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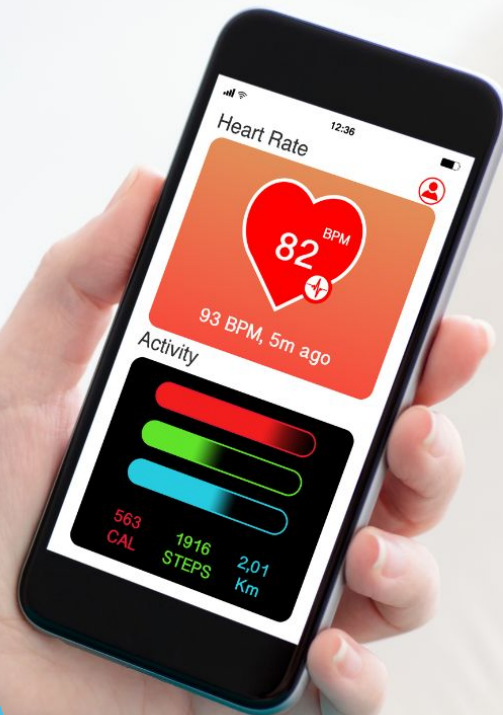
Si Speedinvest

dealroom.co

Digital therapeutics

Medical intervention “beyond the pill”

December 2022



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European early-stage venture capital firm investing in healthcare and tech.

Inkef is a venture capital firm based in Amsterdam, backing promising early stage companies in Europe. Inkef takes pride in being a patient, long-term investor with the ability to support companies through several rounds of funding. From the early stages of being a technology or life science venture, Inkef supports entrepreneurs building their ideas into successful international businesses.

+mtip

Pan-European growth investor focused on the Healthtech sector.

MTIP is a leading Swiss-based growth equity firm investing in European healthtech companies. We leverage our deep sector expertise to help the founders scale up successful and sustainable digital health businesses. At MTIP, we are driven by the mission to empower healthtech innovation with the potential to impact and improve millions of lives.

Si Speedinvest

Pan-European early-stage venture capital firm with a dedicated Healthtech investment team.

Speedinvest is one of Europe's most active Seed funds with 40+ investors based in Berlin, London, Munich, Paris, and Vienna. Our six sector-focused teams are the first to fund Europe's most innovative startups, and our in-house operational pros offer founders hands-on support throughout every stage of their journeys. Wefox, Bitpanda, TIER Mobility, GoStudent, and Wayflyer are among our portfolio of 250+ companies.

dealroom.co

Global startup & venture capital intelligence platform

Dealroom.co is the foremost data provider on startup, early-stage and growth company ecosystems in Europe and around the globe.

Founded in Amsterdam in 2013, we now work with many of the world's most prominent investors, entrepreneurs and government organizations to provide transparency, analysis and insights on venture capital activity.

Why this report on digital therapeutics (DTx).

Distinct from digital health, DTx are software-based medical interventions designed to directly treat a disease. These are tested for safety and efficacy in clinical trials, evaluated by regulatory bodies, and prescribed by healthcare providers.

DTx are designed and tested much like traditional prescription drugs, with one distinction: rather than taking a pill or an injection, **patients are treated with software.**

DTx manufacturers are learning that getting the attention of physicians to prescribe a digital therapy, can be difficult and expensive. Patients also must be willing to adopt digital treatments, which typically require more effort on their part than taking a pill. However, DTx are gradually finding their place in the healthcare ecosystem as regulation and reimbursement is taking shape, together with the rising engagement and adoption by physicians and patients.

A big thanks

Contributions and insights from conversations with:



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Co-founder & CEO
Oviva



Sylvain Piquet
Co-Founder & COO
Five Lives



Saemundur "Sam" Oddson
Co-founder & Chief Clinical
Officer
Sidekick Health



Francesca Wuttke
Founder & CEO
Nen Health

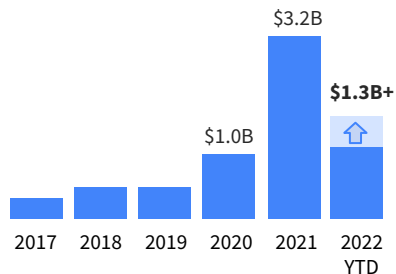
Key takeaways.

