

The Next Wave of Self-Care Digital Health

*A catalyst towards an outcome-oriented
consumer health industry*

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Speakers



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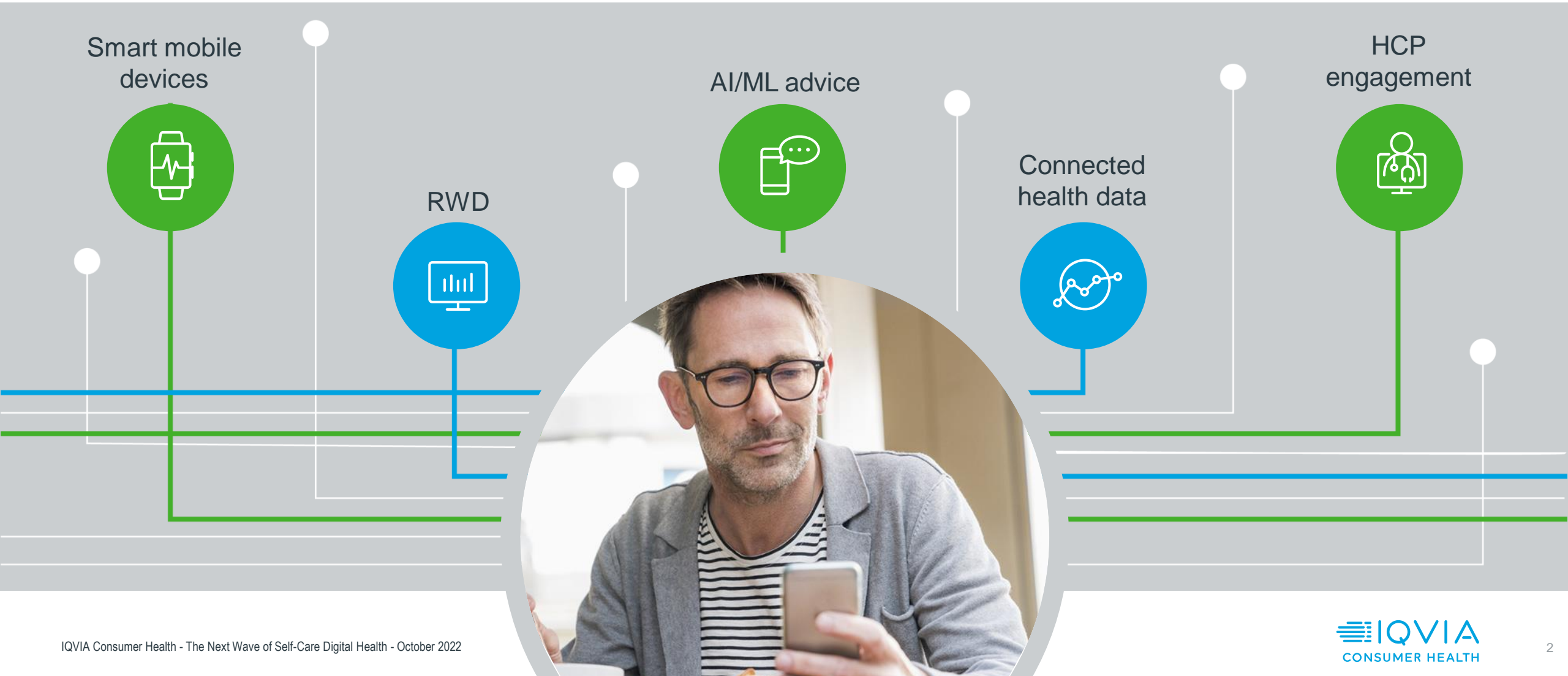


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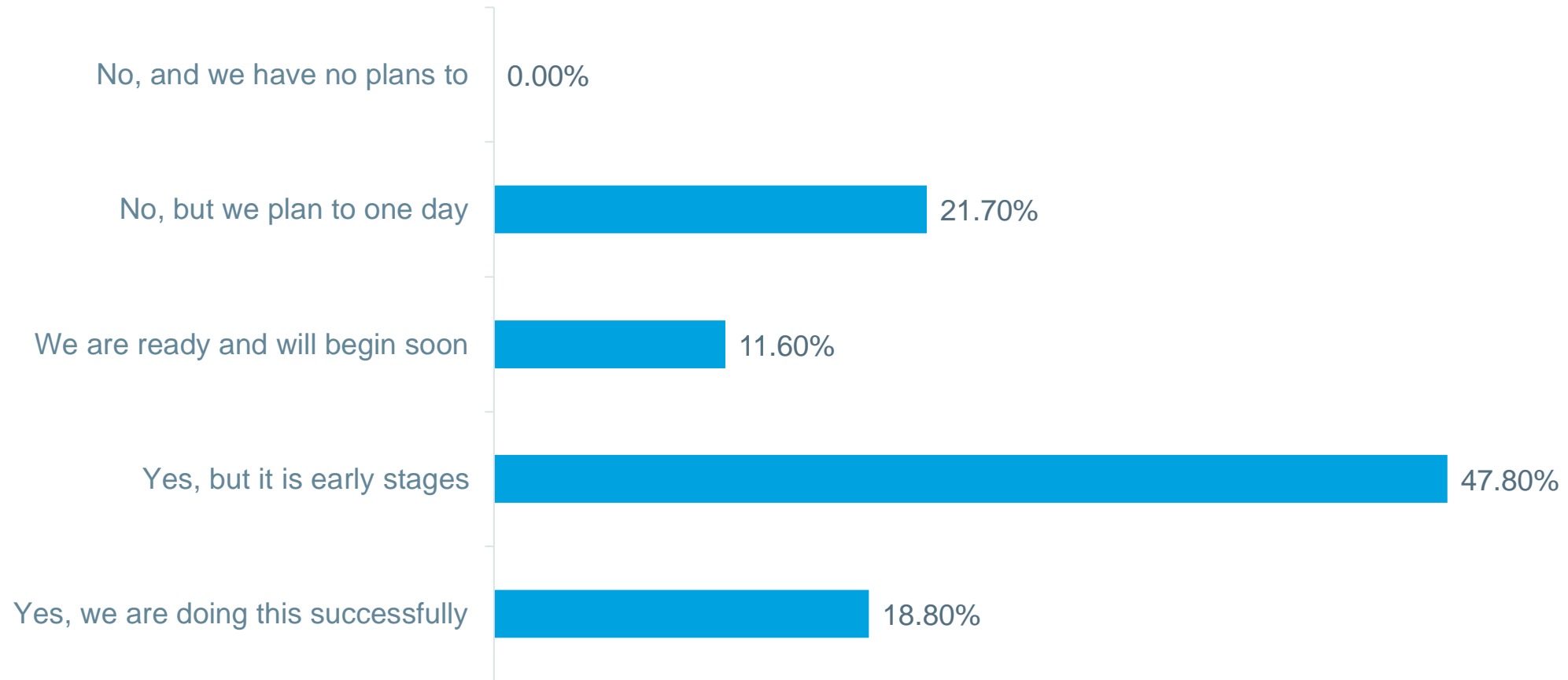
Digital health is about combining new digital technologies with data to improve health outcomes for everyone

