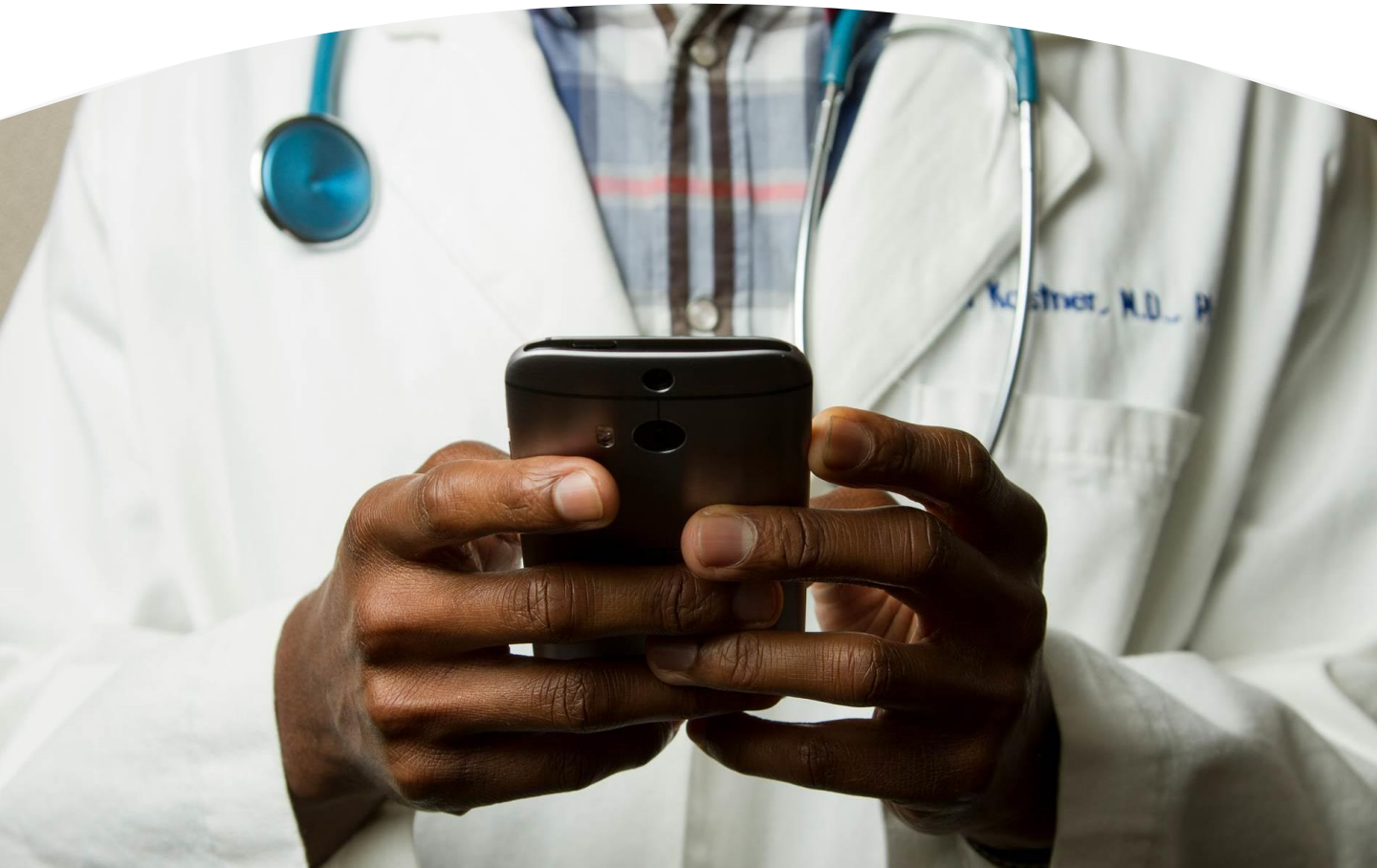
WAVESTONE

Digital Health Radar 2024

Summary



Digital Health Radar 2024

Opening Insights

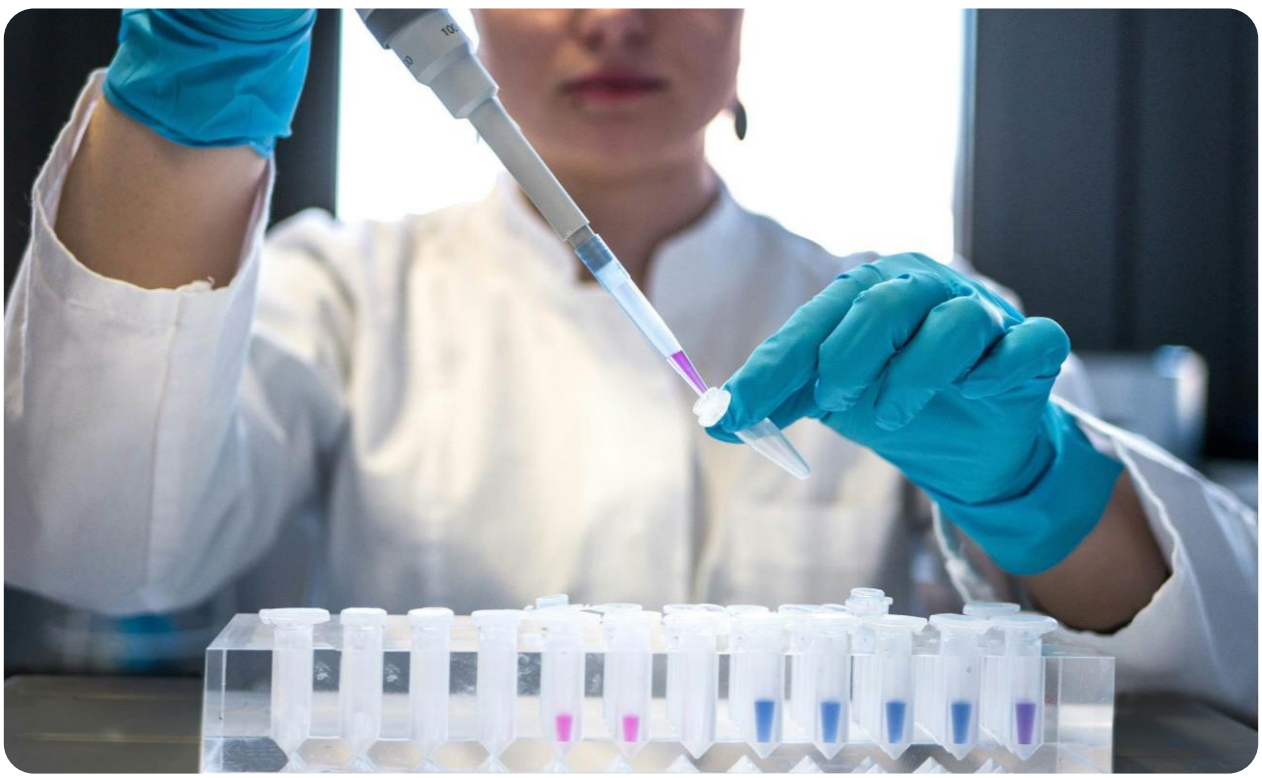
Since COVID, we and our clients have observed a discernible change in how healthcare is delivered to patients globally. Digital health is seen as a transformational part of this change in healthcare provision. This is evidenced by renewed impetus in the startup space with investment reaching $3 billion in 2021. Our first interviewee, Lucy Jung, founder and CEO of Charco Neurotech, noted this trend, highlighting the rise in healthcare-focused product development and technology.