Global VC funding in digital therapeutics has increased 4x since 2017 to \$1.2B in 2022YTD.

Though VC activity in 2022YTD is down 63% compared to full year 2021, 2022 has already surpassed 2020 levels.

Investment figures haven't hit the highs set by 2021, but VC funding this year shows that 2021 was an anomalous year, and VC activity has returned to "normal" levels of growth.

Global VC investment in digital therapeutics startups

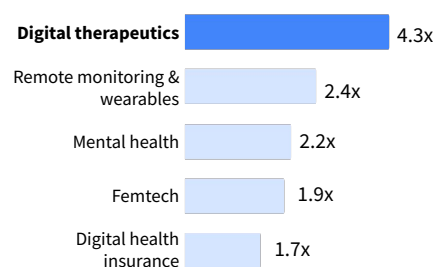


Digital therapeutics has been the fastest growing segment in healthtech by VC investment.

Still, digital therapeutics have relatively high growth in VC funding and low combined enterprise value compared to other healthtech segments.

Combined enterprise value of digital therapeutics startups has grown 8x since 2017, now totalling \$31B.

VC funding growth 2022E vs. 2017

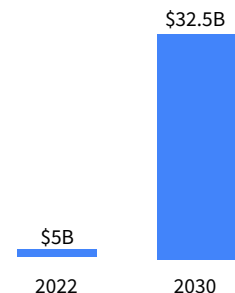


There's huge untapped potential in digital therapeutics.

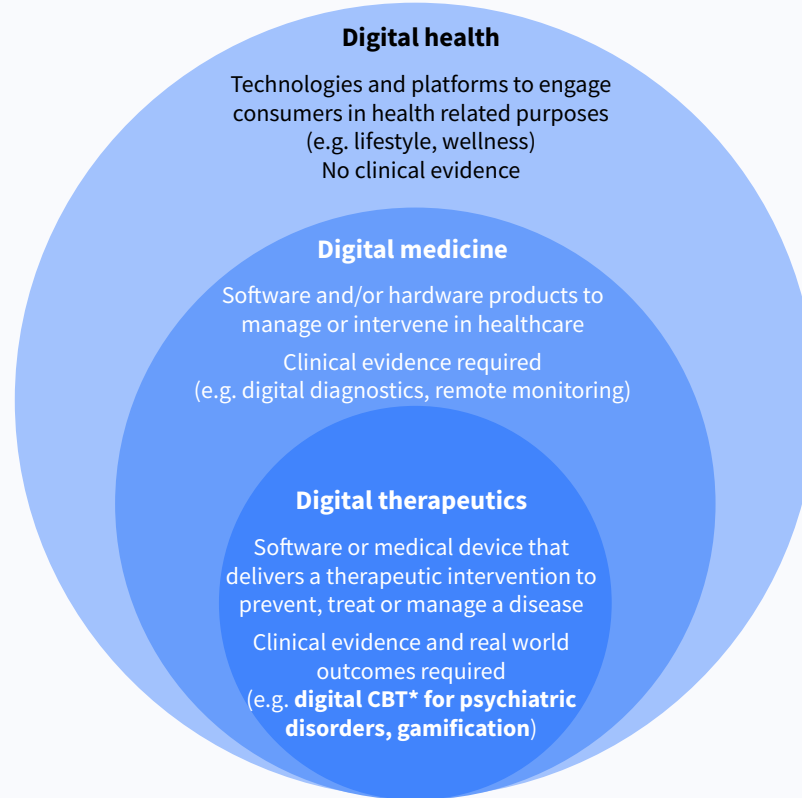
Digital therapeutics is projected to grow from \$5B today to \$32.5B in 2030*.

Digital therapeutics are gradually finding their place in the healthcare ecosystem as regulation and reimbursement is happening.

