



Associazione  
Italiana per  
l'Intelligenza  
Artificiale

# AI Algorithms for Digital Therapeutics

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# THE DIGITAL TRANSFORMATION

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## DTx

**Software** that delivers therapeutic interventions to prevent, manage or treat a medical disorder or disease. **Clinical evidence and Real World Evidence are required**

## Digital Medicine

**Software and hardware** for clinical measurements and/or to intervene directly on health. **They require clinical efficacy trials** and are typically classified as medical devices

## Digital Health

**Technologies, platforms and systems** that engage users for purposes related to lifestyle improvement, well-being and health. Other objectives may be to **acquire, store or transmit health data**, or to support clinical activities. To be deployed, applications in this area **do not require clinical trials**, nor regulatory supervision from any type of national or international body

# THEORY AND PRACTICE

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## THEORY

The digital medicine is based on software and hardware solutions, which **do not necessarily** have to use artificial intelligence techniques

# THEORY AND PRACTICE

512  
DEVICES

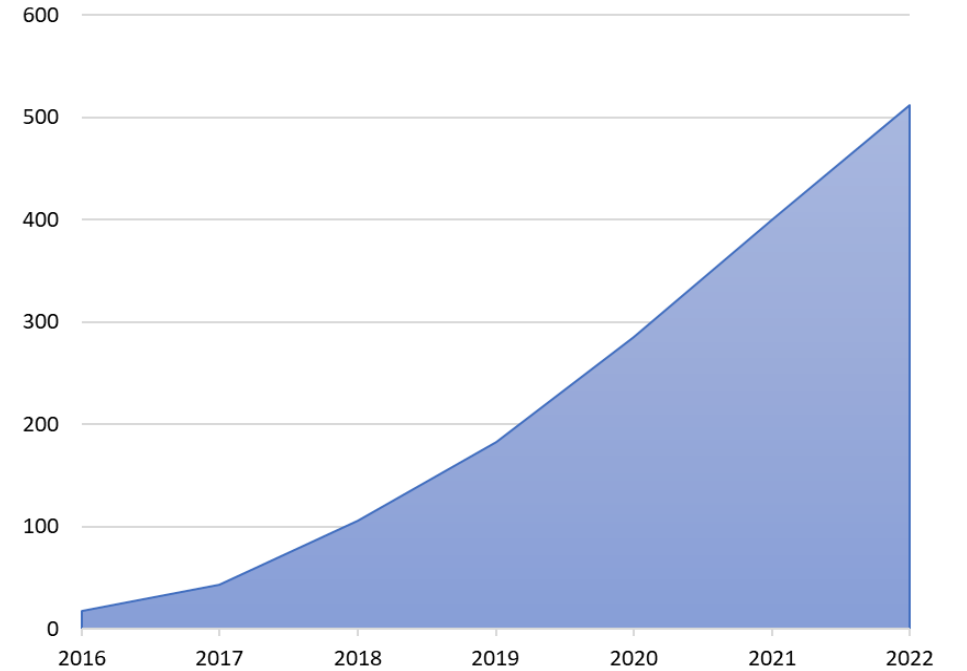
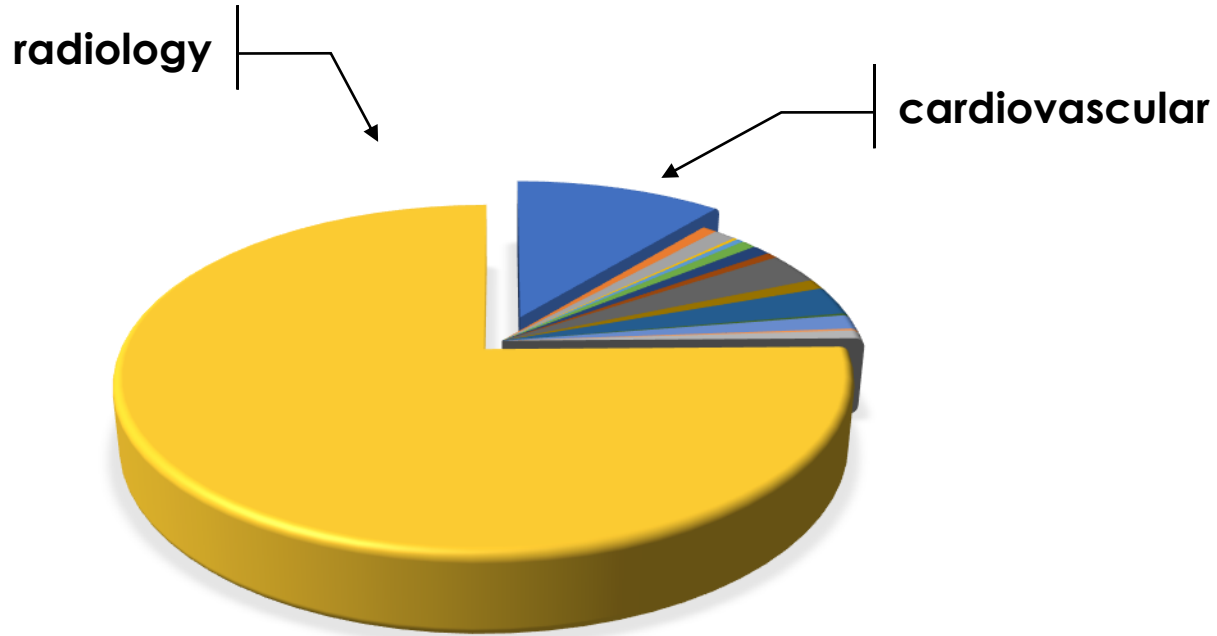


+ AI

THEORY

PRACTICE

The digital medicine is based on software and hardware solutions, which **do not necessarily** have to use artificial intelligence techniques



# Lenire [FDA 03/2023]



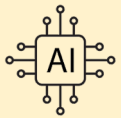
Treating **Tinnitus** Symptoms



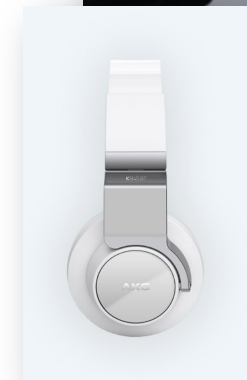
It uses the principle of **bimodal neuromodulation**: it provides mild electrical impulses to the tongue combined with sound reproduced through headphones to drive long-term changes or neuroplasticity in the brain to treat tinnitus.