How we at IQVIA Consumer Health define digital health



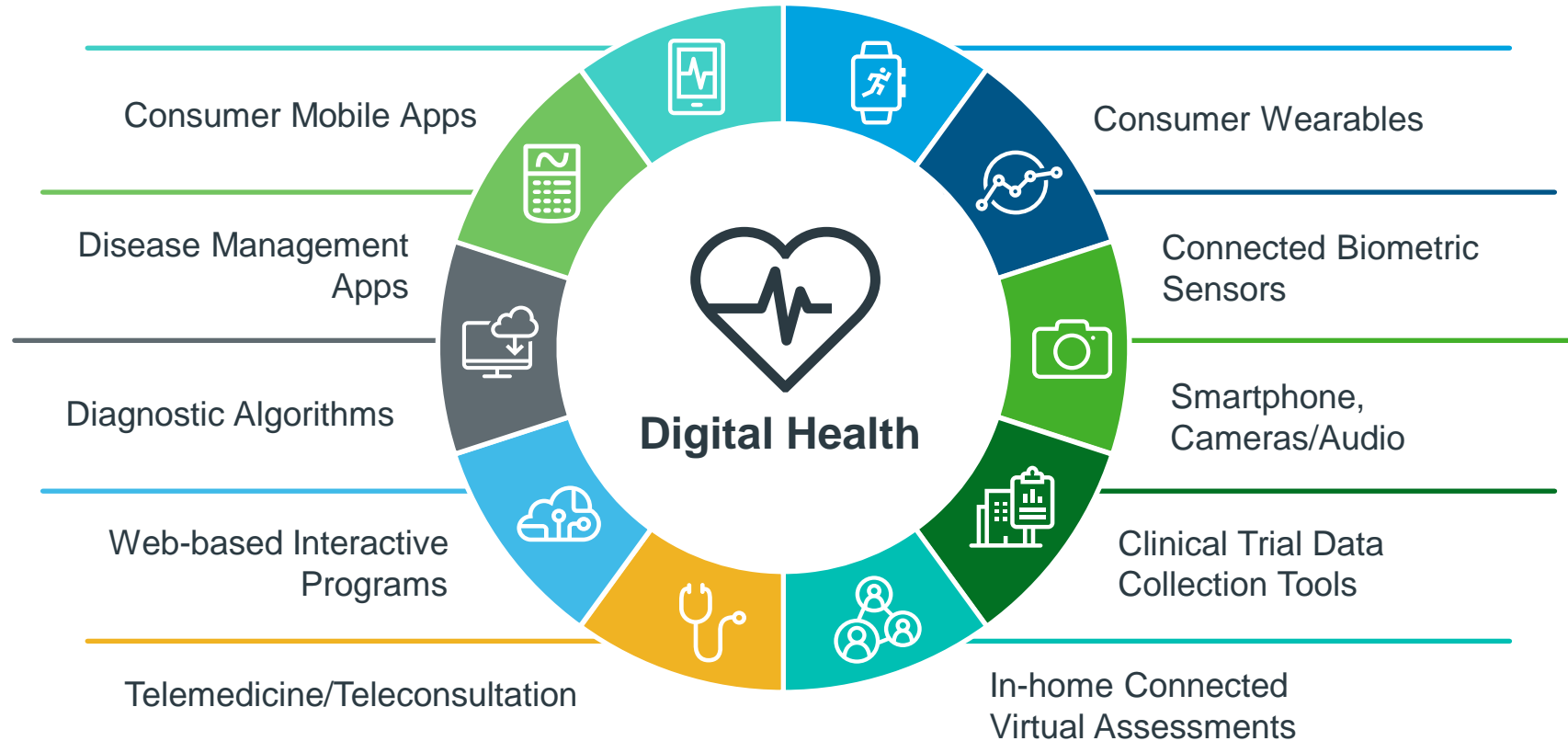
Are your brands integrating digital solutions as part of their offering?

A poll conducted during the live broadcast



'Digital Health' is disrupting how consumers think about health

Emergence of digital health tools has placed consumers at the centre of their own wellbeing



Digital health tools are beneficial for consumers, HCPs and the industry

The “sweet spot of innovation” is evolving with the consumer

Improved outcomes and consumer experience are new innovation KPIs. It's time to change!



Consumer needs

Do we have digitally supported, holistic & personalized offerings?



Tech/Reg/Sci Feasibility

Do we create Digitalized & virtual studies and digital health products?



Commercial Viability!

What is the best business models for integrated & digitalized health solutions?



Brand Fit!

Do we need to adapt the current scope of brands?



Is your innovation strategy evolving with consumer needs?