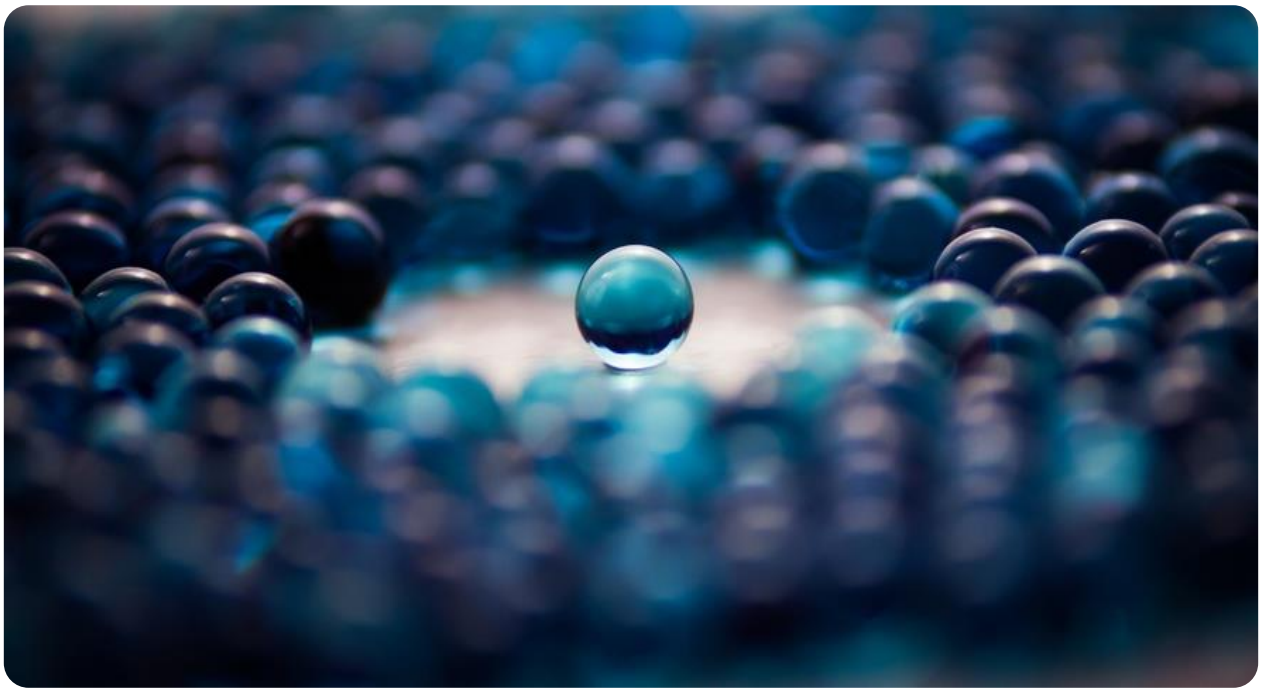
However, the situation is not entirely positive. In 2023 investment declined to $1.1 billion, indicating that other economic and geopolitical developments may be leading to volatility. Factors such as the emergence of open-access GenAI, the war in Ukraine, the Palestine-Israel conflict, issues in the Gulf of Aden, rising gas prices, and general inflation may all play a part.

Pharma's response to digital health has been mixed. Whilst Biogen closed its digital arm, Eli Lilly and Company released its own digital health solution: LillyDirect™ and AstraZeneca has taken the plunge to spin out its digital health development arm into Evinova, leading to mixed signals across the board. Utilising startups to supercharge innovation could be a way to bridge the gap for those cautionary Pharma companies wishing to expand.

"When we started in 2019, there weren't many people in the product development and tech area that were looking into healthcare. There was lots of research concepts but not many companies or support in this space. I'm excited to see the importance of this rising over the years."

Lucy Jung Co-founder & CEO, Charco Neurotech





"The general trend is towards partnership, towards partnering with startups like ourselves because we can provide the development capability, we can provide the platform. They don't need to do all that. They don't need to hire software engineers. They need project managers or project owners which is an easier role to fill in Pharma."

Jamie Campbell Associate Director of Commercial Partnerships, Avegen

In our 2023 White Paper 'Competing through Customer Value' we discussed how partnering between startups and pharma can allow companies to generate value for patients and customers at a quicker pace. This view is something Jamie Campbell, Associate Director at Avegen, points out, describing the efficiencies that can come with employing external expertise. Digital health solutions can also help to remove some of the cost from providers, freeing up investment to other parts of the healthcare system and enhancing value for customers. Looking to the startup scene may therefore help to discern the future of this dynamic space.

Whilst the digital health startup market within the US is well developed, with several examples of unicorns (such as 23andMe as of 2015 or Tempus as of 2018), the market within Europe has not been as fruitful. There are several potential reasons for stagnation. These include the universal healthcare models commonly utilised in Europe, which can make profitability more challenging and consequently less appealing to investors. Additionally, Europe's fragmented nature results in numerous smaller markets, collectively totaling 500 million potential users, as opposed to a single market of 350 million potential users in the US.

There are some very good examples within Europe of companies developing beyond a single market, companies, such as Owlstone Medical, have become profitable and successful across multiple markets, bridging the gap to the US and globally. Considering these green shoots, we have analysed the European startup market and highlighted the key developments, trends and examples of companies that we are eager to watch that have innovative solutions or that are making waves in the market. You can find out more about our methodology here.