Clinical trial on **112 patients** and RWE of 204 users, with 79.4% improvement



The frequencies of the sounds played by the headphones must be **customized**



AI = CONTROL + DEVICES

# Tinnitracks [non-FDA]



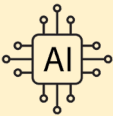
Treating **Tinnitus** Symptoms



Filter music based on the specific tinnitus frequency



Clinical trial on **98 patients**, with 65% improvement



The application filters the music played **in real time**, optimizing it according to the frequency of tinnitus



AI = CONTROL + DEVICES

# MedRhythm [FDA Breakthrough Device Designation 2020]



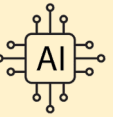
**Walking** in stroke patients



Use of rhythmic auditory stimulation, to facilitate walking and the ability to synchronize movements



Clinical trial on **11 patients**



The application analyzes the cadence and quality of walking and **dynamically adapts** auditory stimuli



**AI = CONTROL + DEVICES**

# CognICA [FDA 10/2021]



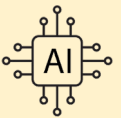
Assessment of **cognitive functions**



Implement a rapid test, based on displaying images at a rapid pace on the iPad screen and asking you to identify them as animals or non-animals



Clinical trial on **91 patients**, with 94% accuracy



The classification of the patient, based on response speed and accuracy, takes place with a **regression system**

## FDA clears AI-powered digital test for early dementia



A self-administered, artificial intelligence (AI) platform for cognitive assessment in multiple sclerosis (MS)

Seyed-Mahdi Khaligh-Razavi<sup>1,2\*</sup>, Maryam Sadeghi<sup>3</sup>, Mahdiyeh Khanbagi<sup>2</sup>, Chris Kalafatis<sup>1,4,5</sup> and Seyed Massood Nabavi<sup>2</sup>

AI = MACHINE LEARNING FOR DIAGNOSIS



# CanvasDx [FDA 06/2021]



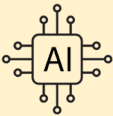
Early diagnosis of **autism spectrum disorders**



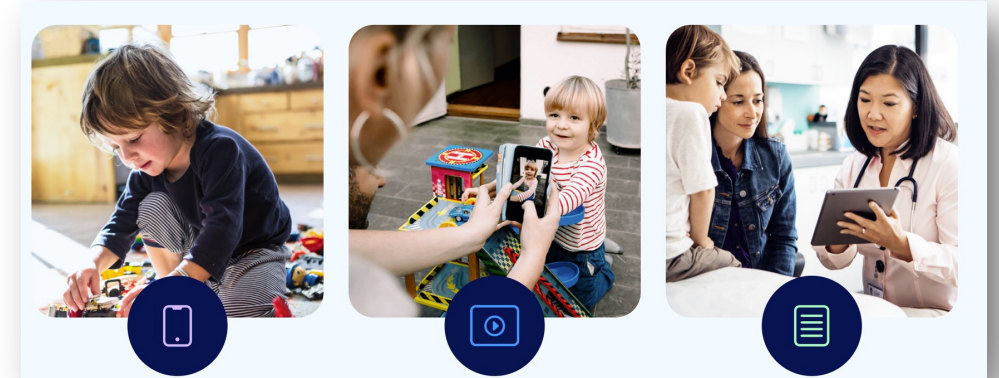
An app collects behavioral data, videos and feedback from healthcare professionals



Clinical trial on **425 children**



The application classifies the various cases through a machine learning algorithm (**gradient boosted decision tree algorithm**)



## Cognoa's AI-based autism diagnosis aid gets FDA de novo clearance

Canvas Dx can be used by physicians for autism diagnosis in children aged 18 months to 72 months.

**AI = MACHINE LEARNING FOR DIAGNOSIS**

# RhythmAnalytics [FDA 5/2019]



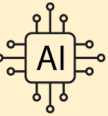
Identification of **cardiac arrhythmia**



System that allows you to detect and analyze cardiographic traces, and other data collected with sensors



Testing on **120,000 episodes**, with superior reliability to expert panels



The arrhythmia identification system is based on **anomaly identification** mechanisms, trained on millions of cases

## Biofourmis' RhythmAnalytics™ Platform Receives FDA Clearance for AI-Based Automated Interpretation of Cardiac Arrhythmias

A cloud-based, deep learning software platform can aid healthcare professionals in detecting over 15 types of cardiac arrhythmias using ambulatory ECG monitoring recordings.



AI = MACHINE LEARNING FOR DIAGNOSIS

# Pivot Breathe [FDA 10/2017]



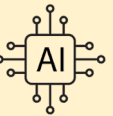
Tobacco **addiction**



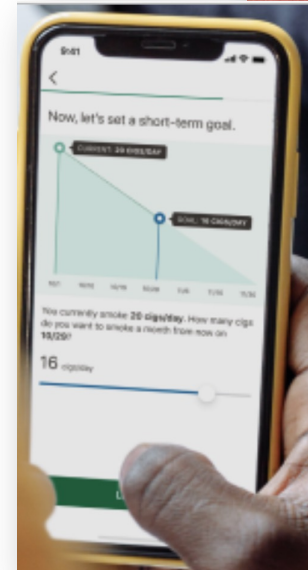
Coaching app that uses a sensor to read carbon monoxide levels in the breath



Clinical trial on **319 patients**, 35% success



The virtual coaching system is **adaptive** and personalizes the experience based on the user's characteristics