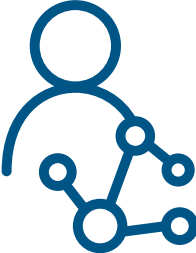
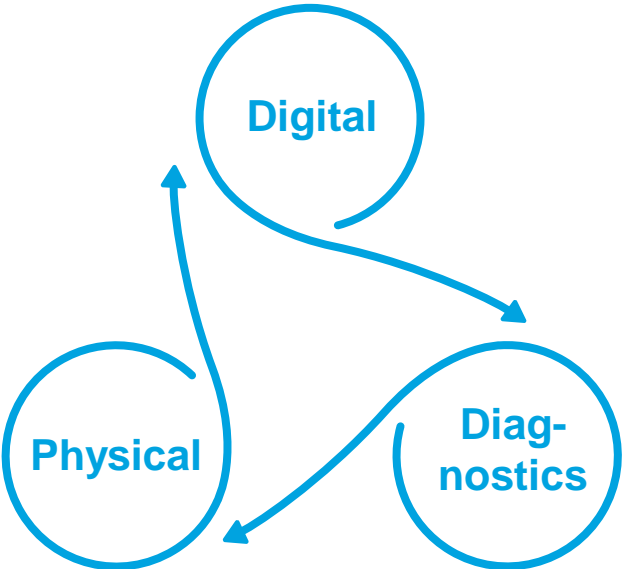
Digital Health technologies support the next level of outcomes

The combination of physical and digital products will lead to services and platforms driving future innovations and the delivery of selfcare

 **Connected Intelligence** 

 **“Personalized” Consumers** 


 **Better Selfcare**



More control on **individual** health & wellness



Health solutions are delivered in new ways **disrupting** existing value chains

 **Is it time to shift business models in order to provide better value to consumers?**

Industry focus should be on improved health outcomes and value-based services

Holistic self-care is moving beyond symptom treatment, driven by the rise of digital health tools

Advanced Health & Wellbeing

- **Advanced innovation** beyond formulation
- **Evidence-based** products for an ageing society
- **More access to OTC drugs** through RX to OTC switches
- **Long-term health** prevention services



**Inform – Advise - Diagnose
– Treat – Prevent - Manage**

Digital Innovation

- Integration of new **digital experience**
- **Digital therapeutics**
- **Advanced diagnostics & personalization**
- **Digital biomarkers**



Are your brands offering more than just treatment of symptoms?

New Consumer Health Data Universe




Digital health tools – A “Win-Win” for consumers and the industry



Consumer Benefits

- Health status monitoring
- Diagnostics
- Health and behavior advice
- Health motivation
- Personalization



Mobile data information & collection

Digital Health Tools



Industry opportunity

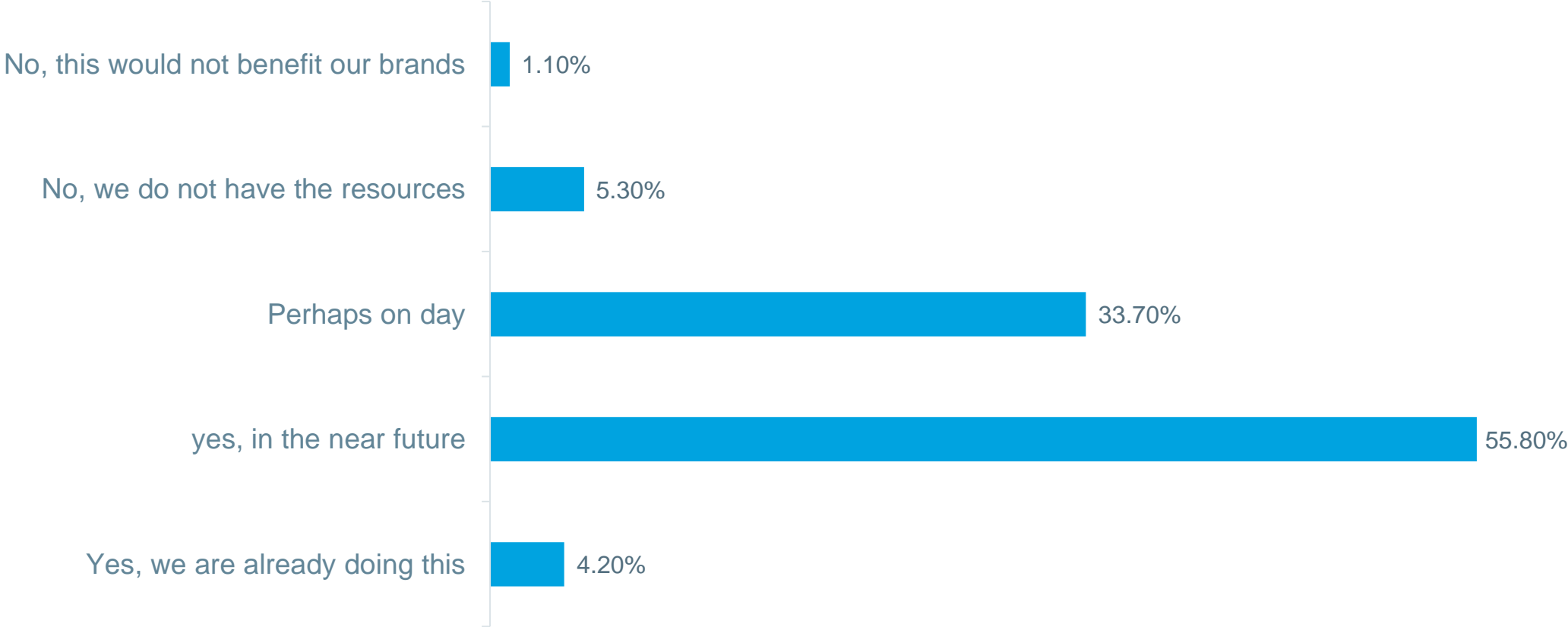
- Consumer-centric research
- Real-time data / Continuous data
- Novel endpoints



Are you making the most of the new consumer health data universe?