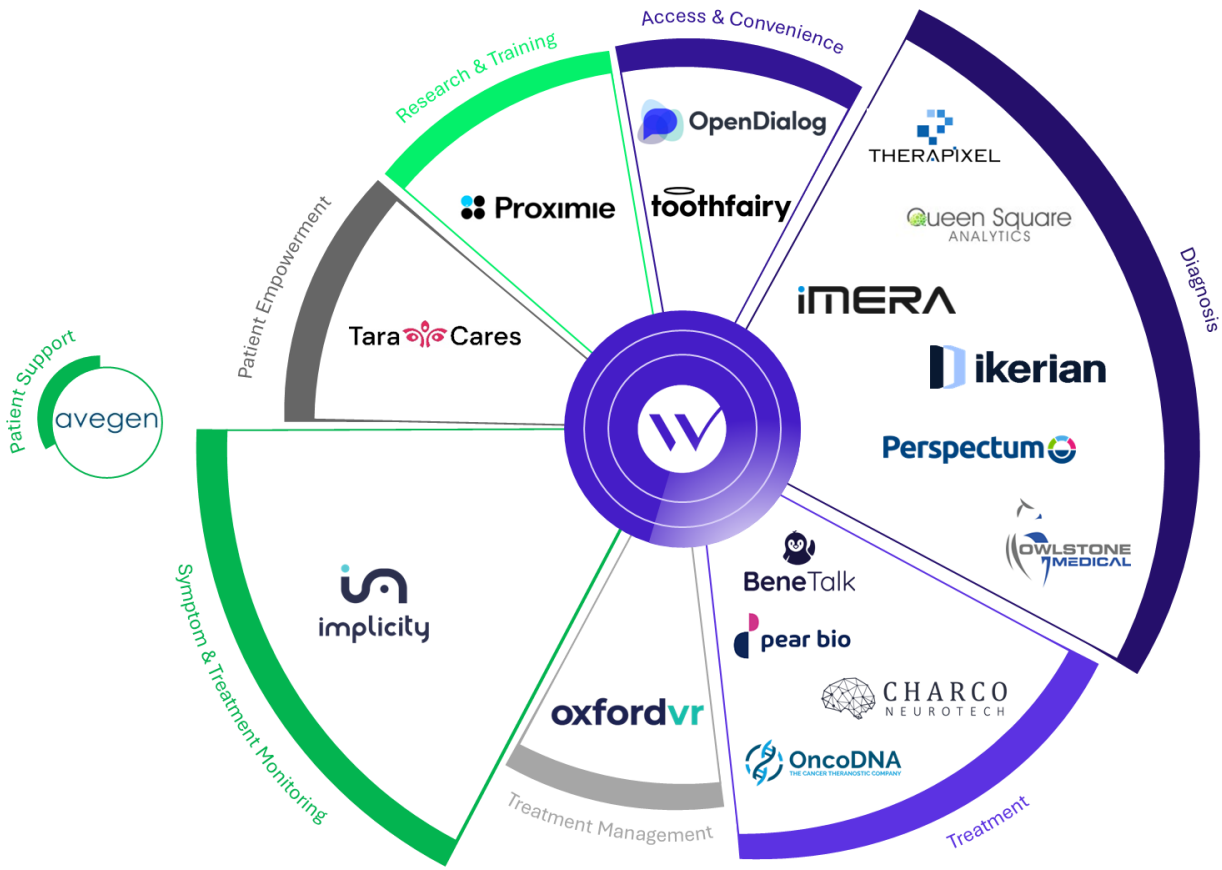
The Digital Health Radar Startup Longlist 2024

Our longlist illustrates our interpretation of the dimensions of the digital health startup space. Displayed are the unique and innovative offerings that have the potential to transform patient care.

An important point to note is that telemedicine and mHealth propositions are conspicuous by their exclusion from the Radar. The number of these have skyrocketed following COVID and continues to grow; in 2020, 250 new digital health apps were added to the app store per day[1]. Due to the scale of this sector, we have therefore limited their appearance in our Radar to a few special-case examples we believe to be truly innovative. This includes Mika, an AI-powered companion for cancer patients and care givers, BeneTalk, a habit building app for stammering that analyses speech and provides real time feedback.

Our Shortlist

Our shortlist depicts what we believe to be the potential future leaders in digital health innovations.