AI = VIRTUAL COACHING

# Insulia [FDA 7/2021]



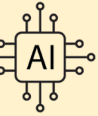
Treatment of **type II diabetes**



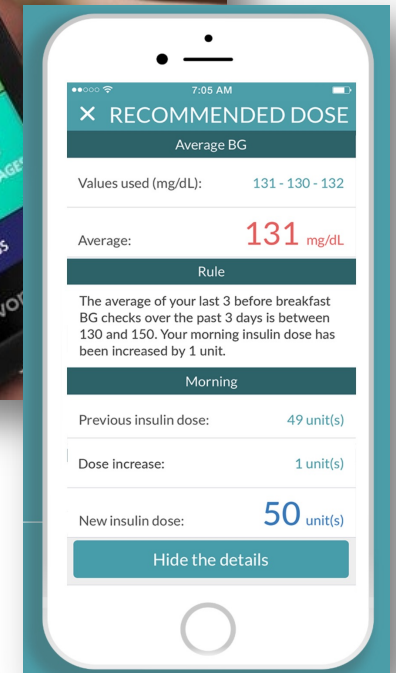
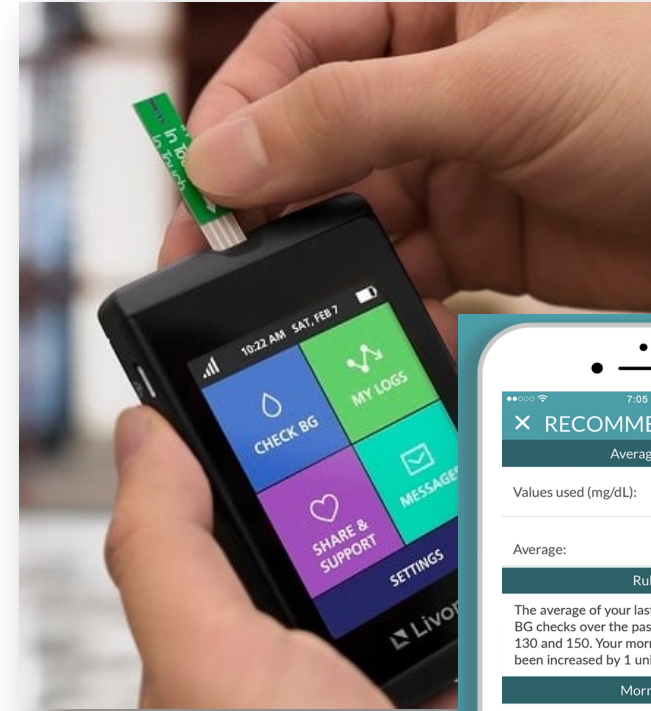
Integrated system of sensors and personalized recommendation, about the correct dosage of insulin



Clinical trial involving **191 patients**



**Expert system** that encodes domain knowledge, between recorded values and recommended doses



**AI = VIRTUAL COACHING**

# RelieVRx [FDA 7/2021]



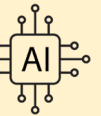
Treatment for **chronic pain reduction**



It includes a VR headset and a device that amplifies the sound of the user's breathing to assist in breathing exercises. Use the principles of cognitive behavioral therapy (digital CBT)



Clinical trial on **188 patients**, efficacy on 65%



Use of **immersive environment**, with strong characteristics of human-machine interaction



AI = 3D + VIRTUAL REALITY

# EndeavorRx [FDA 6/2020]



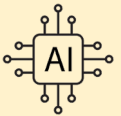
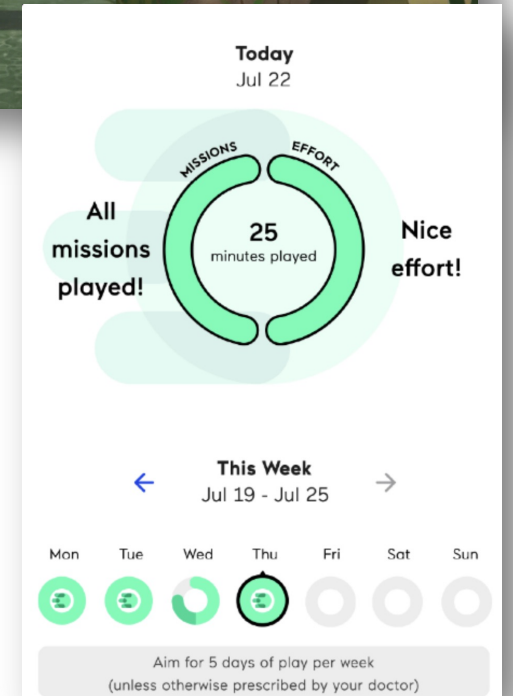
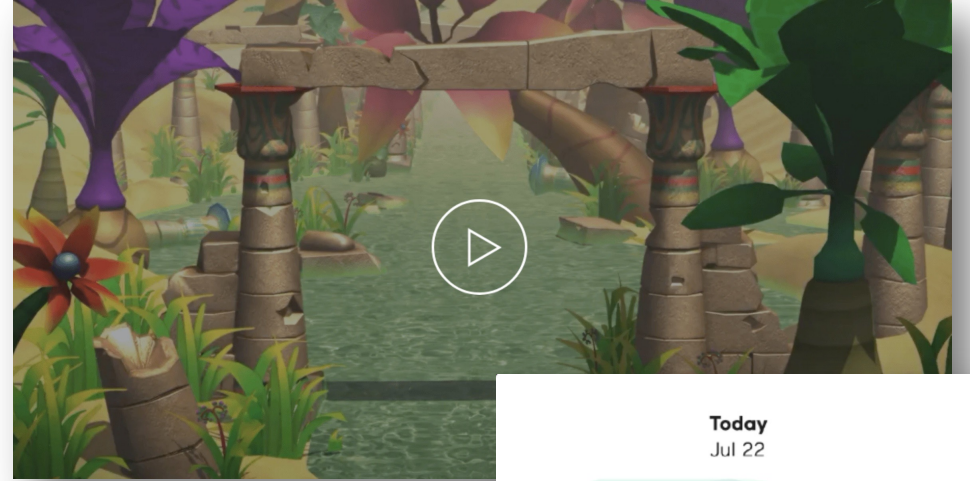
Improved **attention** in children 8-12 years



Video game that develops specific cognitive areas, which require particular stress in children with attention deficit hyperactivity disorder (ADHD)