Global digital therapeutics market*



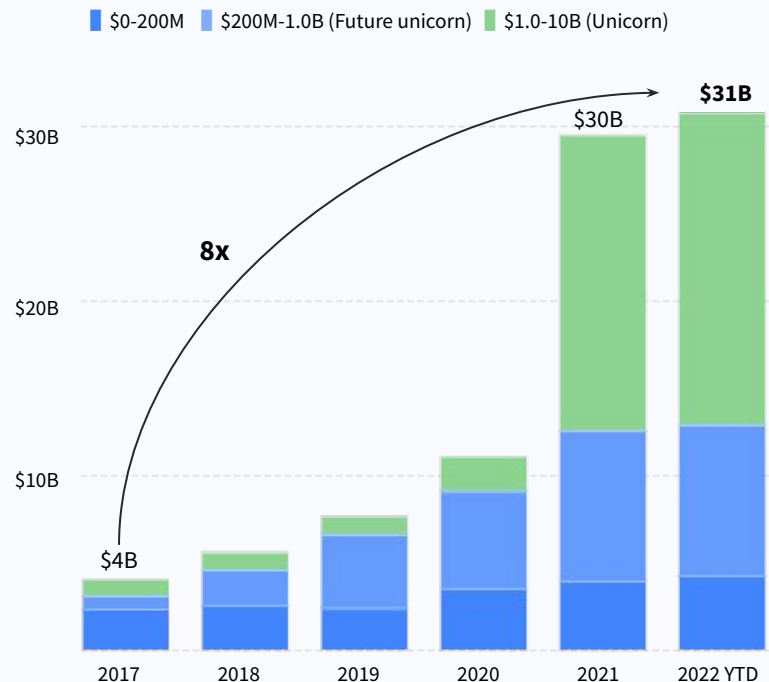
Digital therapeutics deliver evidence-based intervention via software or medical device to replace or complement disease treatment.



Combined enterprise value of global digital therapeutics startups has grown 8x in the last five years, now totalling \$31B.










Combined enterprise value of digital therapeutic startups

[» view online](#)



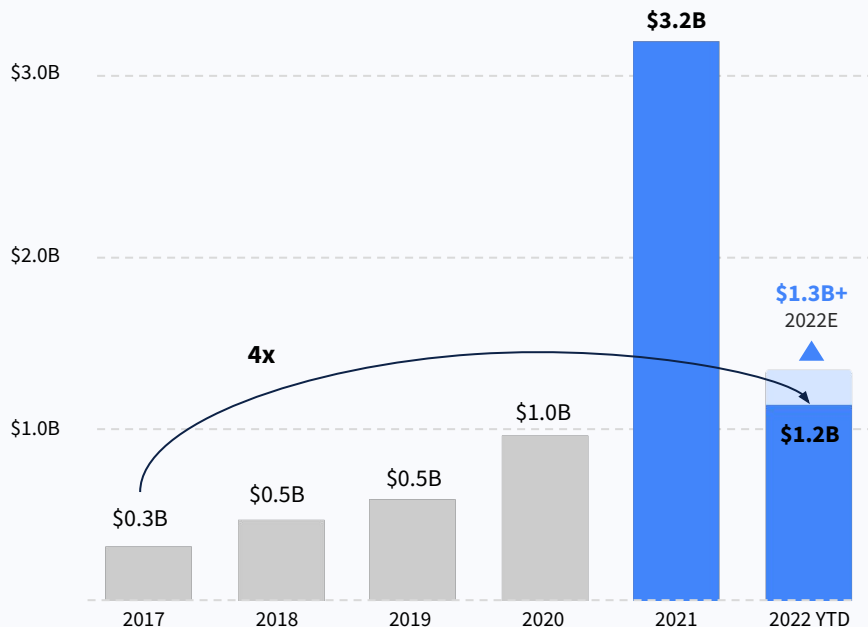
Most valuable digital therapeutic startups

[» view online](#)

