Perspectives from the HEALTHINKERS

# Digital Health Innovation:
## How to realise technology's full potential across the patient journey

HEALTHINKERS
Designing the future of healthcare

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# Introduction

In today's healthcare ecosystem, digital health technologies—from apps to disease monitoring systems to digital therapeutics—act as the connecting threads between healthcare systems, the pharmaceutical industry, healthcare providers (HCPs), and patients. Now more than ever, we're seeing digital health innovation (DHI) help to improve patient experiences and outcomes across care journeys in a wide range of disease areas.[1]

HEALTHINKERS, curated by Healthware Group, an EVERSANA INTOUCH agency, and sponsored by Menarini, is a new group of multidisciplinary healthcare leaders who are committed to designing the future of health and building the next generation of DHI to benefit patients around the world.

Frontiers Health 2023 marked the first in-person meeting of the HEALTHINKERS. Four key opinion leaders (KOLs) convened for an advisory board to discuss the growth of DHI, its role in the cardiovascular and asthma and allergy spaces, and why patient centricity is critical to DHI's success. In this white paper, we'll synthesise the KOLs' insights and explore next steps to realise the potential of DHI to improve patient care.

**Featured HEALTHINKERS members:**

**Dr Nana Bit-Avragim**
EIT Health (Germany); DHL (Germany)

**Prof Jean Bousquet**
Institute of Allergology, Charité Universitätsmedizin (Germany);
*Clinical and Translational Allergy*

**Prof Stefano Omboni**
Italian Institute of Telemedicine (Italy); Department of Cardiology, Sechenov First Moscow State Medical University (Russian Federation)

**Dr Paul Tunnah**
Healthware Group, an EVERSANA INTOUCH agency (UK)

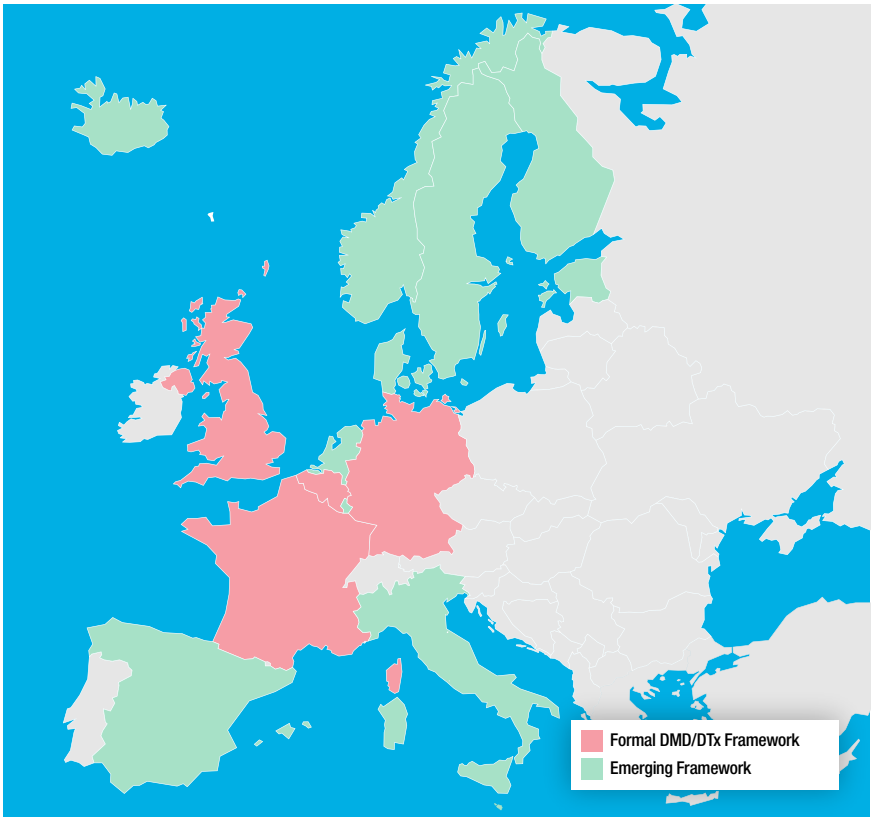
# Overview: The DHI landscape

DHI spans a broad range of technologies that benefit industry, HCPs, and patients alike.[1,2] During the Frontiers Health session, the HEALTHINKERS focused on patient-facing innovations used to augment traditional in-person care and close gaps in the HCP-patient relationship: from wellness tracking devices to remote patient monitoring tools, virtual care management, and digital diagnostics and therapeutics.