Clinical trial on **600 children**, success on 73%



**Videogames** are among the most classic development environments for artificial intelligence technologies

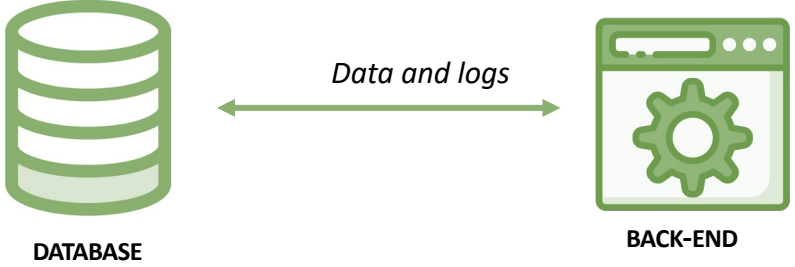
AI = 3D + VIRTUAL REALITY

**Further opportunities**



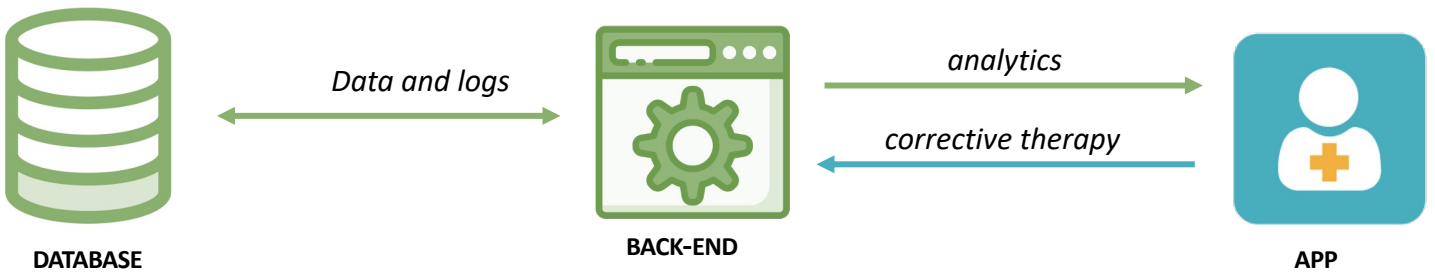
# AI IN DIGITAL DEVICES

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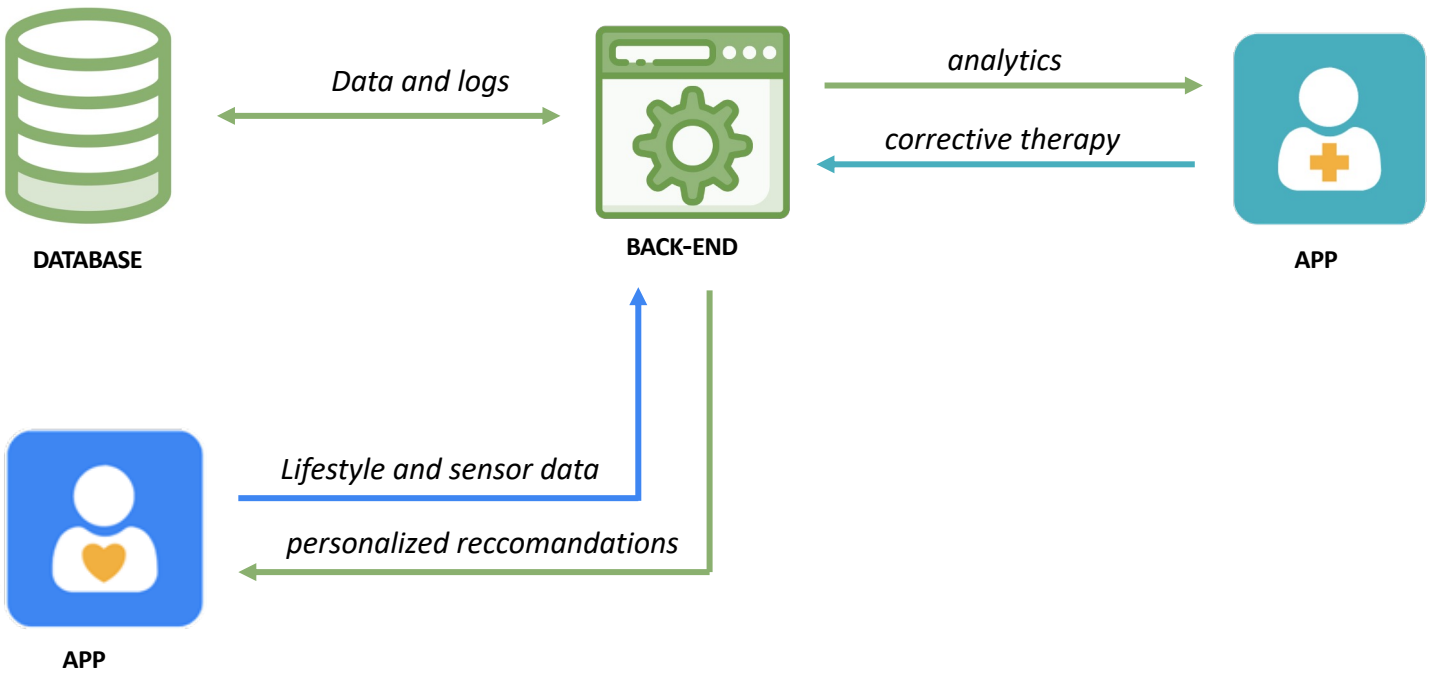