 Hinge Health Musculoskeletal Valuation: \$6.2B United States	 NOOM Diabetes-obesity Valuation: \$2.0B United States	 virta Diabetes-obesity Valuation: \$2.0B United States
 sword Musculoskeletal Valuation: \$2.0B USA, Portugal	 biofourmis Chronic care Valuation: \$1.5B United States	 mindmaze Neuroscience Valuation: \$1.5B Switzerland
 omada Chronic care Valuation: \$1.0B United States	 vida Chronic care Valuation: \$440-660M United States	 Oviva Diabetes-obesity Valuation: \$320-480M Switzerland

Global VC funding has increased 4x since 2017 to \$1.2B in 2022 YTD. Still, 2022 YTD falls short compared to 2021 record, but it already has outpaced funding in 2020.

Global VC investment in digital therapeutics » [view online](#)



Largest rounds in 2022

biofourmis
Chronic care
\$320M Series D
United States

omada
Chronic care
\$192M Series E
United States

mindmaze
Neuroscience
\$105M Late VC
Switzerland

Big Health
Mental health
\$75M Series C
UK, USA

Hello Heart
Cardiology
\$70M Series D
Israel, USA

sidekick
Chronic care
\$55M Series B
Iceland

CureApp
Behavioural
\$51M Series G
Japan

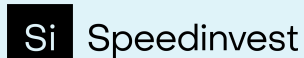
Cognito Therapeutics
Neuroscience
\$50M Early VC
United States

DTx represent an exciting therapeutic for the treatment of patients suffering from chronic and hard to treat diseases, and have the potential to decrease dependency on non-specific pain medication such as opioids.



Estelle Botbol

Associate
Speedinvest



“

Trials are very likely to continue in the future, which is great news for patients that will receive clinically validated therapies tailored to their needs. But unlike drugs or implants, DTx apps constantly need to prove themselves to users to make sure their interest does not wane off over time.

In addition to therapeutic efficacy, long-term use will rely on gamification, bug fixes, system upgrades, live support, and intuitive UI/UX. Not adjusting the product intelligently runs the risk of patients deviating from their treatment plan and creating unwanted effects."

What differentiates digital therapeutics from other digital health is the credibility and trust that lies within the clinical outcomes.

DTx value chain

Baseline framework

Product basis
Therapy duration, frequency, risks and side effects

DTx product development

Product's ability to function as a standalone or part of a multi-product platform
Core tech (e.g. AI, ML)

Clinical evidence

Clinical trials to assess product safety and efficacy
Real-world data and real-world evidence

Regulation and reimbursement

Evaluation on product authorization and distribution processes
Product cost that patients need to pay and/or product coverage by insurance or other parties

Commercialization, engagement and implementation

Guidelines and trusted resources for clinicians to adapt to DTx products
Clinicians and patients use and engage with the DTx-related therapy

