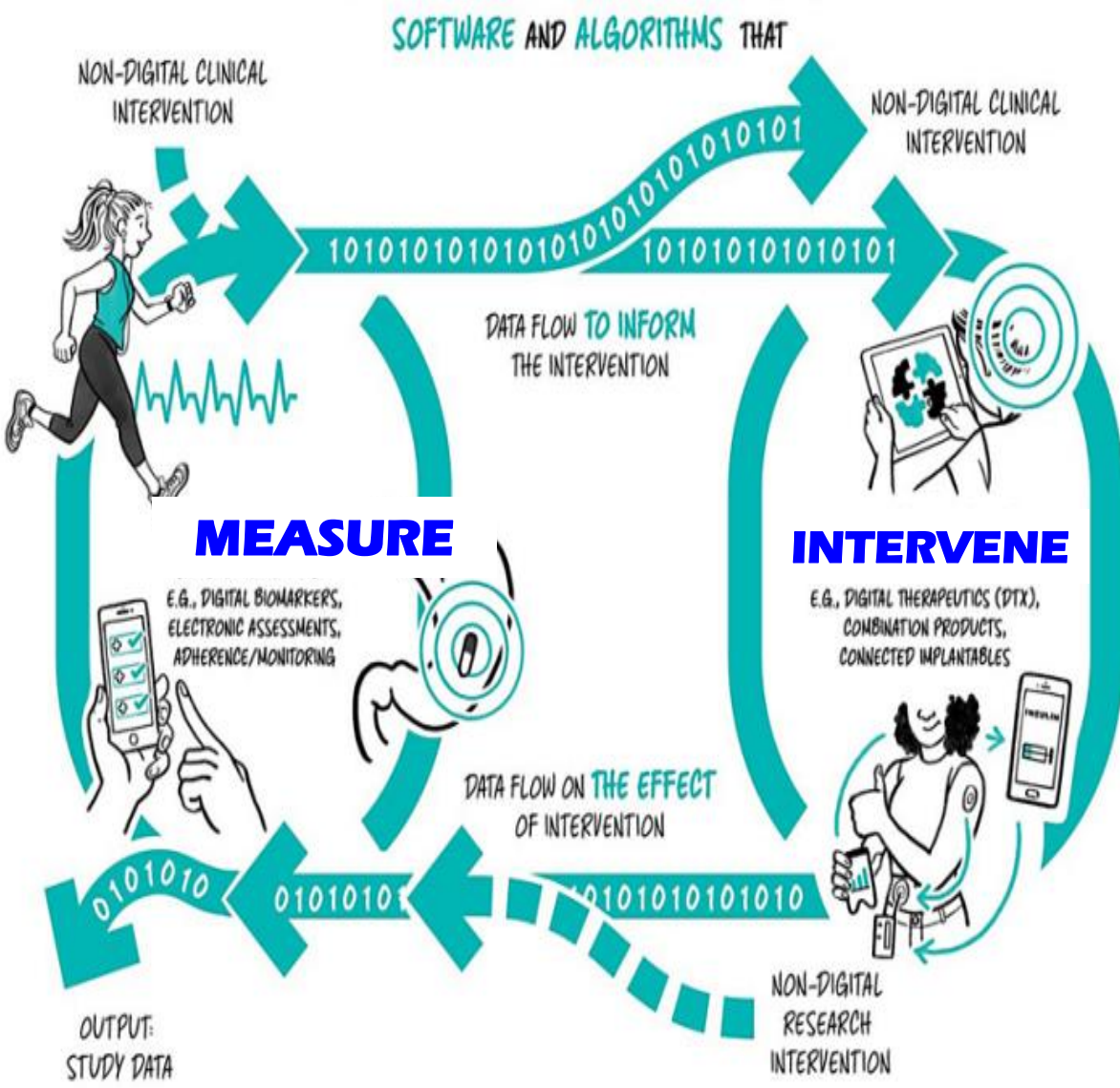
EVIDENCE



2

Digital Medicine
Technologies

Digital Medicine



Digital Health Tools

- measurement
- intervention

to optimize

- healthcare processes