Our interpretation of market insights

Overall, we see four key trends across the startup market:

1. Providing information to patients and investors fuels success
2. Gathering information and patient insights improve prospects
3. Companies addressing multiple touchpoints across the patient journey show great potential
4. There is a growing requirement for evidence-led DTx and healthcare solutions

Market Insights

1. Providing information to patients and investors fuels success

One critical observation we gained from cycling through 574 companies, was that this market is vast. To float to the top, startups are benefiting from using validated research to differentiate themselves and increase credibility. There are numerous examples of this throughout our long list.

One-way startups are doing this is by focusing on information provision to drive patient education, adherence and drive value and success. What has become of increasing importance to patient providers and users is that the information provided is accurate and ever increasingly actionable.

Across the board, the results are consistent – evidence-based approaches are key for patient engagement. This includes patient studies across conditions and therapy areas, including asthma, diabetes[3] and hypertension[4]. Likewise, studies such as Tinschert et al. 2019 show the importance of evidence-based information in gaining patient trust in AI chatbots.

Whilst you may be able to provide information to patients, what can you do with that information?

We saw a saturation of digital apps that focused on bringing patients to doctors; however, reducing the impact on healthcare systems by preventative measures is incredibly important, especially if we wish to achieve sustainable healthcare systems.

It is therefore essential we look to education, based on peer reviewed information, to support patients in everything from treatment choice to behavioural support. This is a gap seen by TaraCares who turned individualized research into meaningful insights to inform hormone healthy ageing for subscribers of its MIMOSA platform. Founder and CEO Jyoti Sharma spoke to us about the importance of centering science in the conversation around age-related health

The company looks to enable its users to gain a better control of their bodies holistically, which brings agency and inevitably can reduce impact on the individual, employers, and healthcare systems. Healthy ageing and better understanding of our bodies and the changes that they go through as we progress through life is of increasing importance to patients (and consumers).

However, with greater evidence often comes greater regulatory oversight. To combat some companies are beginning their propositions by recommending information, slowly building the greater scrutiny needed for building a medical device or digital therapeutic. This method has the added benefit of enabling trust building and credibility in the space.

"We are levelling up the science for healthy ageing. By personalizing science based on individual differences for hormonal shifts and transition including Menopause we are shaping the future of female work for generations to come and delivering a health-oriented employee-employer care model

Jyoti Sharma Founder and CEO, TaraCares

2. Gathering information and patient insights improves prospects

Of course, there is a duality to this information. As more patients begin to use digital health solutions, more information based on consumption becomes available to the companies themselves. Lucy Jung of Charco Neurotech spoke to us about some of the benefits she found from leaning in to this open and curious approach to patients to provide pivotal insights for its CUE1 wearable. Lucy reflected on a conversation she'd had with a committee member and friend who was living with Parkinson's. He pointed out to her the difficulties in conveying the complete and diverse struggles of the disease by looking purely at clinical data. One day, he had visited London for a doctor's appointment. Whilst seated he realised he had become unable to get up, left going in circles on the tube and unable to move. He'd asked her: **"if I wasn't able to make one step that day, how can you measure that?"** Those words stuck with Lucy and have shaped Charco Neurotech's approach to its patients; utilise clinical trials whilst staying close and curious with the people they are trying to help.

On a human level these insights are essential to remember the purpose and impact of these digital health solutions and provide direction for opportunities for development, potential risks or areas for diversification. Likewise, adding meaning to your data can create buy in for investors and consumers alike.

> **"We're not looking to one answer. We're looking for lots of answers... It's not just clinical measures that are important – remember to think about the people"**
>
> **Lucy Jung** Co-founder & CEO, Charco Neurotech

3. Companies addressing multiple touchpoints across the patient journey show great potential

When investigating the performance of our longlist we began to see a trend with numerous offerings reaching funding, development or clinical milestones when addressing multiple touchpoints across the patient journey. For example, we have seen companies such as Ikerian, with its RetinAI platform, supporting clinical research flows as well as AI enabled eye diagnostics and decision support reaching funding and partnership milestones.

We value connection with people using or waiting to use the device. Once the loop is broken, innovation suffers."

Lucy Jung Co-founder & CEO, Charco Neurotech

4. There is a growing requirement for evidence-led DTx and healthcare solutions

Need for Validation

The European medical space is arguably one of the most evidence-led industries in the world, highly vetted and highly regulated. It appears the digital health space is catching up to the established standards of this industry and its pharma companies which hold the wealth and influence to support new startup success. Producing our Radar, the shift towards investment in technologies evidencing their clinical value was apparent; perhaps helping these offerings to stand out against the plethora of unvalidated telehealth solutions that have flooded the market in recent years.