Though we've seen significant progress in the DHI space in recent years, the adoption landscape is fragmented. In most European countries, DHI solutions are treated as software as a medical device (SaMD). However, some countries have developed specific regulatory frameworks to allow for assessments of digital health solutions and enable access.[2]

Among Europe's digital health leaders is Germany, which introduced DiGA in 2019. With the Fast-Track Process for Digital Health Applications, German regulators created a pathway for reimbursement and access for digital health solutions.[2,3] France built on this in 2023 with PECAN, which enables early reimbursement for digital health tools.[2,4]

## Europe Overview: Digital Medical Device (DMD) and Digital Therapeutics (DTx) Policies[2]




Note: This is an evolving landscape. This map reflects the latest information as of June 2023.

Despite important steps toward advancing the use of digital technologies in healthcare, companies have seen a significant drop in digital health investment since the boom in 2021.[5]

"The investment environment is not what it was two years ago, and there's a real pressure on health systems to show that any drugs, devices, or digital health solutions are generating value," Dr Tunnah said.

Another critical success factor for DHI will be effective partnership across the healthcare ecosystem—between industry, patients, HCPs, and payers—to ensure solutions are truly useful, build a path to market, and encourage systemic adoption.

"There are some really good digital health interventions out there, but they will only deliver benefits if they're used by patients and doctors," Dr Tunnah said.

***"Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual."***

**—U.S. Food and Drug Administration**

# Opportunities for DHI across patient journeys and therapeutic areas

There are many opportunities for DHI to support patients throughout their care journeys. Below, we visualise where DHI can add value today.

## Examples of Digital Health Along the Care Journey

### Awareness, Prevention, and Activation

- E-learning to improve health literacy and awareness
- Online communities for patients to share and gain support
- Digital kiosks to collect data and educate patients
- Digital triage to assess care needs virtually before in-person visits
- Data ownership models that empower patients
- Secondary data business models to facilitate rapid innovations
- Integration of digital biomarkers to flag health risks
- Data models to simulate patient care

### Diagnosis

- Data- or AI-driven diagnostic tools
- AI-assisted clinical decisions
- Telemedicine and digital imaging to engage hard-to-reach individuals
- Teleconsultations to share information with other HCPs and improve diagnosis
- Decentralised and adaptive clinical trials
- Machine learning and natural language processing in predictive care
- Digital biomarkers

### Treatment

- Online drug prescription and dispensation
- Reimbursable digital therapeutics
- Telemonitoring of vital signs to personalise care
- Remote surgery
- Integrated care
- Outcome-based models for chronic conditions
- Digital biomarkers

### Adherence and Behaviour

- Participatory digital medicine
- Digital touchpoints to facilitate behaviour change
- Telerehabilitation
- Telepharmacy (medication review and management, including remote adherence tracking)
- Telemonitoring to obtain feedback on health status and adjust treatment as needed
- Smartphone apps to engage and empower patients to perform self-care
- Digital therapeutics reimbursement models
- Patient-centric design in hospitals
- Validation of devices by patient groups
- Patient advisory boards
- AI education for HCPs

### Continuous Care

- Remote patient monitoring (active and passive) and diagnostics
- Personalised therapy adjustment and telepharmacy
- Telemonitoring to ensure patient health status and long-term medication adherence
- Remote rehabilitation and at-home care services
- Digital triage to assess whether patients need an in-person visit to address concerns
- Digital twins to simulate patient care in data