- health outcomes

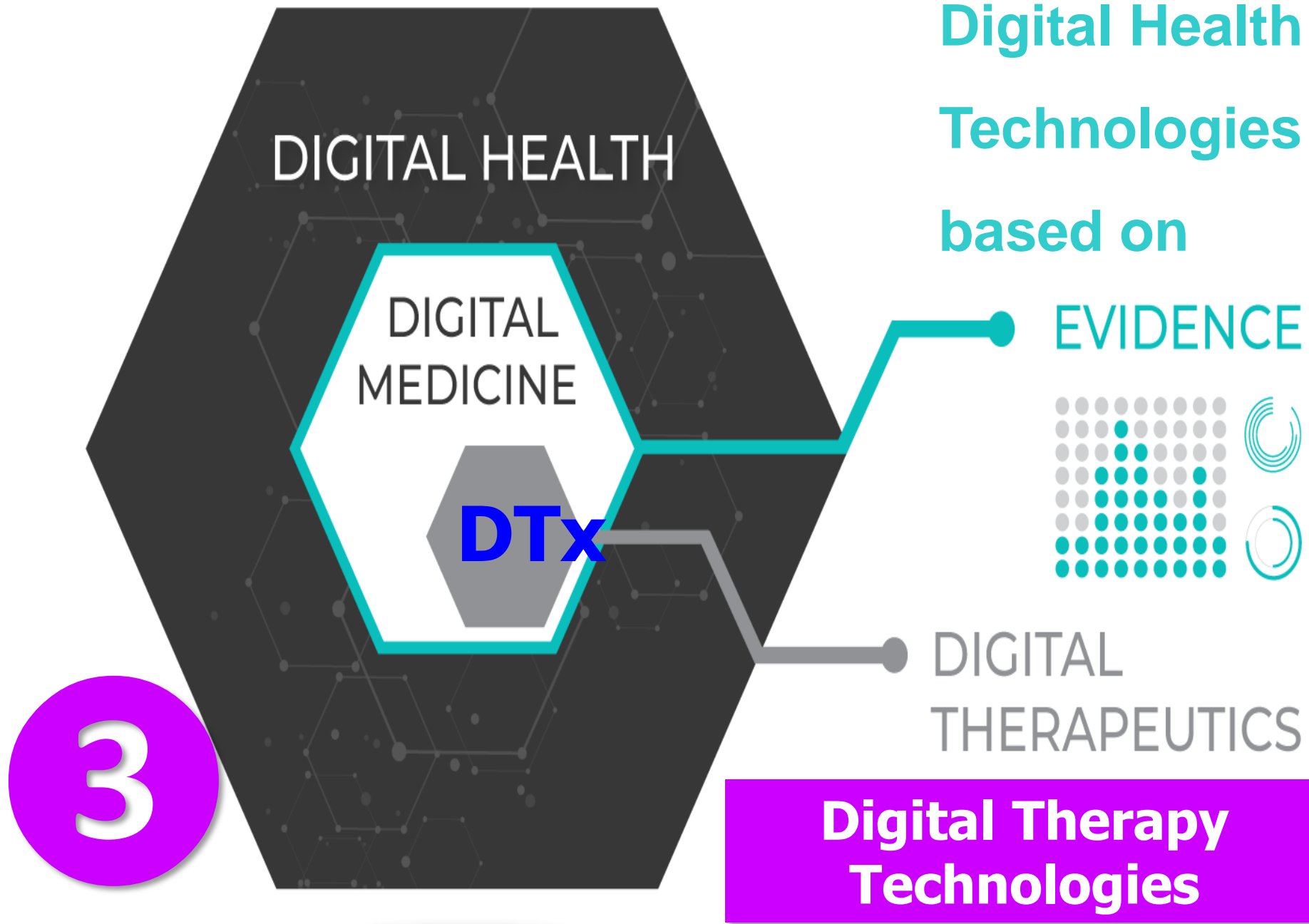
based on

- scientific evidence

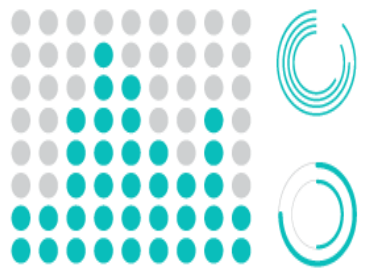
Applying digital technologies in drug discovery and clinical development