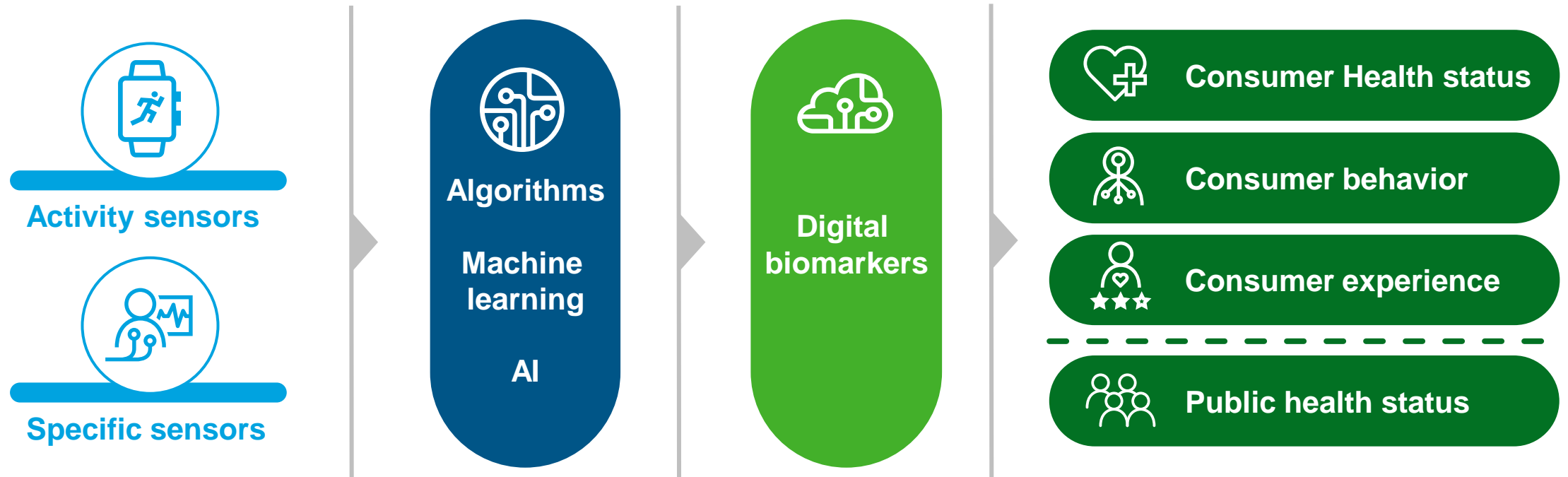
Do you think digital biomarkers could be utilized in the future to develop new claims for your brands?

A poll conducted during the live broadcast



Digital biomarkers provide new types of health information

Out of the real-world and real-time context in a continuous way



“Digital biomarkers are objective, quantifiable, physiological, and behavioral measures that are collected by means of digital devices that are portable, wearable, implantable, or ingestible”

Sensor technology and data analytics / AI is a fast-evolving area providing new opportunities for digital biomarkers

Wristables | Clotheables | Patchables | Eyeables | Earables | Ringables | Insertables | Implantables | Ingestables | Tattooables

GPS data / Proximity data

- Activity / Behavior
- Social interaction

Vital signs data

- Stress
- Physical energy
- Heart fitness
- Sleep
- Pain
- Body temperature

Physical data

- Sleep (motion tracking)
- Executive functions
- Mental alertness



Sound data

- Coughing & Sneezing
- Mood status
- Snoring

Photo / Video data

- Skin health & diagnosis
- Photoplethysmography for vital signs
- Stress
- Sun exposure

Biochemical data

- Glucose level
- Hydration level
- Gas emissions



Are you already using sensors and related data analytics for measuring real world clinical outcomes or for consumer health monitoring?

Digital biomarkers are core for the entire self-care ecosystem



PRODUCT & CLAIMS DEVELOPMENT

New Type of Evidence

- **Consumer-centricity**
through decentralized clinical / RWE studies
- **New type of digital evidence**
leading to new indications / claims
- **Deeper insights**
on product benefits to inform innovation strategies
- **IP development**
connected to digital biomarkers
- **Companion solutions**
based on digital study endpoints



PERSONALIZED HEALTH SUPPORT

Consumer's Companion

- **Monitoring of health**
for prediction / prevention for short-term or long-term health issues & wellness
- **Behavior support**
with matched digital biomarkers
- **Digital therapeutics**
using digital biomarkers as a control tool



TAILORED PUBLIC HEALTH SUPPORT

Public Health Evidence

- **Surveillance**
Recognize trends / outspread of relevant health events
- **Alert systems**
providing specific information for vulnerable groups
- **Marketing campaigns**
Using public health signals for CH products