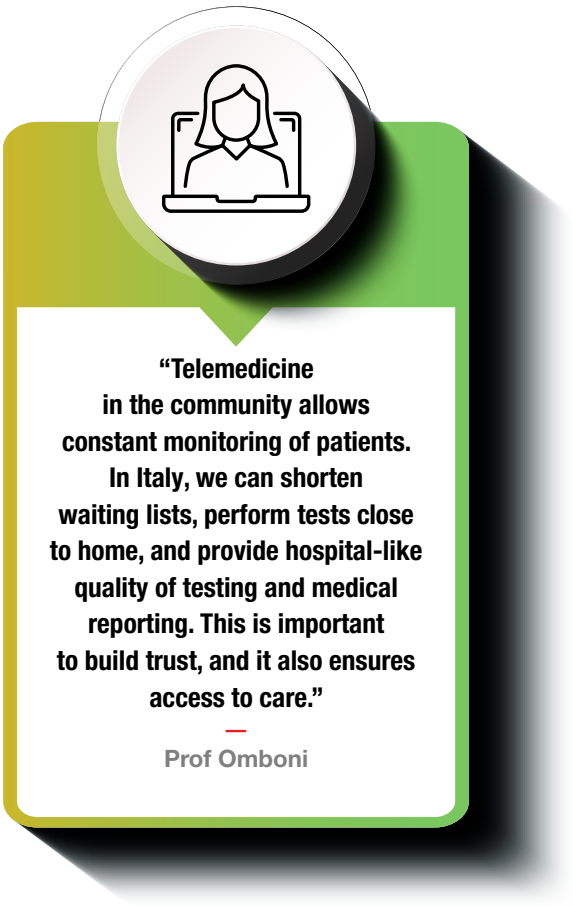
Digital health technologies and telehealth

# Deep dive: DHI and telemedicine in cardiology

In cardiology, Prof Omboni explained, "telemedicine is the real driver of digital health" throughout a patient's journey. For example, telemedicine and DHI can help prevent and screen for cardiac disease (to diagnose hypertension early, or to prevent acute coronary symptoms) and support home care services for people with chronic heart disease after they're discharged from the hospital. These technologies can also be used to optimise care through screening, surveillance, and virtual patient support.

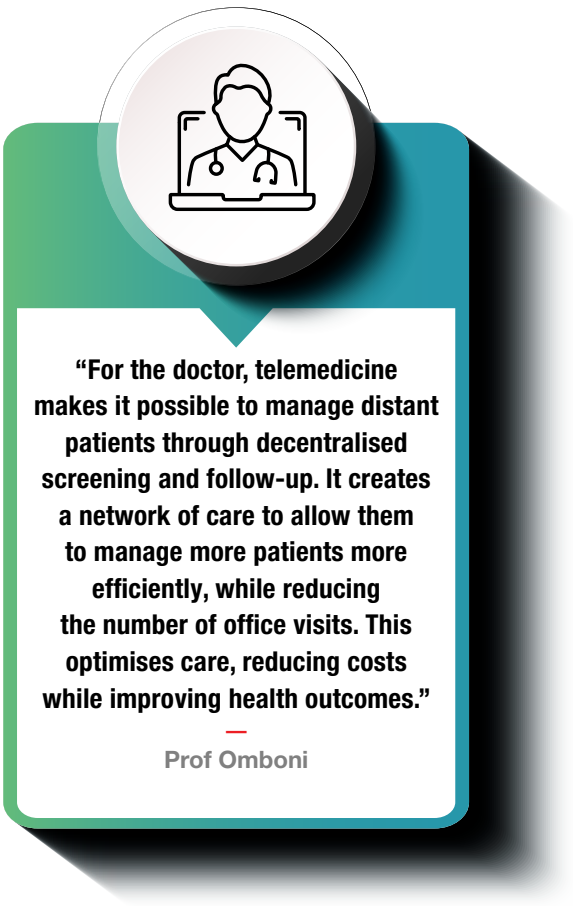
One key application for DHI is in the remote tracking of medication adherence: "Many patients aren't under-treated; they just don't take their drugs. Telemedicine is a way to strictly monitor these patients and empower them to manage their disease," Prof Omboni said.