Digital Therapy



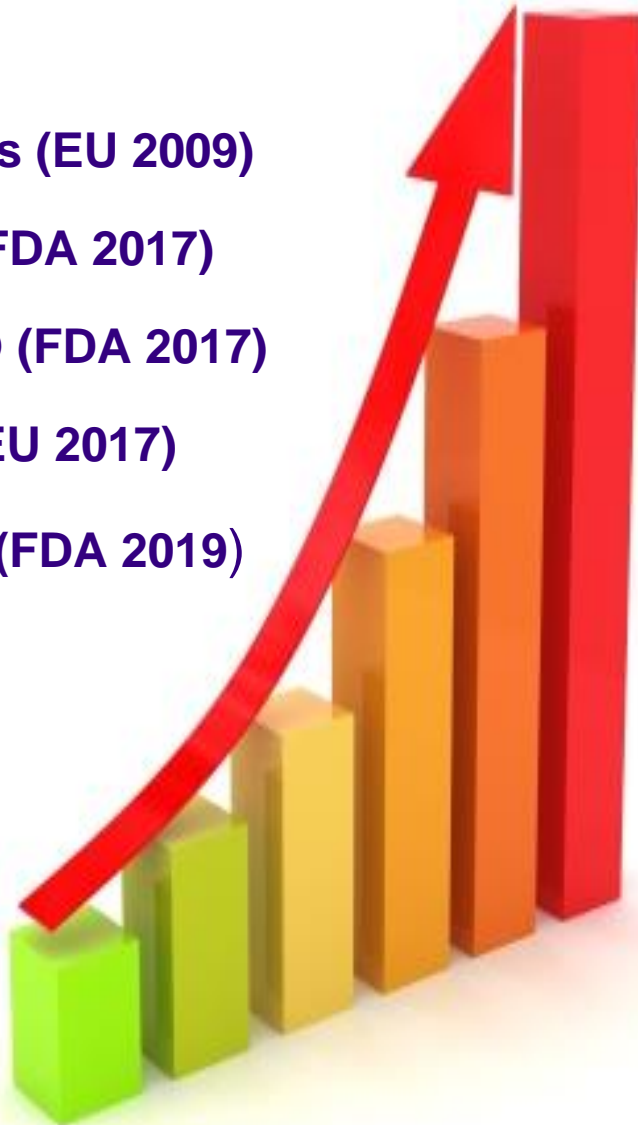
Digital Health Technologies based on



What are Digital Therapeutics?

Marketed

- a. Deprexis (EU 2009)
- b. Reset (FDA 2017)
- c. Reset-O (FDA 2017)
- d. Zemy (EU 2017)
- e. Oleena (FDA 2019)



Late Development

- a. AKL-T01 (FDA expected 2019)
- b. Somryst (FDA expected 2020?)
- c. CureApp Smoking Cessation (2020?)

Early Development

- a. MDD daVinci Digital Therapeutics
- b. Obesity daVinci Digital Therapeutics



What are Digital Therapeutics?