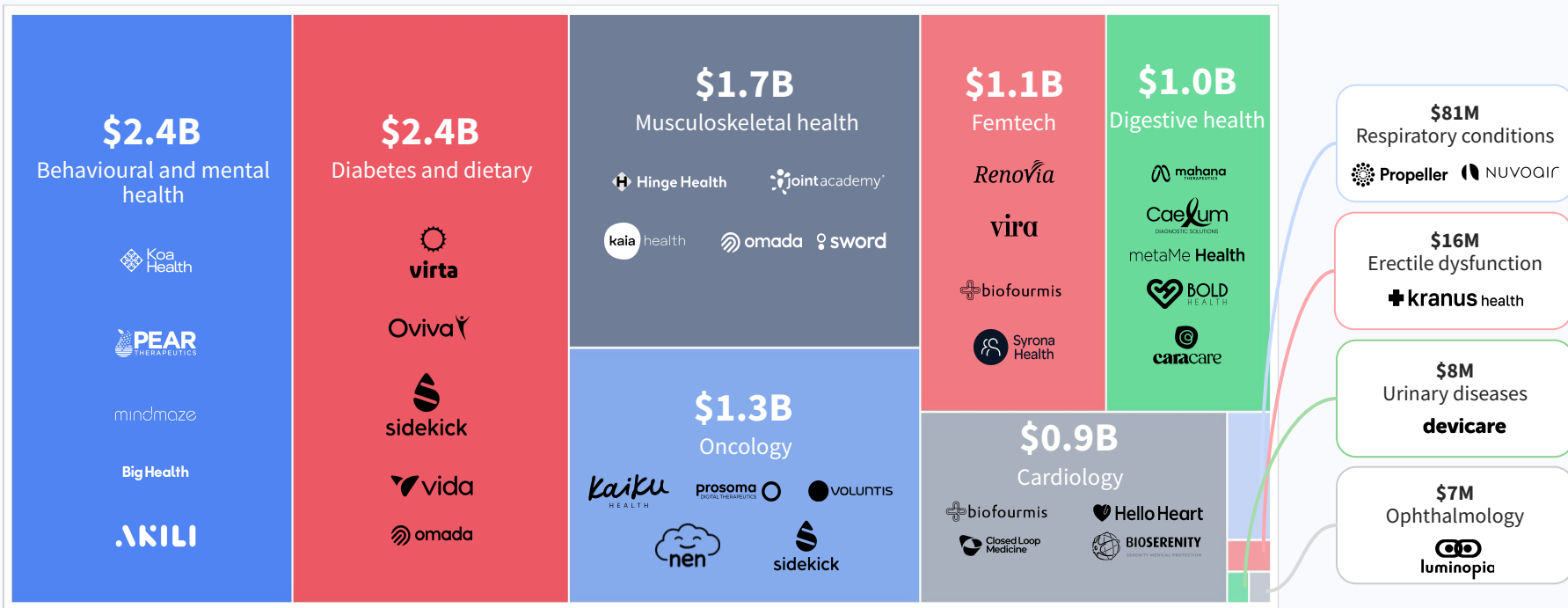


DTx factors evaluated by healthcare decision-makers*

- Patient centricity
- Clinical impact
- Product Usability
- Security and data privacy
- Real-world data
- Technical aspects

Digital therapeutics focuses on a range of different therapeutic areas. Still, some areas need the attention from founders and investors.

Combined VC funding (2017-2022 YTD) in digital therapeutic startups by selected therapeutic areas » [view online](#)



DTx can address pain management through play, leveraging gamification approaches and CBT to modulate pain and improve their overall wellbeing and outcomes.



Francesca Wuttke

Founder & CEO
Nen Health



“

“We chose pediatrics and oncology because there is a huge need, and I think we can fill that need for kids and for their families. But also for healthcare providers, which are frustrated that there's not more that a pain psychologist can do.

Apart from the initial diagnosis of cancer, managing the child's pain is the second-worst part of the cancer journey. Pain psychologist can deliver CBT, which we know has excellent outcomes, well-validated, but it's a matter of access. **The benefit of digital therapeutics is that they really serve to democratize healthcare and provide health equity and access to underserved populations.**”