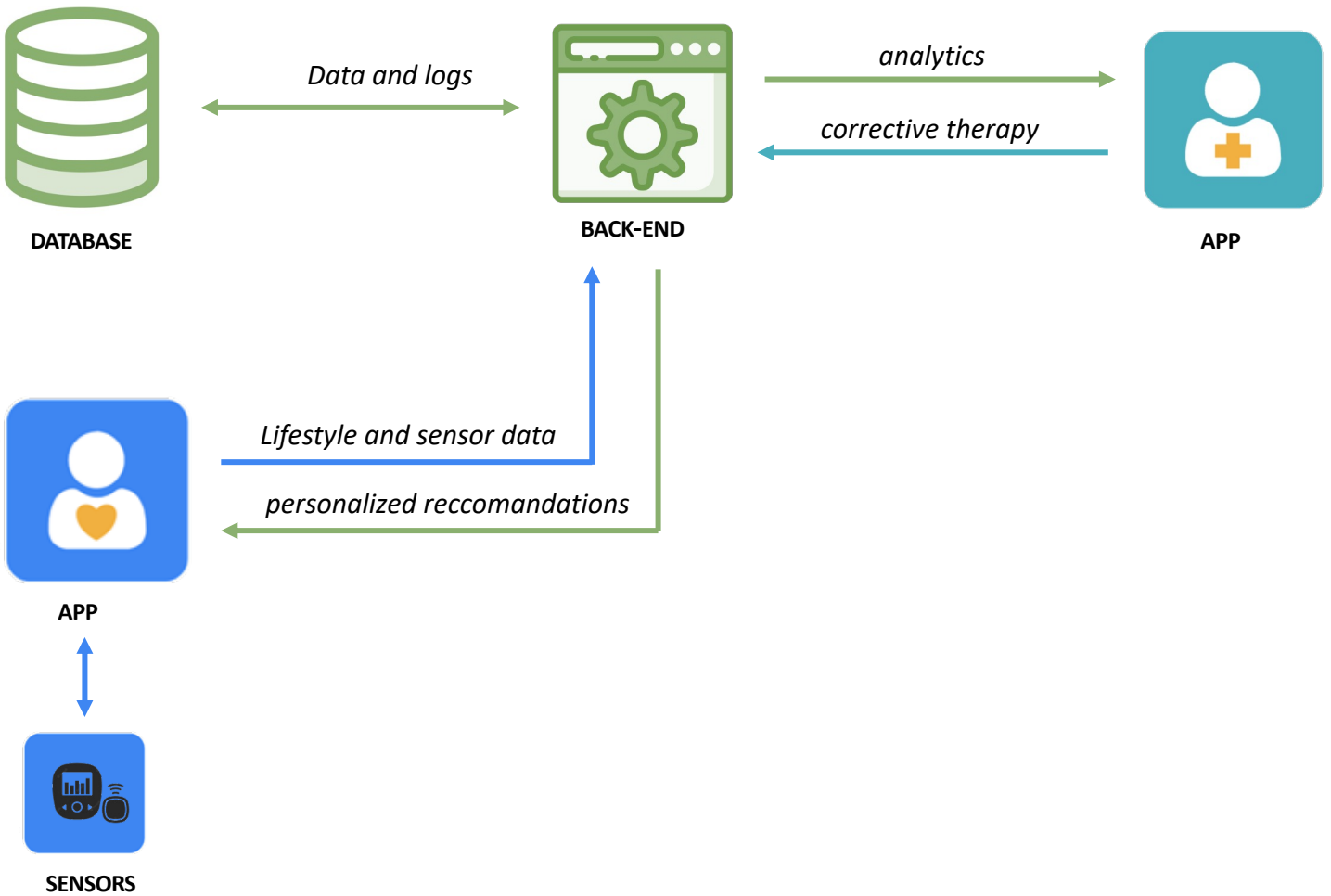
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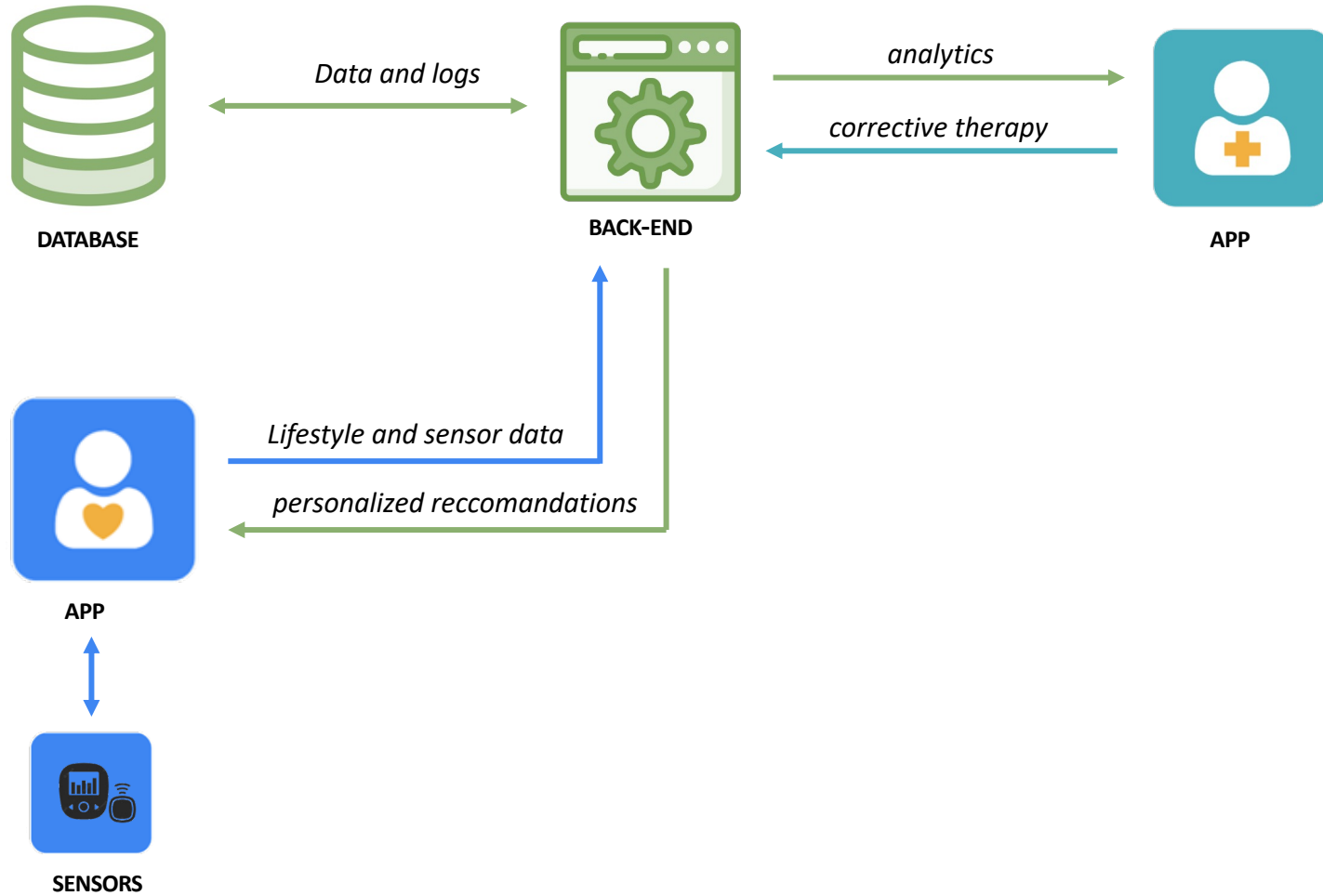
# AI IN DIGITAL DEVICES