- therapeutic interventions

- **Active Ingredient is an Algorithm**

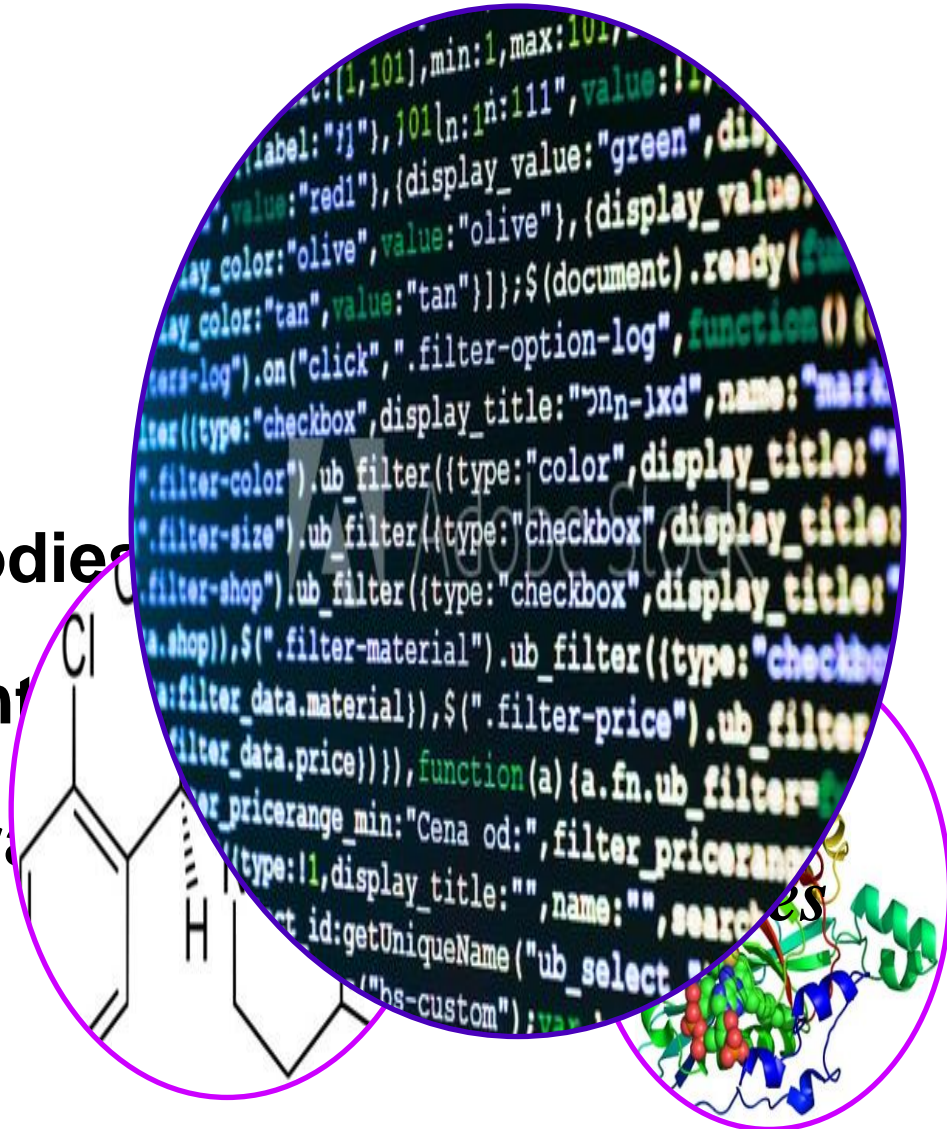
- developed through RCTs

- approved by regulatory bodies

- subject to HTA assessment

- reimbursed by NHS / insurers

- prescribed by a Physician



How is the Active Ingredient prepared?