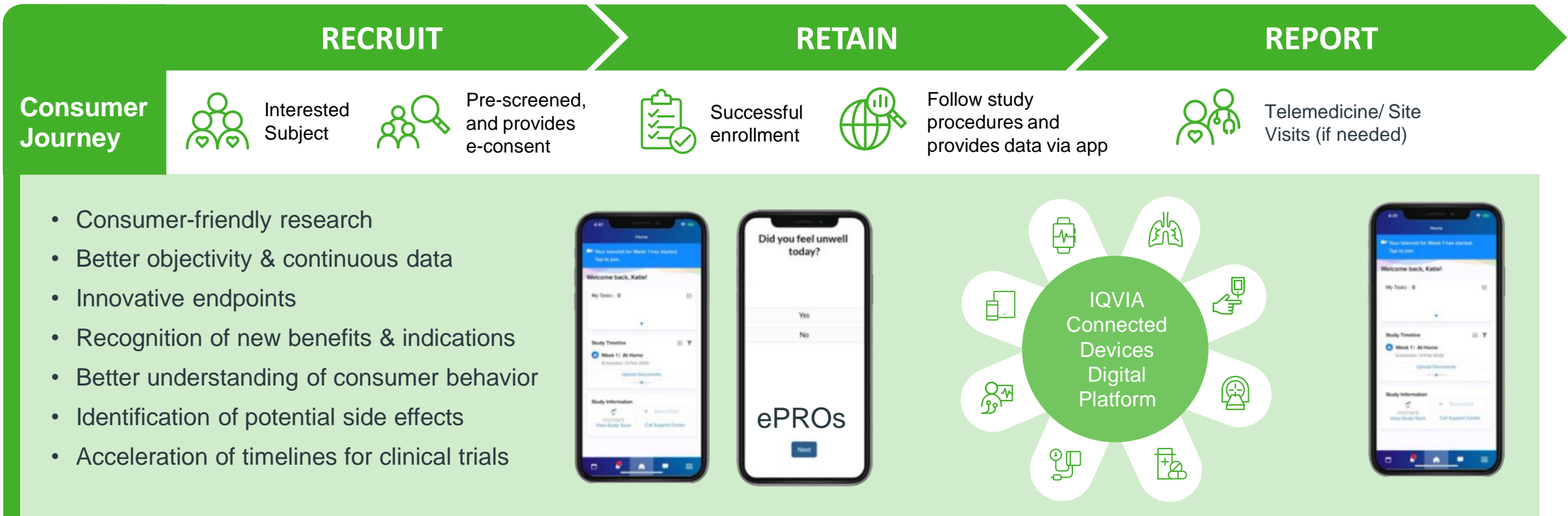


Should you use digital biomarkers as a source for competitive claims and digital health services for consumers?

Digital tools can be used to develop consumer-centric clinical / real world (RW) evidence

New Type of Evidence

Validated or consumer-grade devices can be integrated in decentralized trial approaches



A very consumer-centric approach enabling data collected in “home use” context

Case study: ePRO through a virtual study related to post-marketing clinical follow-up for nasal spray devices in EU

New Type of Evidence

Background & Objectives



A multi-national OTC client needed clinical support for PMCF for a series of medical devices in 5 different EU countries.

These products were substance-based medical devices or topical / spray products in the area of allergic rhinitis / cold



Methodology



100% virtual RWE study

Social media recruitment campaign, screening questionnaires, product related questionnaires, reminders, compliance, dashboard updates, AE/SAE, data analysis and CSR for regulatory purposes

Population

18–65 year-old participants in 5 different EU countries

ePRO collection



Outcome



- Collection of outcomes according to regulatory needs to fulfil the requirements of the EU Medical Device regulations
- Clinical report of results according to regulatory requirements
- Real world consumer feedback on the effectiveness and safety of OTC products

Efficient & convenient data collection directly from consumers' home

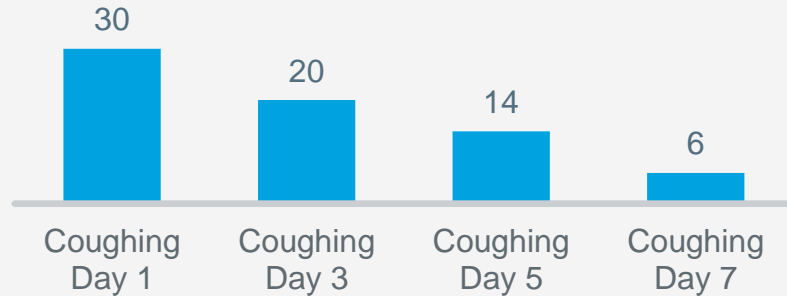
Inspirational Case study: Digital tracking of cough & sleep (clinical or real-world evidence (RWE) study)

New Type of Evidence

1

Can your product reduce the number of cough events?

No. of cough events



Proofing the reduction of cough frequency over time can lead to new claims for Cough and Cold (C&C) products

2

Sleep quality is affected by C&C and allergic rhinitis¹



Would a claim around improving sleep quality not be relevant for C&C / allergy sufferers?

¹ Liu J, Zhang X, Zhao Y, Wang Y. The association between allergic rhinitis and sleep: A systematic review and meta-analysis of observational studies. PLoS One. 2020 Feb 13;15(2)
² Abdelhafeez M. Effectiveness of intranasal steroids on rhinitis symptoms, sleep quality, and quality of life in patients with perennial allergic rhinitis. Eur Arch Otorhinolaryngol. 2022 Jan;279(1):249-256.



Should digital biomarkers be considered for your next RW or clinical study to enrich outcomes?

Consumer companions can provide significant value for individuals

Consumer's Companion



Data input

Activity & other sensor data

Visual & acoustic data

Medical data

Other type of structured or unstructured data / information

Processing

Artificial Intelligence

Machine Learning

Deep Learning

Natural Language Processing

Results

Understanding

Learning

Prediction

Translation

Health information

Health status information

Behavior recommendation

Health action

Direct

Prevention

Optimization

AI-driven tools help to turn relevant data into health-related behaviors triggering better health outcomes

RWD and companion
app in Action Case
Study:

Nicorette QuickMist®
SmartTrack™

Spray



Tap



Track



The patient need for support 'beyond the pill'

Our Mission:
*To save the lives
of Smokers*

Nicorette® has pioneered NRT innovation and quitter support for over 40 years

Nicorette® is the #1 selling brand of NRT globally distributed in 65 countries

Innovation is at the heart of what we do:



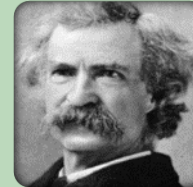
1st NRT to market



Have the most formulations for smoker's unique needs



Offer resources to help smokers quit for good - including online videos, websites, research and utilising new technologies



Giving up smoking is the easiest thing in the world.

I know because I've done it thousands of times

- Mark Twain

The patient need for support 'beyond the pill'

76%

**OF UNAIDED
QUITTERS
RELAPSE IN THE
1ST WEEK**

2X

**MORE LIKELY TO
QUIT WITH NRT**

3-5X

**MORE LIKELY TO
QUIT WITH
BEHAVIOURAL
SUPPORT**

Increasing NRT compliance & providing additional support will ultimately improve quit outcomes

Introducing Nicorette QuickMist® SmartTrack™

The World's 1st Connected OTC medicine

Personalise
your quit
journey with
Nicorette®
SmartTrack™



Spray

For rapid craving relief



Tap

To record NRT usage



Track

Progress towards individual goals
with a personalised quit plan

RWD in action

Consumer empowerment: how individuals can leverage their own real world data



- Set own goals
- Track progress against goals
- Understand patterns of behaviour