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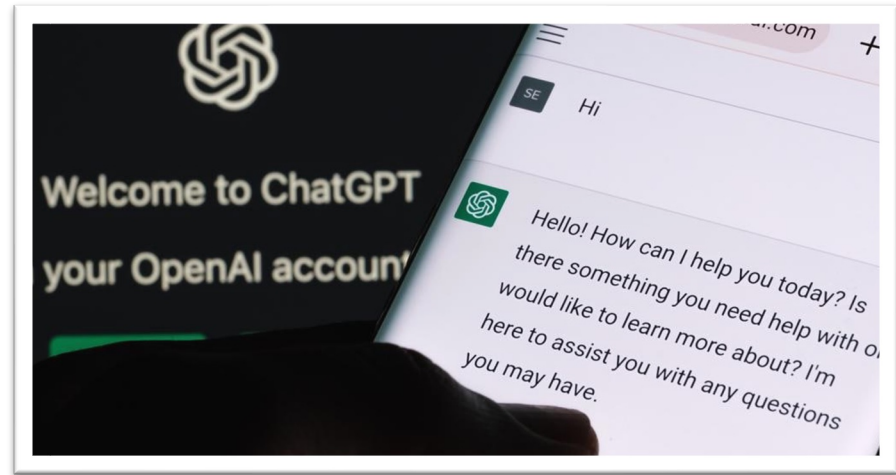
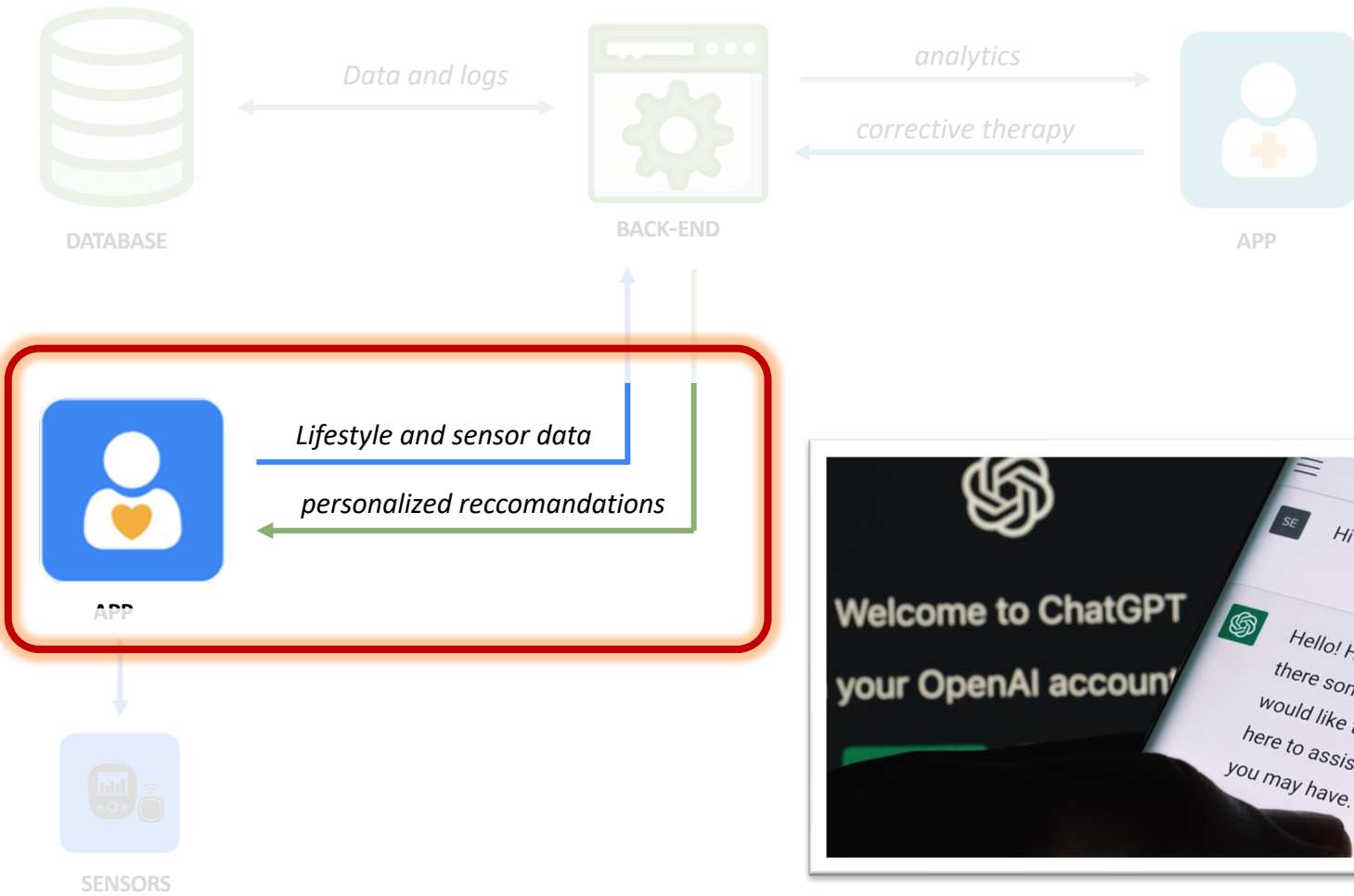
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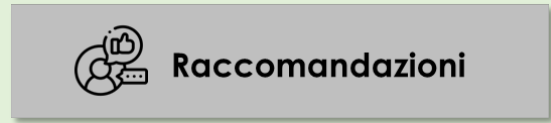
## AI