Clinical Expertise

- *Specialists,*
Academia

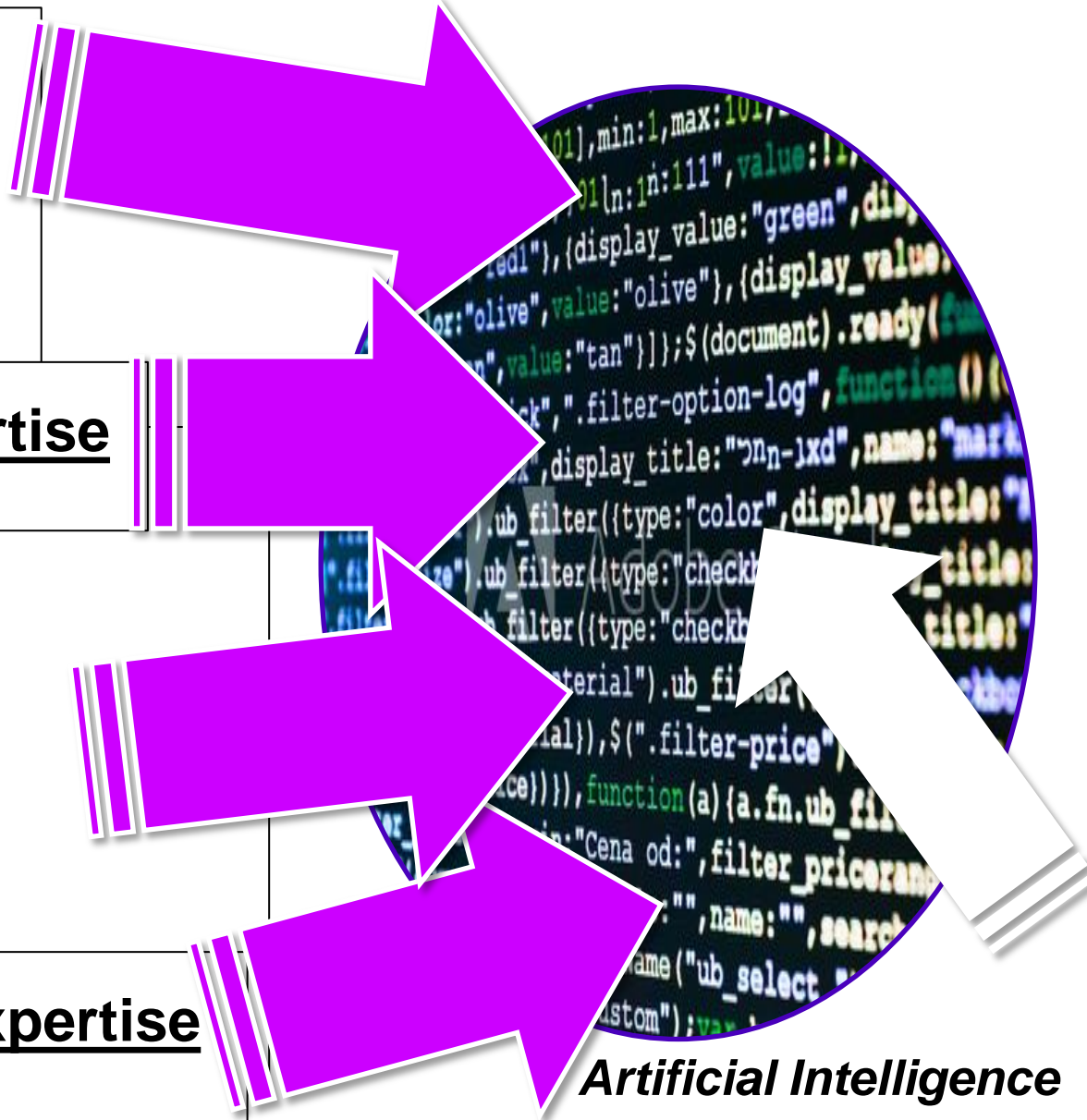
Software Expertise

Experience

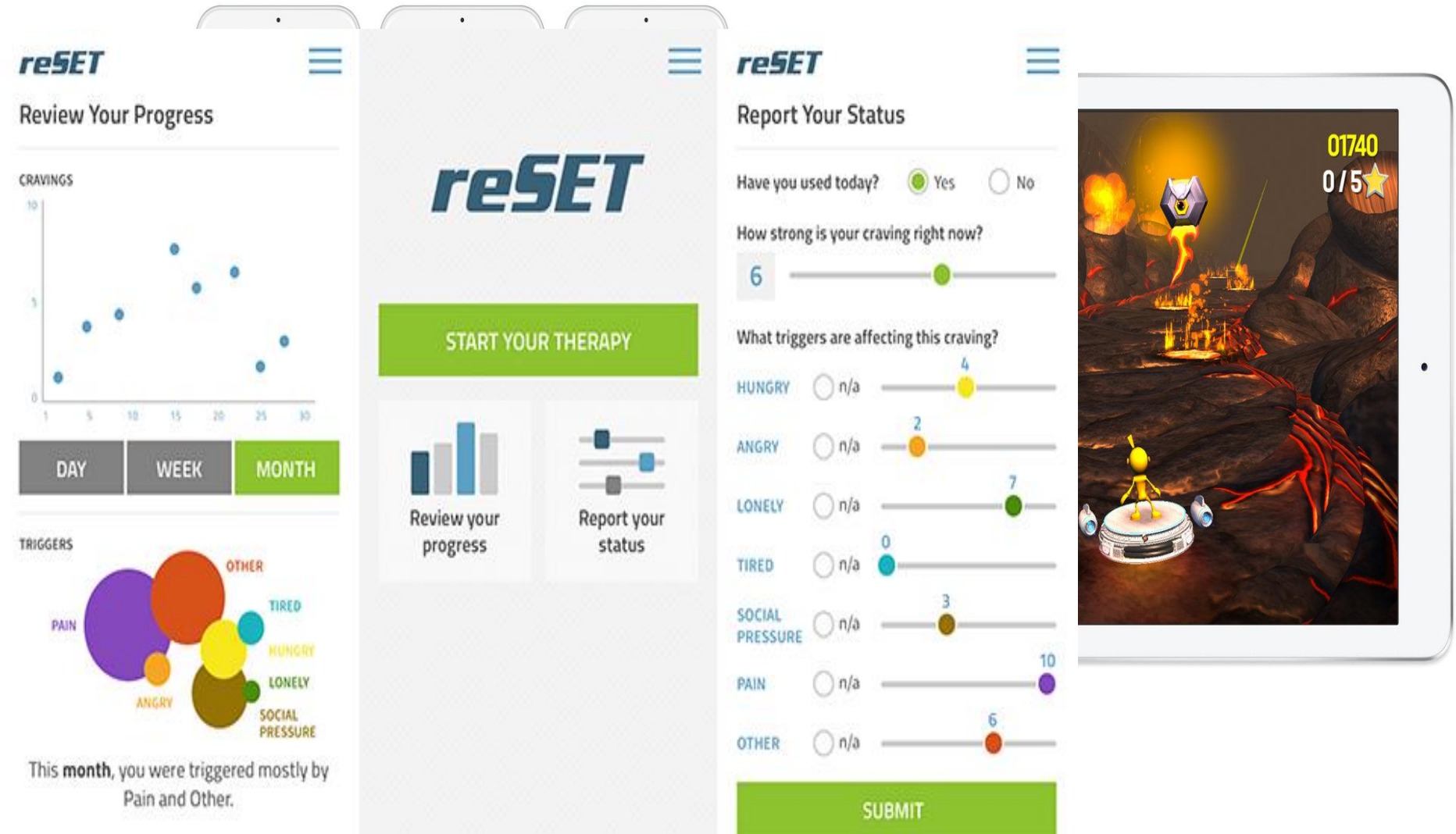
- *Patients,*
- *Caregivers*
- *GPs*

UX / UI Expertise

Artificial Intelligence



Algorithms must take the «form» of



mApps, Games, Sensors....

How do Digital Therapeutics work?

Combination with a drug

- Monitoring of adherence to therapy
- Drug Dosage Recommendations
- Recommendations on AE management
 - *Diabetes (Voluntis w Roche, Sanofi)*
 - *Oncology (Voluntis w AZ, Roche)*
 - *Asthma / COPD (Propeller w GSK, Novartis, Chiesi; Teva; Adherium w AZ)*

Standalone

- Cognitive Behavioural Therapies – CBTs
- Other therapeutic options
 - *Dependencies (Pear Therapeutics)*