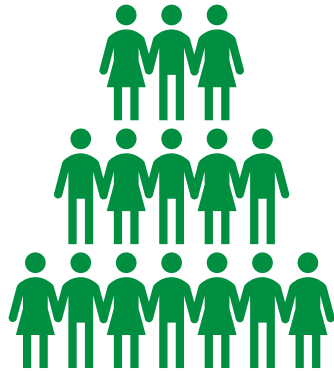
Increases awareness & motivation

RWD in action

Improving health outcomes: How J&J can utilise the data



Deeper understanding of quitting smoking



Insights into different user groups



Improving features & utility



Leveraging to improve health outcomes

RWD in action

Key considerations & Challenges along the way



Data Privacy



Software as Medical Device (SaMD) considerations



Regulatory Framework for Connected Medicines

There are complexities to navigate

but also **HUGE**

benefits to consumers & the Self Care industry



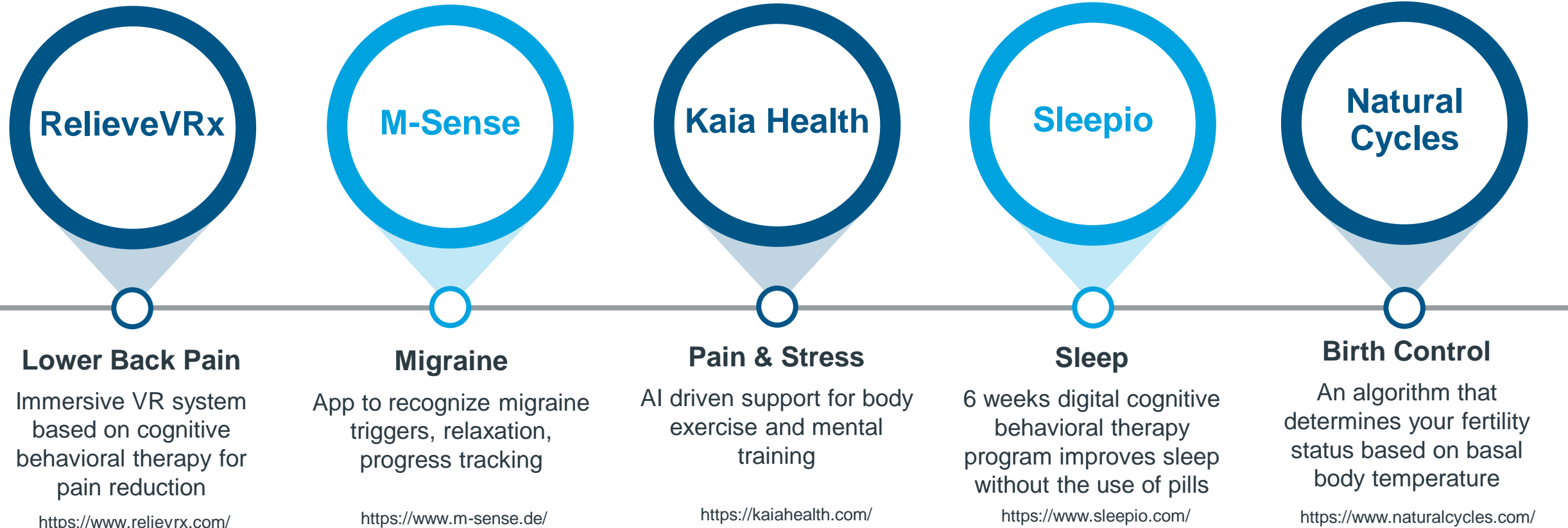
Driving Better Health Outcomes



Digital therapeutics as an additional outcome-oriented service

Consumer's Companion

Evidence-based therapeutic interventions driven by software to prevent, manage, or treat a problem









Non-pharmacologic treatment & prevention at home

Behavior data from digital devices

One of the most explosive forces in public and individual health

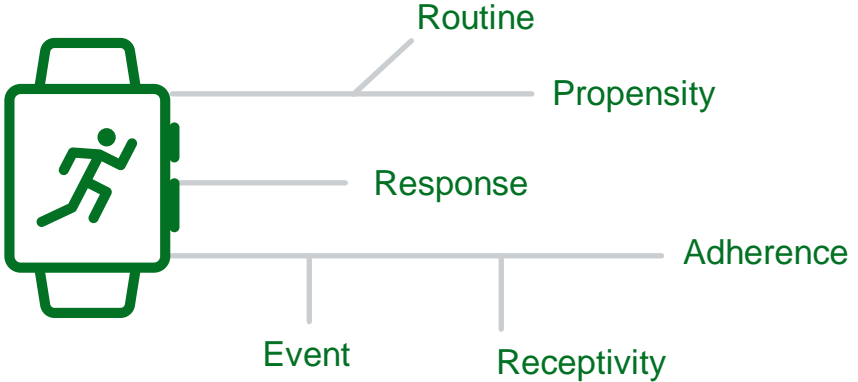
Behavioral data

Refers to information produced as a result of actions such as:

 Steps walked	 Exercise	 Body position
 Cardiac activity	 Sleeping time	 App interactions

Behavioral markers

Using behavioral data, markers tend to characterize a person's routines, understand events and response to interventions.



The diagram features a smartwatch icon on the left. Six lines extend from the watch to various labels: 'Routine' (top), 'Propensity' (top-right), 'Response' (middle-right), 'Adherence' (bottom-right), 'Event' (bottom-left), and 'Receptivity' (bottom).