## Benefits of DHI in Cardiology for Patients and HCPs



**"Telemedicine in the community allows constant monitoring of patients. In Italy, we can shorten waiting lists, perform tests close to home, and provide hospital-like quality of testing and medical reporting. This is important to build trust, and it also ensures access to care."**

Prof Omboni



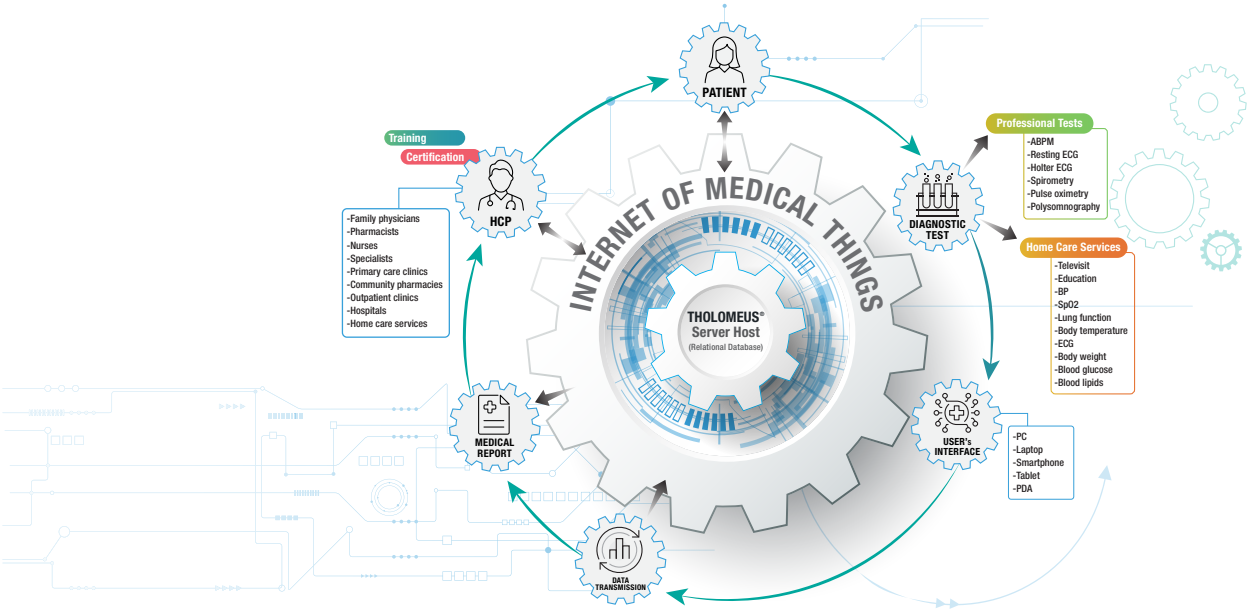
**"For the doctor, telemedicine makes it possible to manage distant patients through decentralised screening and follow-up. It creates a network of care to allow them to manage more patients more efficiently, while reducing the number of office visits. This optimises care, reducing costs while improving health outcomes."**

Prof Omboni

## Case study: Tholomeus®

Tholomeus® (Telemedicine and HOme teLemOnitoring for MEdical sUrveillance of chronic diSeases) is a clinically validated, web-based telemedicine solution for chronic diseases. The digital tool links multiple devices that patients use to measure their health (electrocardiograms [ECGs], blood pressure monitors, and more), combines and analyses data from those devices, and presents potential diagnoses of cardiac events to HCPs, patients, and/or pharmacists. The solution features an HCP-administered test, which in the last 10 years has helped 2,000 community pharmacists and HCPs provide ECGs and other simple tests to over 320,000 patients in Italy. Tholomeus* also provides a home test for patients, which has been used by 15,000 Italian patients thus far.[6,7]

**Tholomeus®: A Clinically-validated and Certified Web-based Telemedicine Solution since 2007[7]***




The TEMPLAR Project (TEleMonitoring of blood Pressure in Local phARmacies) is a registry that uses the Tholomeus® platform to collect and analyse data on blood pressure control in the community setting. Researchers compared data from 24-hour ambulatory blood pressure monitoring—collected with Tholomeus®—to blood pressure readings gathered at a moment in time in community pharmacies and HCPs' offices. An initial analysis found that only half of people in the office had controlled blood pressure when read over a 24-hour period, a higher reading than shown through in-clinic readings alone. Some patients' hypertension was masked in the clinic, but it appeared overnight or at other points in the day.[8]