 - *Depression (daVinci Digital Therapeutics)*
 - *ADHD (Akili Interactive)*
 - *Schizophrenia (Pear Therapeutics)*
 - *Obesity (daVinci Digital Therapeutics)*



New digital therapies

reSET®

The future of substance
use disorder treatment is
now available

The first and only FDA-authorized prescription digital therapeutic to help
treat substance use disorder ¹



Bringing the trial to the patient

Fundamentally shift the center of research from the hospital to the patient's home

Traditional Site Based Approach



Science 37 Patient-Centric Metasite™ Model

VS



New tools to monitor clinical trials



Resource Planner

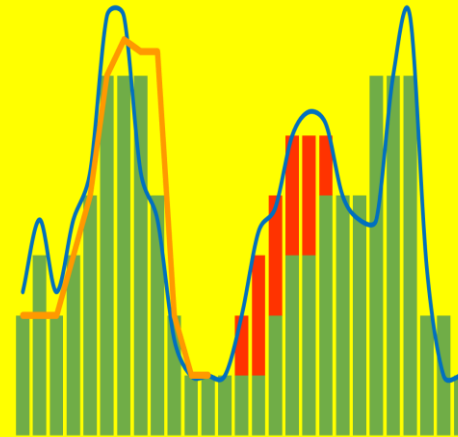
Bringing rigor and discipline into FTE management