Where HCPs and payers are the customer, clinical evidence or publication provides validation in a market that values robust scientific approach. Avegen Associate Director of Commercial Partnerships, Jamie Campbell, detailed the need for evidence to support its cloud-hosted, Digital Clinical Workflows. The company recently received the gold award from HSJ for clinical partnerships as its Klick offering reduced waiting times from 6 to 3 months and decreasing missed appointments by 41%.6

Current Challenges

However, whilst the demand for evidence backed healthcare solutions prevails, the level of evidence required for digital health technologies within each of these segments varies greatly. Ambiguity within the requirements defined by regulatory bodies remains a challenge and organizations are starting to pre-empt more robust regulatory positions in this area, leading to an increase in clinical validation for digital health technologies. Even those digital health technologies that are not regulated as medical devices are starting to collect data to evidence effectiveness and back up claims. The recent AI act from the EU further impacts here, the addition of data privacy and usage regulations for AI make it more complex to get the data and insight needed to provide maximum value for new solutions and enable validation.

Finally, to the point around regulation, ensuring cybersecurity has been thoroughly baked into any digital solution that contains data remains paramount for future or ongoing success. An example of this is RetinAI, an AI-powered eye diagnostic data management platform used to support clinical research workflows. Now boasting 20 processed clinical studies, over 40 peer reviewed publications to date and a 2023 CE Marking Certificate for Discovery as a class IIa device. [7]

Finding the Solution

However, whilst our Radar exemplifies the standouts in the market capitalizing on evidence-led solutions, it appears many have fallen behind. A 2022 study estimates only 20% of health tech companies have good clinical evidence and regulatory filings.[8]

Ironically, the answer to many of these hurdles might lie in some health tech companies featured on our list. For example, TrialBee is a comprehensive recruitment, pre-screening and consent solution designed to drive trial efficiencies through scalable, real-world data and real-time analytics.9

Another great example is uMotif, a patient engagement platform for clinical and post-market research. Its case studies have shown both an increase in compliance and a reduction of study timelines by 30%, demonstrating the expertise and financial benefits of its services.10 Sano Genetics also offer patient search, screening and engagement services in what they call 'a complete circle' platform that utilises DNA analysis to suggest clinical trials to viable candidates.11 These offerings may therefore help to generate robust evidence with greater ease and speed

"One place many digital health companies fall down is that they don't collect any clinical evidence. We believe it's really important to back up our claims with evidence and outcomes."

Jamie Campbell Associate Director of Commercial Partnerships, Avegen

A View to the Future

Regulators must also catch up to these changes. As Lucy Jung states, regulators must, and are adapting to the evolved digital care pathway. An example of this can be seen in Germany with the introduction of DiGA in 2019. This initiative includes a Fast Track process for streamlining formal approvals and listings of digital healthcare applications, enabling faster market entry. DiGA is symptomatic of the demand and competition faced in this space with startups needing to offer innovative and effective solutions to meet the DiGA directory criteria.12

Changes can be seen in the rest of Europe too, with the European Health Data Space (EHDS) proposing new regulations that mandate data sharing in the healthcare space, implying greater access to health data.

Alongside these new technologies comes a need for companies to adapt their internal governance, ensuring compliance with new directives such as the AI Liability Directive (AILD) and the previously mentioned AI Act.

Startups and pharma alike must prepare for the challenges of assessing and elevating risk management, traceability and cybersecutiry.13

"Technology's one thing, regulations and trials are still traditional pathways of pharmacological process (phase 1/2/3) when digital care is a quite different pathway. I feel positive that regulators are realising this and adapting and pushing out regulations. This is a challenging area but it's amazing to see people are more interested and founders are getting involved. I'm hopeful. There's a lot to do and we need to collaborate across industries"

Lucy Jung Co-founder & CEO, Charco Neurotech

With dynamism and new players always coming to the market, the digital health startup landscape in Europe remains of critical interest to healthcare systems and pharma. We look forward to seeing how the startup market adapts and changes in the coming months and years and to learn what new developments our shortlist companies have in store.

Select Case Studies

Charco Neurotech

Mission

Lucy tells us: my personal goal is "bringing back smiles to people with Parkinson's". It's the device, the service. It's the total that makes a big difference. We're not a device company, we're a company that cares for people. We want to help other people with movement disorders and neurological conditions.