As episodic, in-clinic blood pressure readings missed about half of patients' uncontrolled blood pressure episodes, the TEMPLAR study proves the benefit of DHI solutions like Tholomeus® to provide more accurate, continuous blood pressure readings and improve treatment for patients with hypertension.[8]

***This chart was prepared and provided by Prof Omboni for Frontiers Health 2023. Colours and design were modified to fit this white paper.**

# Deep dive: How DHI improves understanding of asthma and allergy patients' needs

As both an allergy patient and physician, Prof Bousquet understands that the keys to digital health success are simplicity, accessibility, and patient centricity.

"The patient needs to understand what the app does and shouldn't need to have training to use the app and gain benefit from it," Prof Bousquet said.

Embracing this approach to DHI solutions will support adoption and promote better health outcomes, for example, through easy-to-use DHI solutions that encourage behaviour change to improve asthma and allergy symptoms.

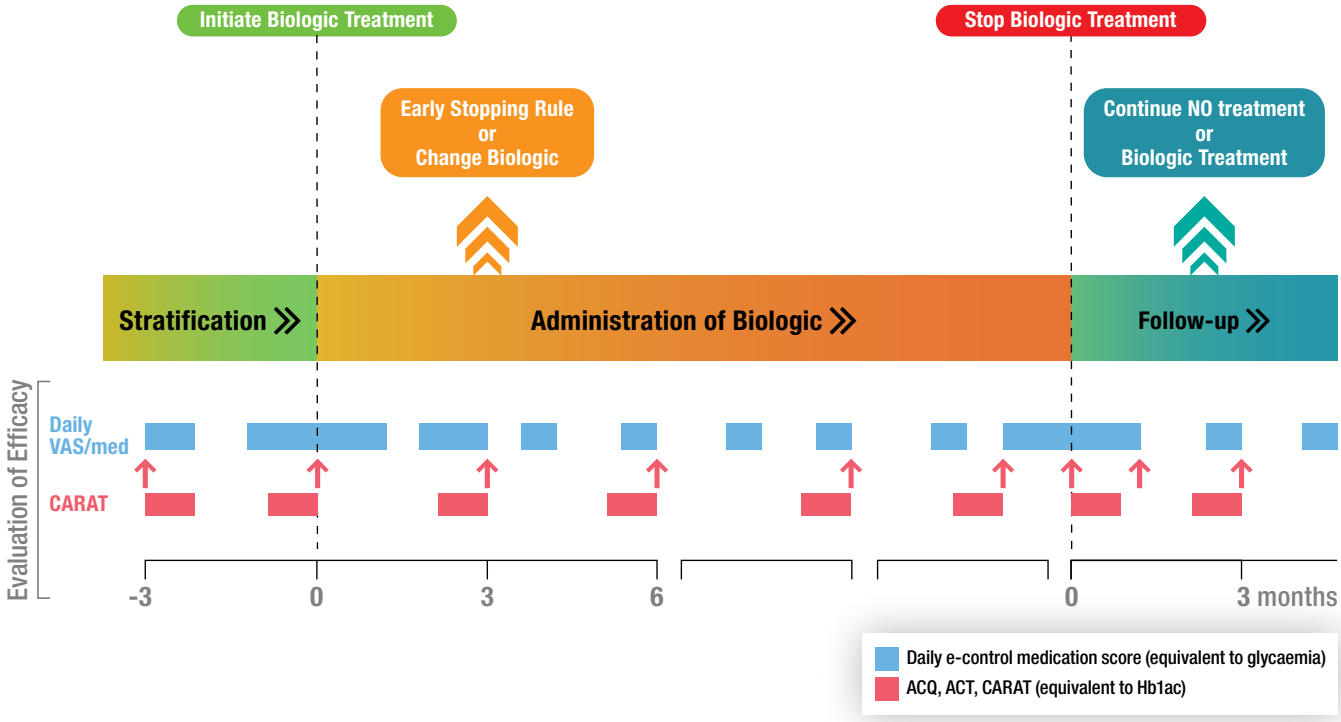
## Case study: MASK-air®

MASK-air® (Mobile Airways Sentinel Network) is a free, four-question app used to gauge how allergy and asthma symptoms impact patients. Users are prompted daily with questions on how their overall, nose, eye, and asthma symptoms are bothering them on a given day. They record their responses on a scale from "not at all bothersome" to "extremely bothersome," which generates useful data on allergy symptoms that patients can use to communicate effectively with their HCPs and improve self-care.[9,10]

To date, MASK-air®—which is available in the Apple and Android app stores—has been used in 35 countries and translated into over 20 languages. The regulatory-compliant and certified app has over 60,000 users who have logged a cumulative 620,000 consecutive days of data in the app. Findings have been published in 55 papers, which validate and build on the patient-reported outcome data in the app.[9-12]

One study used MASK-air® data to develop and validate an electronic daily asthma control score (e-DASTHMA). When used together with frameworks that assess asthma symptoms over a period of weeks like the Asthma Control Questionnaire (ACQ), Asthma Control Test (ACT), and Control of Allergic Rhinitis and Asthma Test (CARAT), e-DASTHMA may present a new treatment approach for patients with asthma. Similar to how clinicians who treat diabetes use HbA1c for long-term monitoring of diabetes control and glycaemia as an indicator of daily symptoms, long-term frameworks can assess asthma symptom control over time with e-DASTHMA as a daily metric.[13]

### The Diabetes Solution for the Management of Severe Asthma*




*This chart was prepared and provided by Prof Bousquet for Frontiers Health 2023. Colours and design were modified to fit this white paper.