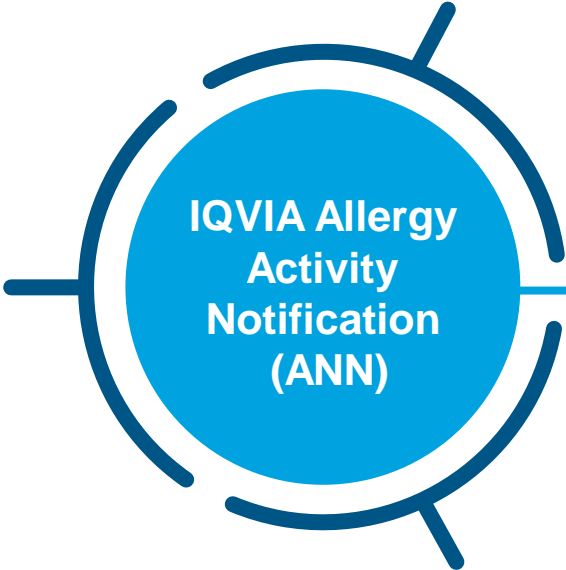
“Behavioromics”
It is about a person's routine, intervention, and propensities

Case study: Allergy prediction before seasonal outbreak

To better predict and adjust sales volumes, production & marketing strategies to fit consumer needs

Based weather trends, product information, and consumer data

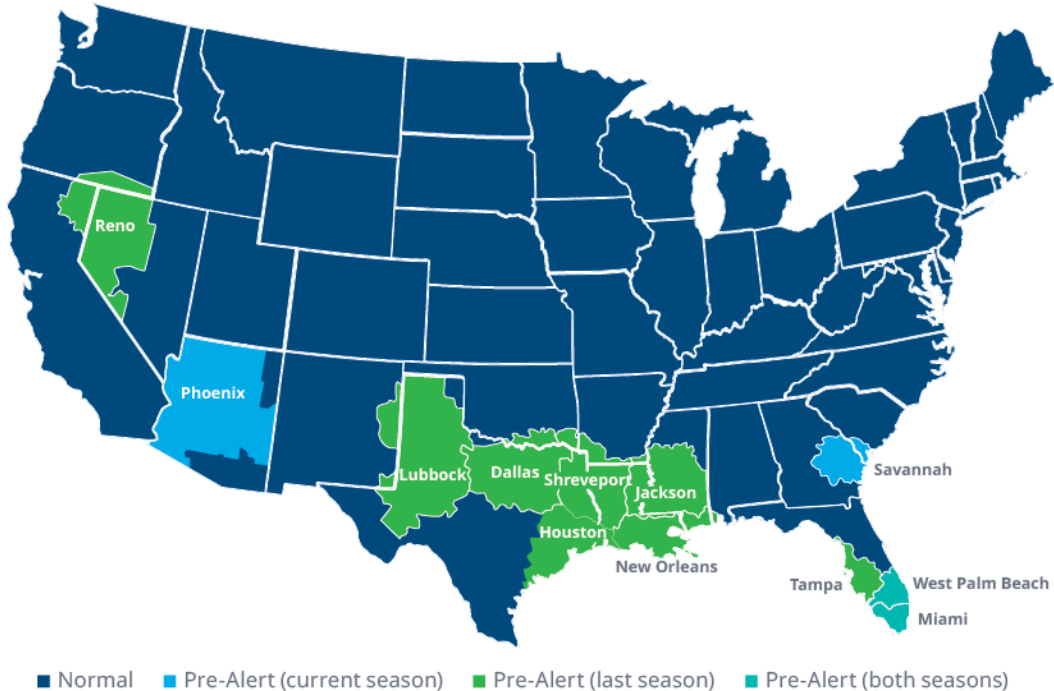
Uses near real-time data to monitor and project the population affected by airborne allergens



Example US

Forecast, tracks and target (available in US, UK)