Tech

The CUE1 is a non-invasive, wearable, medical device for people with Parkinson's, to improve movement and quality of life

Purpose

The principle offering of the company stems from 19th century French neurologist Professor Jean-Martin Charcot who found his patients' symptoms dramatically improved when they travelled to him by carriage. It was soon surmised the vibrations of the carriage ride seemed to offer therapeutic benefit. In modern day, this idea has since been researched with studies finding vibration stimulation to result in improvement in stiffness, slowness and gait among other symptoms.

Testing

Pilot tests have seen participants with Parkinson's improve their MDS-UPDRS scores by an average of 9.3 points, 3 times the level considered clinically significant. 100% of participants reported that they would want to use the device again. Continuing to study – 3,200 people currently using the device and being studied for they're using and the symptom category.

CEO
Lucy Jung

Website
charconeurotech.com

HQ
UK

Category
Wearable / Digital Therapeutic

Therapy Area
Parkinson's with a focus on stiffness, slowness and gait

Funding
Seed funded. Last investment November 16th, 2021, of £7.4m

Avegen

CEO
Dr. Nayan Kalnad

Website
avegenhealth.com

HQ
UK

Category
Patient Support

Therapy Area
Long term conditions

Funding
Privately funded with intention for series A funding

Tech

Customizable digital health platform

Purpose

Clinician Nayan Kalnad and Neeraj Apte created Avegen in 2015 following a successful and educational experience in Pharma and tech with the mission of making the world a healthier place. Avegen is driven by patient insights and cutting-edge research

Testing

Avegen has conducted multiple studies on its apps to ensure its claims are backed up with evidence. This includes a published study for Heart Health finding a 51% reduction in 6-month readmissions and a 30% increase in clinical capability. Its randomised clinical trial for its Together for Her app found a 90% increase in health literacy and a 142% increase in dietary diversity. It also tracked 1.9 million installs, positioning the app in India's Top 3 for parenting at the time of the study.

TaraCares

Mission

Levelling up the science for healthy ageing

Tech

Responsible AI-based digital support tool and education

Purpose

Equipping every human to master their unique healthy ageing journey with personalised research and health insights (with menopause navigation as an initial use case) by tackling misinformation, misdiagnosis, and mismanagement. Integrating academic research, clinical excellence and computational science.

Product

MIMOSA, the modular platform developed by TaraCares, is revolutionizing the way corporates address menopause. With its evidence-led, science-backed approach, MIMOSA offers continual access to research, and scientific evidence tailored for the user. From tracing 29 hormonal health determinants to preparing for medical appointments, the platform provides a comprehensive solution for women navigating menopause. More than just a tool, MIMOSA represents a shift in mindset. It encourages organizations to move beyond superficial menopause policies and invest in science-backed, actionable strategies. By understanding their menopause demographic and individual pain points, companies can create a more inclusive, supportive work environment. In doing so, they not only retain valuable talent but also foster a culture of understanding and empathy. MIMOSA looks to avoid the traps of symptom tracking and hormone testing to provide holistic support and information. In a revolutionary ground-breaking move the company has released, MIMI (Menopause Information and Management Interface) after a year-long Beta testing with clinicians from the US, UK and India. Available for premium subscribers of MIMOSA platform, MIMI is the world's first Responsible AI co-pilot. Leveraging cutting-edge responsible AI and a deep understanding of human health, MIMI aims to become an indispensable tool for women and female individuals of all ages seeking to optimise their hormonal wellbeing and health span, from puberty to post-menopause. MIMOSA is available in 20+ countries on Android and iOS through employer paid subscription model.

CEO
Jyoti Sharma

Website
mymimosa.uk

HQ
UK

Category
Patient Empowerment (B2B SaaS, HR Tech for Menopause Health literacy and integrated employee wellbeing)

Therapy Area
Healthy ageing and hormonal shifts

Funding
Privately funded

Methodology

This edition of the Digital Health Radar is based on data observed over the past year.

We analysed both Open-Source Intelligence (OSINT) and conducted qualitative interviews to produce this Radar, incorporating our own opinions and subject matter expertise.