# What patient centricity in DHI looks like

Novel technologies have advanced and personalised healthcare, but many patients still struggle to navigate the healthcare system and access the care they need. To ensure success in DHI, "patient centricity must be a driving and foundational part of digital health," said Dr Bit-Avragim.

Developing DHI solutions that are truly patient-centric means prioritising the privacy and security of patients and their health information.[15] In addition, patients must be aware of the tools available to them, and any new solution must be designed with usability and accessibility in mind. While we can see some of this today—for example, with usability testing of digital solutions, secure telemedicine, and biopharma companies' patient advisory boards—other key tenets of patient centricity are overlooked.

## Patient centricity challenges to address in digital health[14]

**44%** of patients lack confidence they can access care in a timely manner

**42%** of patients have little trust in their healthcare system providing affordable care

**37%** of patients have little confidence they will be treated when needed


*"We still see patient feedback ignored in the DHI solution design process, as well as aggressive approaches to data collection which lack transparency."*

—Dr Bit-Avragim

By co-creating DHI solutions with patient advocates or experts, sponsors can help drive DHI adoption and utilisation. Patient insights can ensure the following are true about new digital health products:

| | |
|---|---|
| ✔ | Solutions are usable and intuitive |
| ✔ | Solutions fit into patients' real lives and accommodate for their needs and cultural beliefs |
| ✔ | Adoption isn't blocked by barriers to access (e.g., with technology or financial reimbursement) |
| ✔ | Patients trust DHI tools to support their health while protecting data privacy |

A patient-centric future in digital health will support access to care through improved communication, education, and use of technology in patient care. Patient advisory boards and partnerships between patients and HCPs can guide the future of treatment, and navigating challenges with data collection and storage will further advance the information we can use to continue to personalise care.

"Today's healthcare system should be a learning ecosystem of patient centricity," said Dr Bit-Avragim. "We must start from the patient need and learn from them, then communicate and collaborate with healthcare professionals, digital health leaders, and others in the market to continuously give back to the patient."

# Current gaps and barriers in DHI adoption

To achieve success with DHI in healthcare, we must first overcome the following challenges across the health journey.