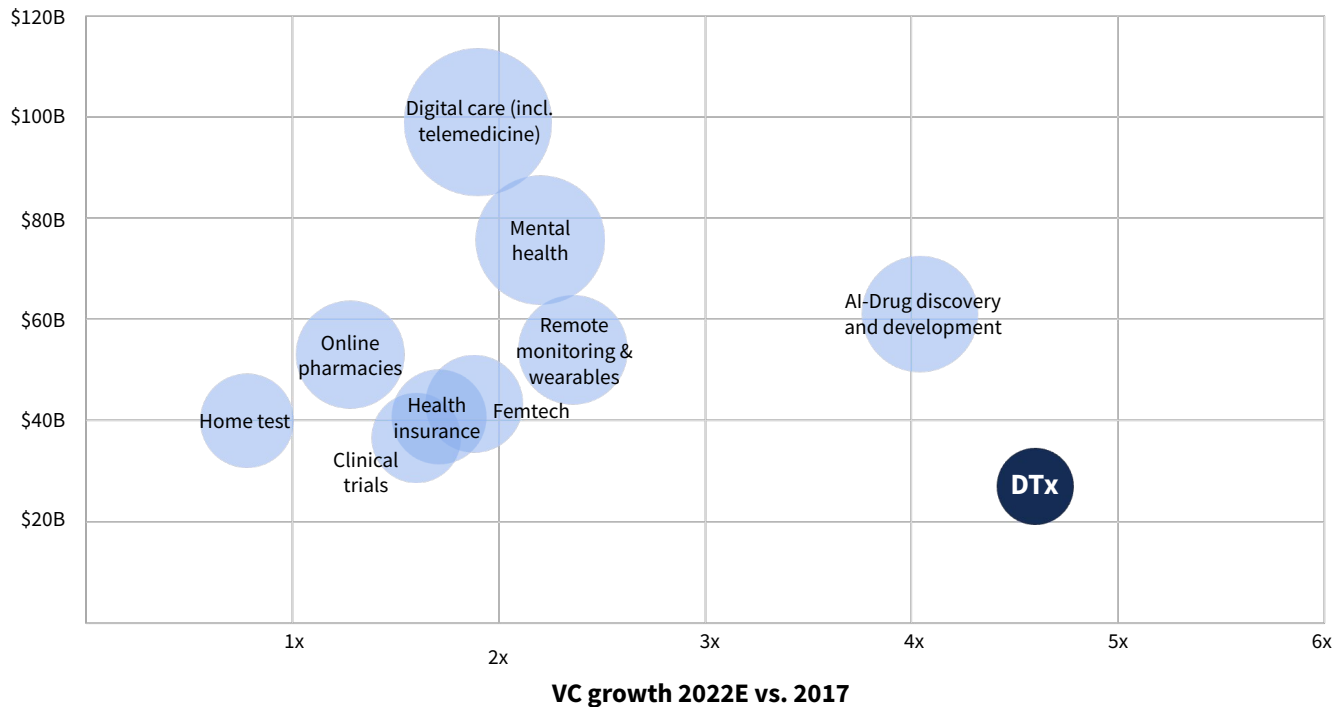
[Read the full interview](#)

Digital therapeutics has been the fastest growing segment in healthtech since 2017.

	2017	2022E	VC funding growth 2022E vs. 2017
Digital therapeutics	\$0.3B	\$1.3B	4.3x
AI-Drug discovery and development	\$0.7B	\$2.9B	4.0x
Remote monitoring & wearables	\$0.7B	\$1.6B	2.4x
Mental health	\$0.9B	\$2.0B	2.2x
Digital care (incl. telemedicine)	\$1.4B	\$2.7B	1.9x
Femtech	\$0.5B	\$1.0B	1.9x
Digital health insurance	\$0.8B	\$1.3B	1.7x
Clinical trials	\$1.0B	\$1.6B	1.6x
Online pharmacies	\$0.5B	\$0.7B	1.3x
Home test	\$1.6B	\$1.2B	0.8x

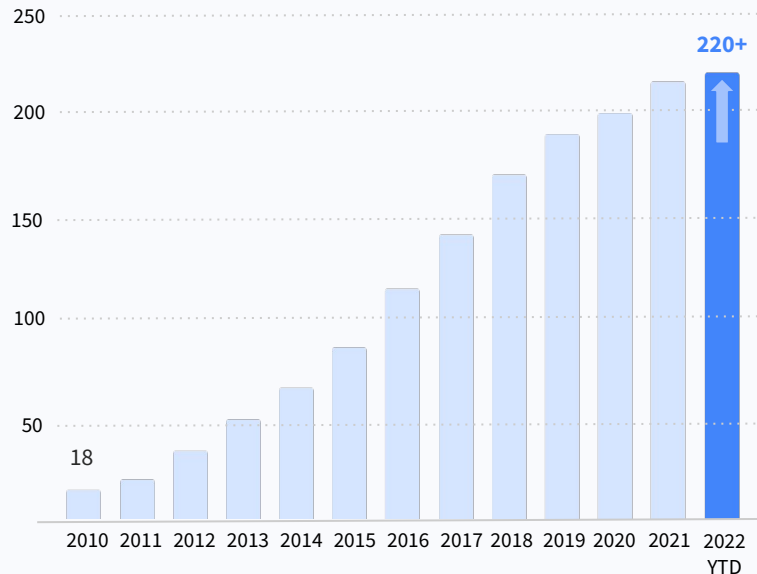
DTx is a nascent healthtech segment on the rise, with relatively high growth in VC funding and low combined enterprise value compared to other healthtech segments.