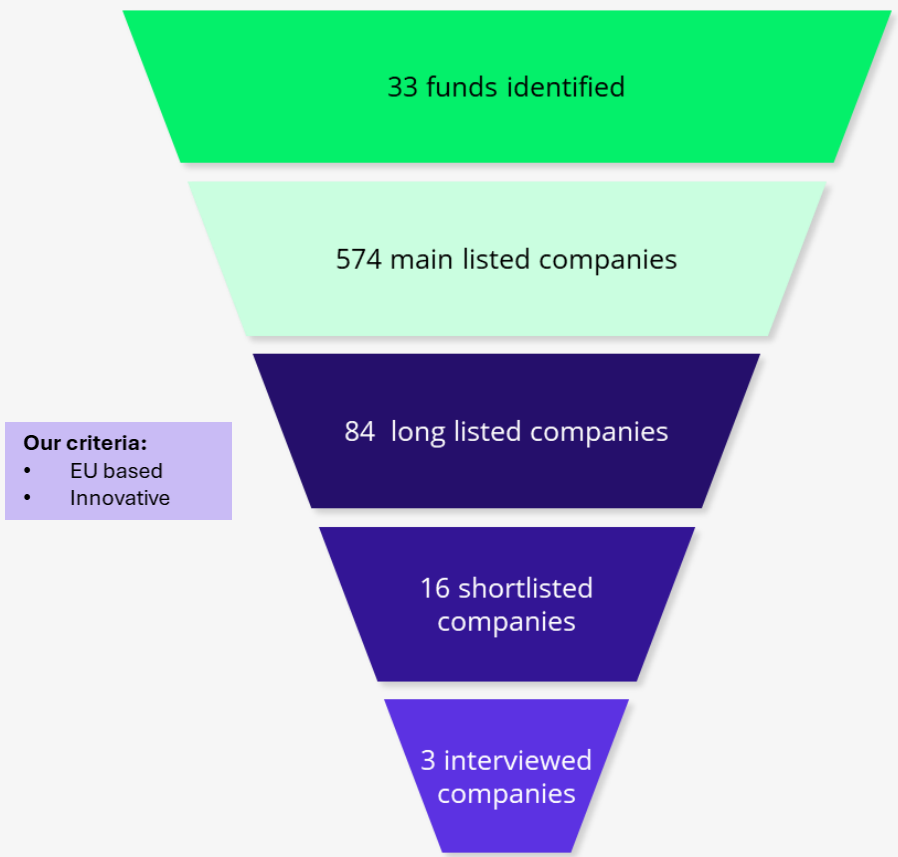
Depicted are 84 long listed innovative, European startups we have attempted to segment into the primary function their solutions appear to offer.

However, we know there are many more digital health innovators in the European ecosystem that we need to hear from. If you are interested in being involved in the next edition, please get in touch [link].

In our search we reviewed 33 funds, researched 574 companies, long listed 88, shortlisted 16 and interviewed 3 of the most exciting market innovators in the European Digital Health space (in our opinion of course). Their offerings ranged from digital therapeutics to wearables and utilised techniques ranging from AR, VR through to AI and beyond.

Our Selection Criteria:

- Based in Europe but could have operations in other parts of the world
- Its business model centers around innovations in the digital health space
- Defined as a startup



Glossary and References

Glossary

DiGA refers to Digitale Gesundheitsanwendungen in German or digital healthcare applications. These are applications formally approved and listed in the DiGA directory, following the regulations outlined in the Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG).

Digital Therapeutics (DTx) ultimately enhances patient outcomes through combining technology and medical expertise. Regarding treatment planning and management, DTx is enhanced by leveraging technology for personalised suggestions and recommendations, going beyond processes such as automation or symptom tracking. It includes HCP interactions, recommendations, interpretation of results and targeted interventions that utilize expertise. With monitoring, this is automated, involving patient interactions and targeting and communicating directly or indirectly with the HCP, for example via reports.

mHealth refers to mobile health, a general term for the use of mobile phones and other wireless technology in medical care. mHealth has an array of uses including education of preventative healthcare services, disease surveillance, treatment support, epidemic outbreak tracking and chronic disease management.

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Note on the Radar, it is important to clarify that these are purely our interpretations of the market and the startups we were able to sift through from a vast and everchanging market. Furthermore, we are aware of the subjectivity of some terms included in this report. For example, we saw multiple applications of the term Digital Therapeutics (DTx). We have defined this as therapeutics which ultimately enhance patient outcomes through a blend of technology and medical expertise, usually relating to treatment planning, management, and monitoring.

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Acknowledgments

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Wavestone is a consulting powerhouse, dedicated to supporting strategic transformations of businesses and organizations in a world that is undergoing unprecedented change, with the ambition to create positive and long-lasting impacts for all its stakeholders.

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