## The Health Journey: Examples of Current Gaps, Needs, and Barriers

### Awareness, Prevention, and Activation

- Lack of incentive for preventive care
- Lack of access to meaningful care and systemic well-being resources and knowledge
- Fear, misinformation, and lack of trust due to gaps in communication between patients and HCPs

### Diagnosis

- Delayed or missed diagnosis due to lack of time, lack of facilities, or long waiting lists
- Lack of digitisation of care and gaps in adoption of digital technologies by HCPs
- Lack of healthcare data standards
- Limitations due to regulations or policies
- Lack of patient-centric diagnostic design

### Treatment

- Drug-only treatment with little focus on lifestyle changes
- Treatment delays
- Mismanagement of drug safety, leading to inefficacy
- Lack of AI-based treatment regulations
- Lack of patient involvement in drug repurposing research
- Gaps in outcome-based care adoption

### Adherence and Behaviour

- Lack of adherence to DHI solutions and/or lack of adherence monitoring by HCPs
- Lack of focus on behaviour change as a driver of health
- Use of wrong treatments reduces efficacy, increases risk of adverse reactions, and discourages adherence
- Poor design of digital solutions

### Continuous Care

- Lack of timely treatment adjustments
- Lack of digitisation of care
- Lack of quantitative and qualitative data gathering
- Lack of digital triage integration
- Lack of digital twins technology integration to simulate patient experiences in data

Lack of access to/scarcity of HCPs and healthcare resources

Lack of HCP knowledge and education on digital health and digital therapeutics

Lack of adequate communication between patients and HCPs

Lack of efficient collaboration between HCPs

Lack of easy access to care

Lack of incentives for HCPs to receive digital health education and training

Digital divide for patients and HCPs

Lack of guidelines and reimbursement for DHI

# Recommended actions for the future of DHI

As demand increases for digital health interventions to support patients across their care journeys, the HEALTHINKERS share recommendations for how to bring DHI solutions to market, gain reimbursement, and achieve systemic adoption.

### Generate evidence to prove value of DHI solutions

"If you look at DHI at scale today, few solutions have published evidence to show they work. We need to focus on demonstrating a positive impact first, then we can think about a path to market that ensures our good innovation can scale and benefit patients."

—Dr Tunnah

### Create incentives to encourage adoption and development of DHI – and promote them

"In Germany, DiGA offers digital therapeutics reimbursement mechanisms. It's fantastic legislation that presents a great opportunity, but many of my colleagues haven't heard about it. HCPs should know about this opportunity."

—Dr Bit-Avragim

### Ensure DHI solutions are high quality and meet patients' needs

"Many solutions on today's digital health marketplace are useless. To make them work, we need to improve technology, simplify the use of these technologies, increase connectivity, improve infrastructures, and increase education among patients and HCPs."

—Prof Omboni

### Empower patients to drive DHI awareness and adoption

"We have to educate patients about DHI, but patients can also help educate and implement awareness with doctors."

—Prof Bousquet

### Facilitate stakeholder collaboration

"We'll need to see investors, industry, patient groups, and KOLs applying pressure for a clear pathway to get DHI solutions out there and reimbursed. This is for the good of patients."

—Dr Tunnah

### Build trust between patients, HCPs, and the healthcare system

"Trust is born when the HCP communicates with the patient, but it needs to be nurtured over time through collaboration and communication between the HCP, the caregiver, and the patient. Once the trust is established, then DHI solutions can be adopted and treatment will become more successful."

—Dr Bit-Avragim

### Improve integration and interoperability of technology systems

"It's important that DHI solutions integrate with the existing healthcare system. In Italy, for example, we have the National Platform of Telemedicine to provide a centralised set of telemedicine solutions for public hospitals. Rather than sourcing solutions from different companies, this platform helps public hospitals and private providers offer the solutions to patients."

—Prof Omboni

### Leverage shared decision-making as a DHI adoption driver

"Shared decision-making will be an important improvement in digital health. I can imagine a future where only patients who are adherent to medication– and demonstrate medication adherence via a digital health app prescribed by their doctor– will be covered for their treatment."