Leverage data insights to eliminate resourcing waste and improve productivity

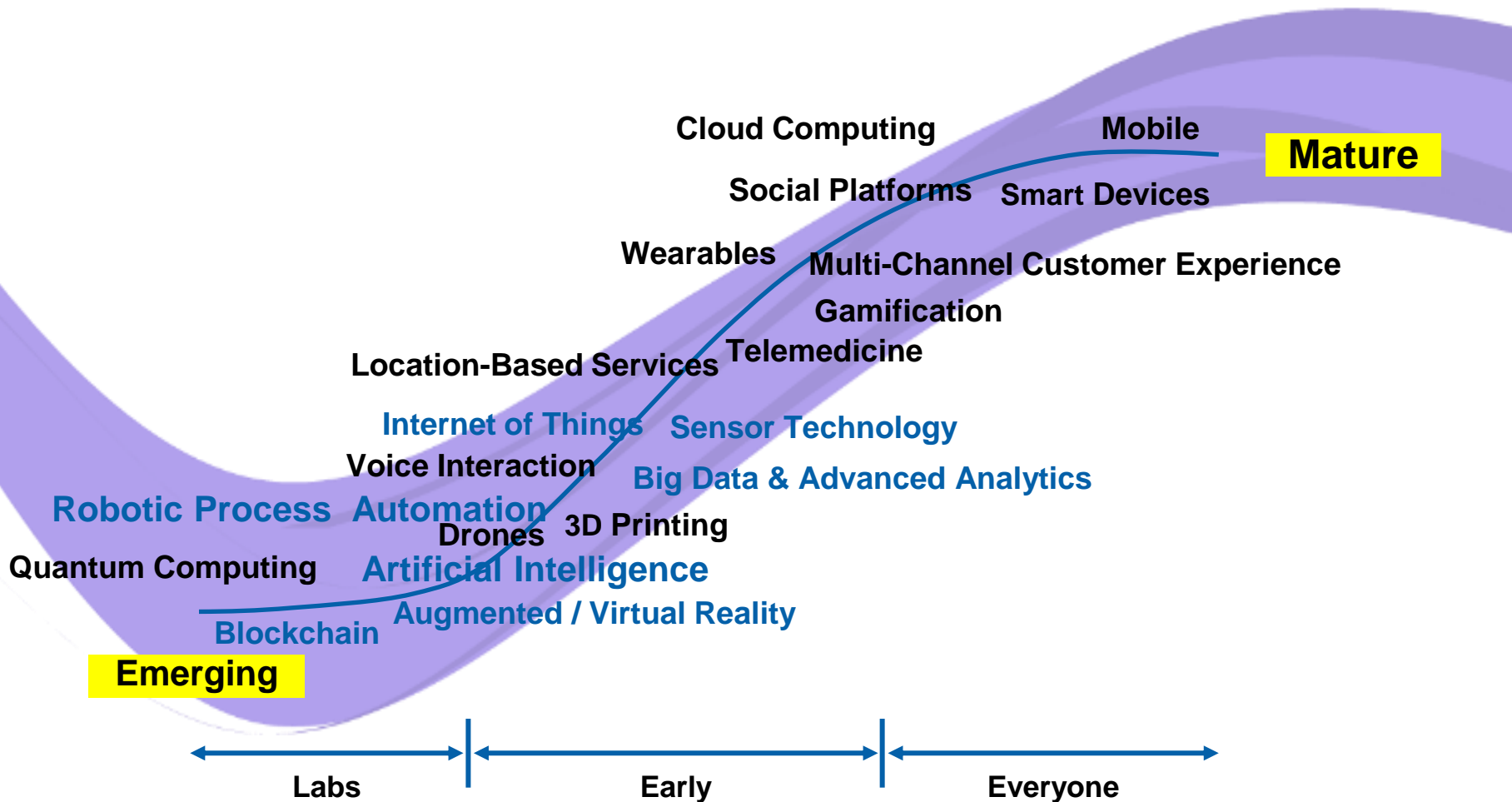
A systematic vision for Intelligent deployment of resources across the portfolio and line functions

Holistic view of Resource Management data to drive the right conversations



- Provide the full picture of how resources are planned, benched, deployed and consumed across the trial lifecycle
- Enable deep learning and data driven allocation

Technology is rapidly evolving, providing opportunities to reimagine Drug Development



Key trends in healthcare

Increase of chronic and multiple diseases

Increased focus on prevention

Increasing expectations of citizens

Shift from public to private funding

Ageing populations
Budget constraints
HC worker shortages

Increasing e-solutions

Shift to community and homecare

Increased demand of Medical Technology and services

Increased role of purchasing & paying institutions

Declining power of HealthCare professional