-  Chatbot
-  Sensing
-  Planning
-  Reasoning
-  Regression
-  Anomaly Detection
-  Raccomandazioni

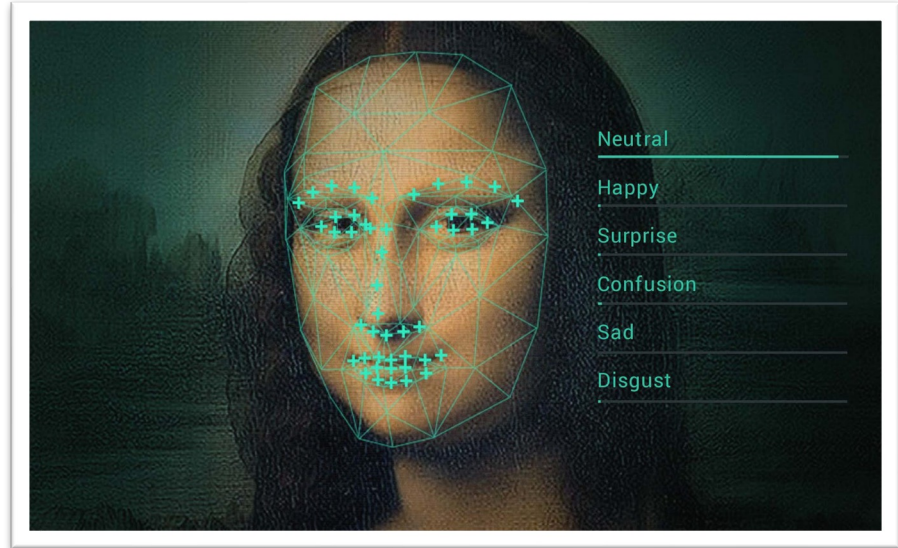
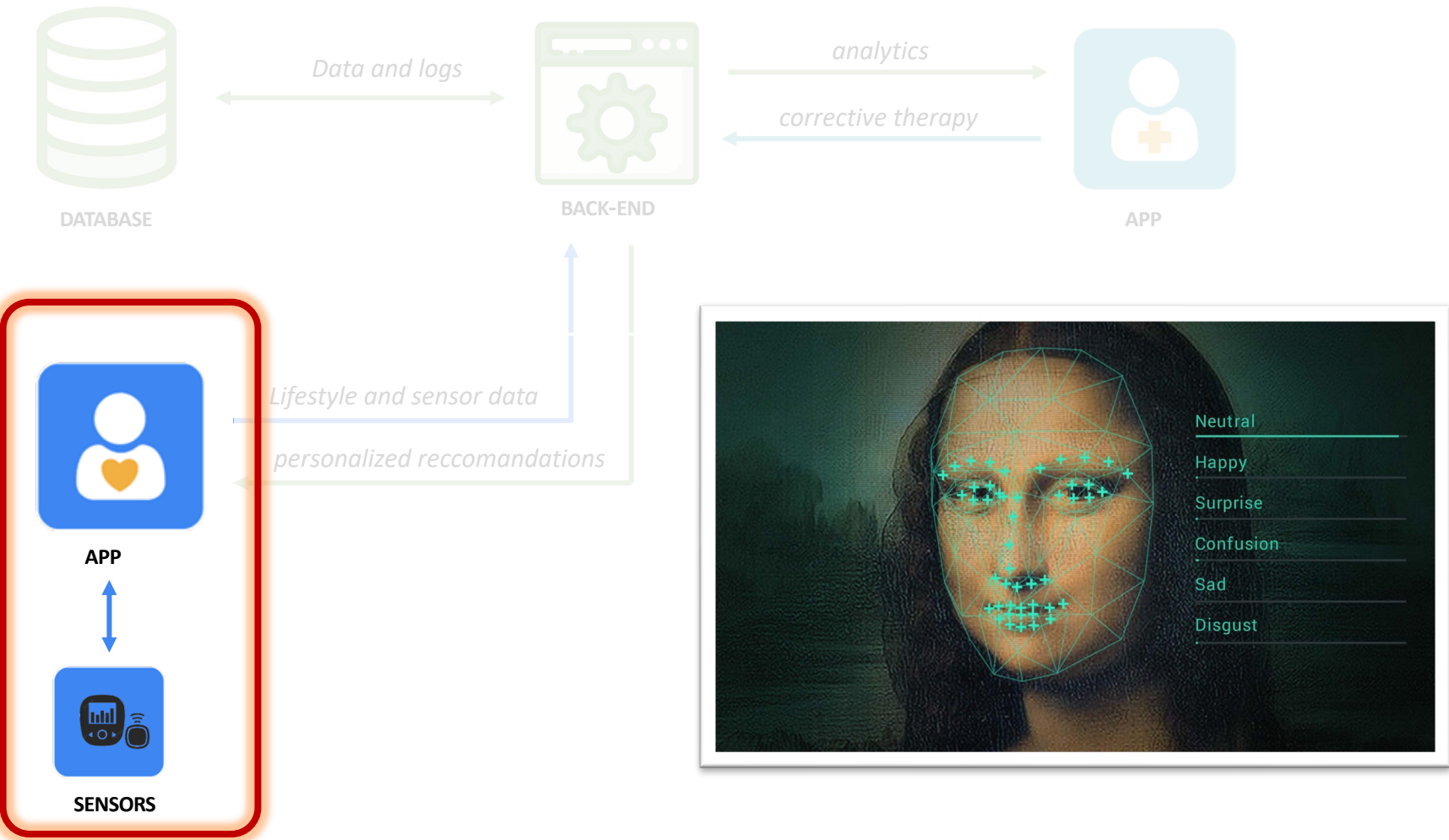
# AI IN DIGITAL DEVICES