—Prof Bousquet

### 2025 outlook

"Person-centric care enabled by technology will become mainstream. Care will move near patients' homes to bring structural changes in health systems and allow the introduction of preventive medicine. Growing dominance of AI will permit molecular diagnosis and disease modelling, the new direction in medicine."

—Dr Bit-Avragim

# About the experts

## Dr Nana Bit-Avragim

**Advisor and Startups Mentor, EIT Health (Germany); Senior Manager/Expert, Life Sciences and Healthcare, Group Digital Pursuits, DHL (Germany)**

Dr Nana Bit-Avragim is a passionate transformer, experienced health and biotech leader, and the next-gen healthcare ecosystem builder. She loves solving challenges and building solutions from scratch. To translate the latest global technological developments into life sciences and align them with the healthcare industry, she successfully built and led a broad scope of innovative programs and partnerships between SMEs, NGOs, healthcare industry, and academia in her previous roles as Director of Entrepreneurship and Innovation at Charité Foundation and Head of Digital Health & Life Sciences program at the German hub of Singularity University. As an advisor and mentor for a few EIT Health startups and early-stage ventures from Europe, the UK, and Israel, Dr Bit-Avragim applies her talents to offer both a strategic vision as well as concrete actions to achieve.

## Prof Jean Bousquet

**Professor, Institute of Allergology, Charité Universitätsmedizin (Germany); Editor, *Clinical and Translational Allergy***

Prof Jean Bousquet holds a chair at Charité Universitätsmedizin, is editor of *Clinical and Translational Allergy,* and has chaired the Global Initiative for Asthma (GINA) from 1999-2000, Allergic Rhinitis and its Impact on Asthma (ARIA), and the WHO's Global Alliance against Chronic Respiratory Diseases (GARD) from 2006-2013. He has a research interest in the mechanisms of allergy, multimorbidity of allergic diseases, severe asthma, and the digital transformation of health and care to sustain planetary health. He has published over 1,000 papers and is the most influential author in asthma.

## Prof Stefano Omboni

**Director, Italian Institute of Telemedicine (Italy); Professor of Cardiology, Department of Cardiology, Sechenov First Moscow State Medical University (Russian Federation)**

Prof Stefano Omboni is a cardiologist, Director of the Italian Institute of Telemedicine, and Chief Researcher at the Scientific Research Department of Cardiology at the First Moscow State Medical University. His work is focused on researching and developing new telemedicine solutions to diagnose and manage chronic diseases. He is the Scientific Coordinator of the TEMPLAR Project, a pharmacy-based Italian registry on ambulatory blood pressure telemonitoring, and of the VASOTENS Registry, an international registry on ambulatory blood pressure and arterial stiffness telemonitoring. He has published original papers in the field of blood pressure monitoring, telemonitoring, arterial hypertension, cardiovascular disease, telemedicine, clinical physiology, and pharmacology.

## Dr Paul Tunnah

**SVP, Managing Director, Global Integration, Healthware Group, an EVERSANA INTOUCH agency (UK)**

Dr Paul Tunnah founded pharmaphorum in 2009, which combines industry-leading publications, strategic consulting, and a content-driven stakeholder engagement agency. He is a recognised author, speaker, and industry advisor with a passion for helping organisations tell authentic stories that resonate, co-create solutions, and unlock the power of digital and social media in connecting with customers and understanding markets. Dr Tunnah holds a BA in Biochemistry and DPhil in Biological Sciences from Oxford University. Dr Tunnah currently serves as Senior Vice President, Managing Director, Global Integration at Healthware Group, an EVERSANA INTOUCH agency. This next-generation integrated consulting group operates at the intersection of the transformation of commercial operations and digital health.

# About HEALTHINKERS

HEALTHINKERS, curated by Healthware Group, an EVERSANA INTOUCH agency, and sponsored by Menarini, is an Advisory Board composed of multidisciplinary healthcare leaders who are committed to designing the future of health and building the next generation of DHI to benefit patients around the world.

**The HEALTHINKERS mission is to:**

1. Collaborate with experts and stakeholders in designing innovative solutions for the healthcare industry.
2. Create a better future for healthcare by embracing digital innovation, new technologies, and novel ideas.

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