Allergy alert status for US states 2/11/2022 vs 2/12/2021

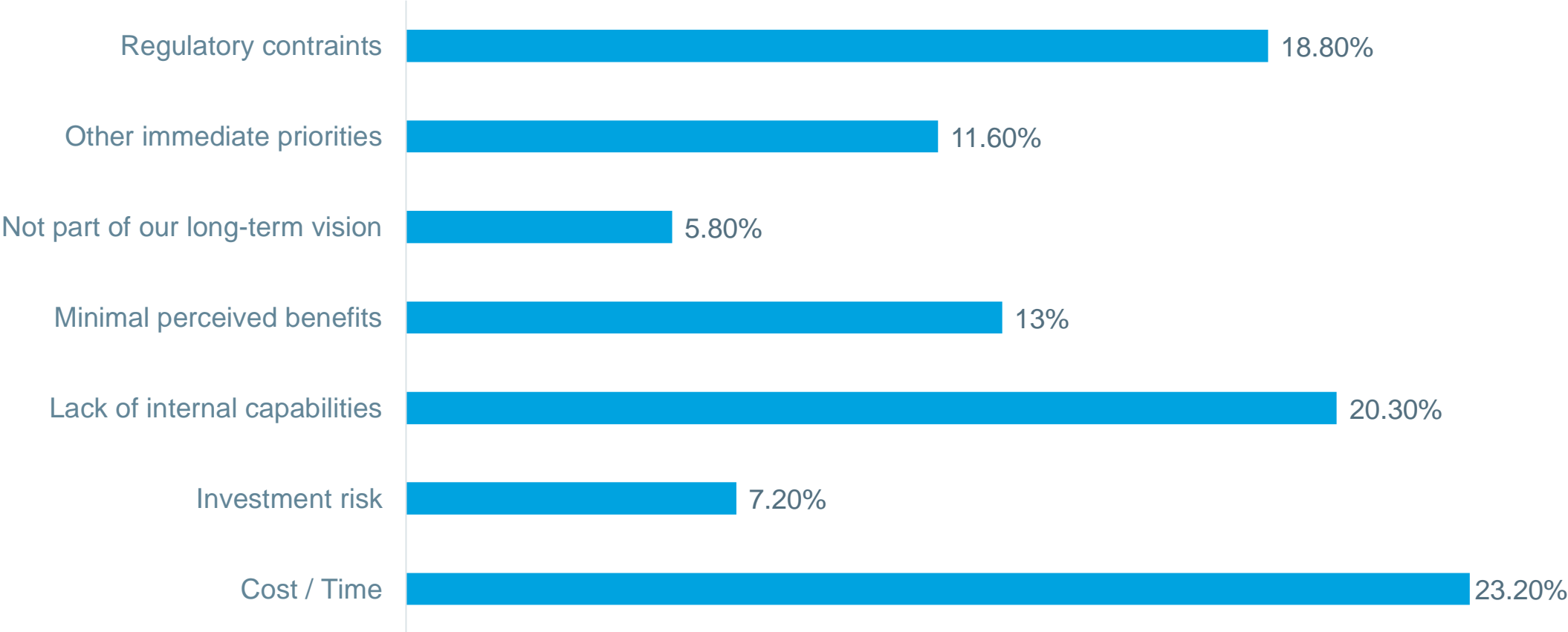


The Changing Environment Demands New R&D Strategies



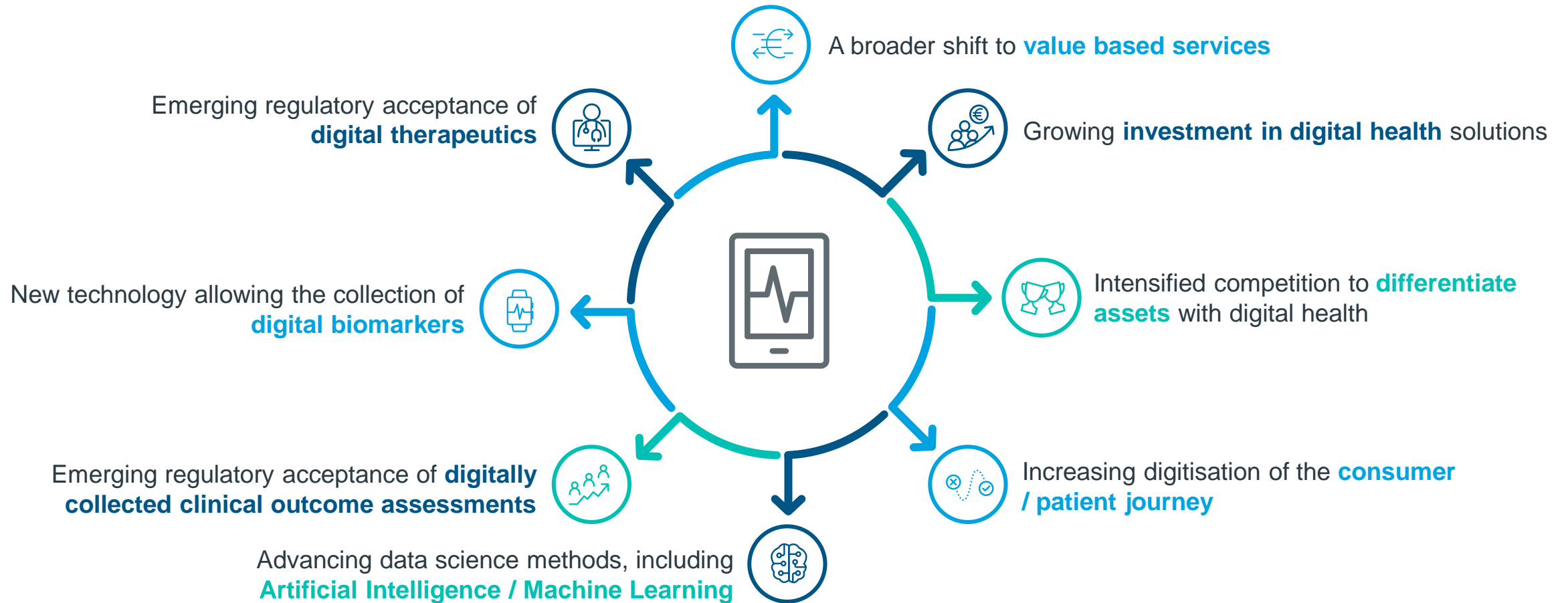
What are the major obstacles restricting digital health strategies in your company?

A poll conducted during the live broadcast



Digital health is becoming a 'must do' for the consumer health industry due to multiple market forces

Forces driving the growth of digital health



Digital Health initiatives are progressing worldwide

Frameworks around the globe are being developed to address digital health transformation

WHO / EU Digital Health Action Plan 2023-2030

- Accepted in Sept 2022
- Leverage & scale-up digital health transformation
- Align digital technology investments
- Respect the values of equity, solidarity and human rights

FDA Digital Health 2020

- Guidance on medical software
- Develop a Digital Health Software Precertification Pilot Program
- Build FDA's bench strength and expertise within digital health unit

FDA Digital Health Center of Excellence (DHCoE)

- Connect and build partnerships
- Share knowledge
- Develop innovate regulatory approaches

APAC region

- Best practice regulatory frameworks
 - TGA (Australia)
 - PMDA (Japan)
 - HSA (Singapore)
-
- Software qualification
 - Consultation
 - AI/ML framework
-
- APAC Medical Technology Association
 - Seeking active role in digital health harmonization

The industry has the chance to be part of the transformation process

Is the industry hesitant in Digital Health due to some uncertainties?

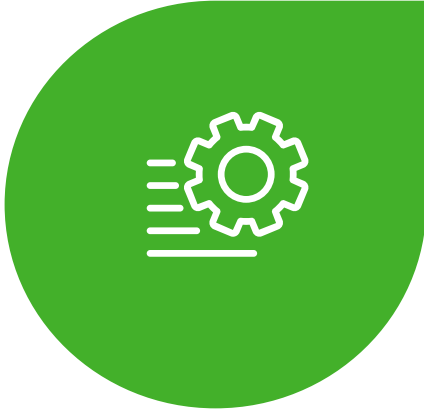
Uncertainty around regulatory situation?



Lack of internal capabilities?



Business model uncertainties?



No strategic fit?



A “Can-Do” attitude is key to be successful in digital health innovation

The CH industry needs to embrace new technologies

Innovative claims & holistic product / services are a huge opportunity



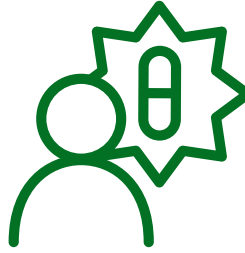
Recognize technology and digitalization as an opportunity for claims and service development



Develop in-house digital expertise and foster open innovation



Integrate digital health & diagnostics in your innovation pipeline



Adapt business models to reflect more outcome-focused and service-related offerings

Advancing consumer expectations require outcome-oriented solutions

Inside Digital Transformation for Consumer Health

November 29 – [Secure your place here!](#)

Your IQVIA Consumer Health contacts



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Thank You

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