## AI



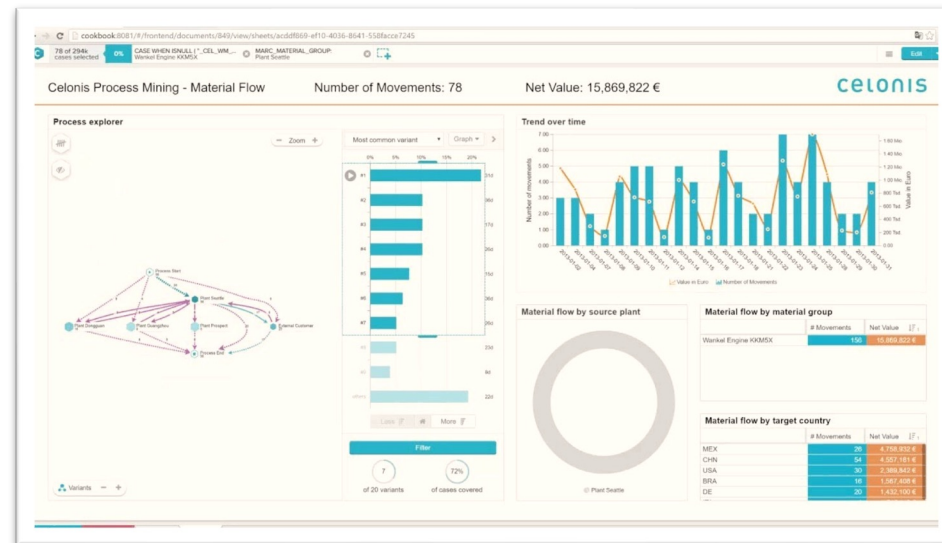
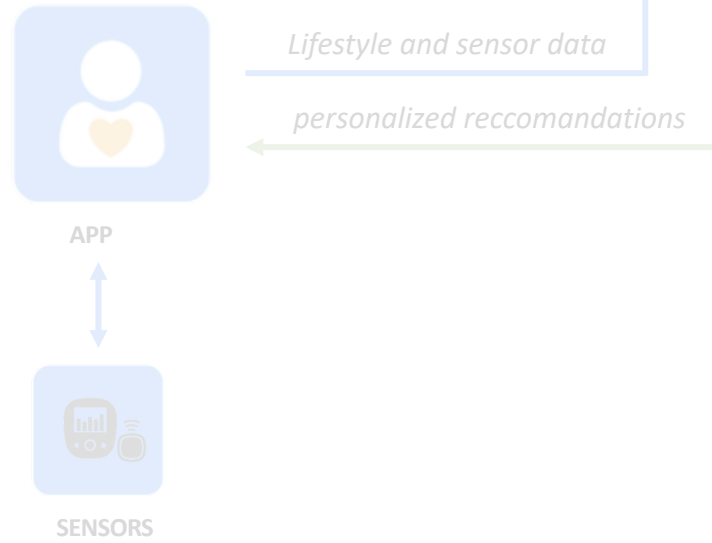
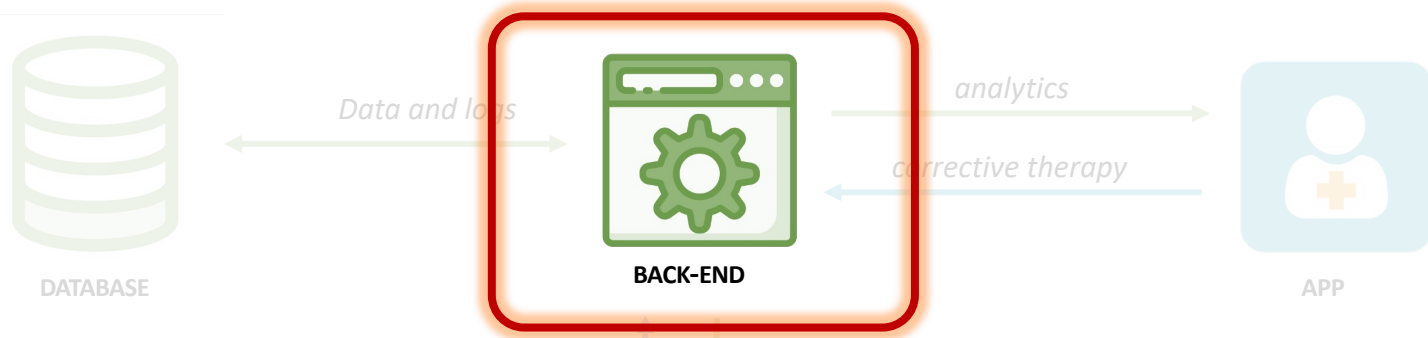
# AI IN DIGITAL DEVICES



# AI





# AI IN DIGITAL DEVICES





# AI

 **Planning**

 **Reasoning**

 **Regression**

 **Anomaly Detection**

 **Raccomandazioni**

# AI-powered DTx in **practice**

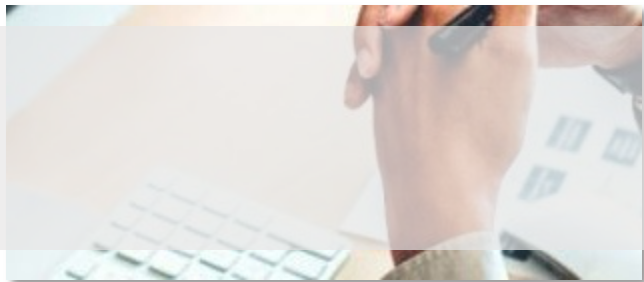




# COST-EFFECTIVE TECHNIQUES AND TOOLS



*Identificazione anomali*



With current platforms for prototyping AI solutions, **anyone can develop a digital app** and make it available on a commercial platform.

# REGULATIONS

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**Artificial Intelligence**  
*for*  
**Medical Devices**



# REGULATIONS



[..] AI system shall be considered **high-risk** where both of the following conditions are fulfilled:

- the AI system is intended to be used as a **safety component** of a product, or is itself a product, covered by the Union **harmonisation legislation listed in Annex II**;
- the product whose safety component is the AI system, or the AI system itself as a product, is **required to undergo a third-party conformity assessment** with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

In addition to the high-risk AI systems referred to in paragraph 1, **AI systems referred to in Annex III shall also be considered high-risk**

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**Thank You!**