Combined enterprise value

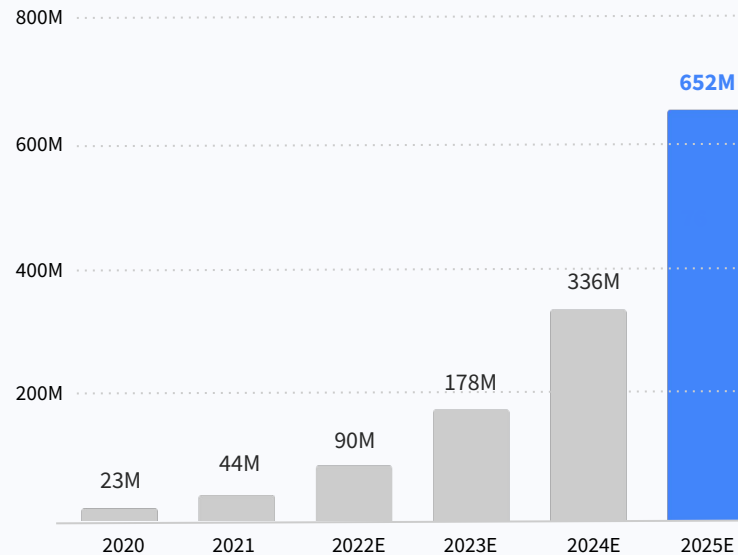


Growth is expected to continue. The number of startup creation in the field and user adoption has increased over the years.

Cumulative number of digital therapeutics startups created



Global number of digital therapeutics users*



Regulation and reimbursement on DTx is gradually happening over Europe. Still, Europe is a global frontrunner in reimbursement, more than the US and Asia.

	Germany	UK	France
Process	Fast-track process for approval, testing, and reimbursement with DiGA ¹	Gradual grant system Clinical effectiveness and economic impact evaluated by NICE ²	Similar to DiGA
Considered as		Medical device (CE Mark)	
Public Insurance Coverage	National population	No dedicated pathways	National population
Private Insurance Coverage	Private insurance not obliged Possibility to negotiate reimbursement	Some products are partially covered	Funding up to a certain amount Co-payment by the patient
Consumer-funded	Very low willingness to pay out-of-pocket	Low willingness to pay out-of-pocket	Low willingness to pay out-of-pocket
Number applications	130 submitted 33 reimbursed (Nov 2022)	11 reimbursed (Nov 2022)	51 submitted 5 reimbursed (Nov 2022)
Total cost incurred by DTx manufacturer		~ €60K-€100K (including fees for the application and approval process, and external consultants)	
Price	DTx manufacturers set their own prices during the first year of reimbursement After approved, price is negotiated	Regional committees Assessed by the NICE framework	DTx manufacturers set their own prices during the first year of reimbursement After approved, price is negotiated



The lack of guidelines and policies can negatively influence a physician's uptake of digital therapeutics.



Saemundur "Sam" Oddson
Co-founder & Chief Clinical Officer
Sidekick Health



“

It's important to remember that technology can't be viewed in isolation or as an add-on, it needs to be fully integrated into an organization's overall strategy. That means improving how the DTx solution fits into a provider's workflow and limiting disruptions that cause them to spend more time on the computer than with a patient.

An additional challenge that needs to be navigated as there are often no clear guidelines for how DTx products should be developed, tested, and marketed. Without clear regulations, it can be difficult for payers to determine whether and how to reimburse patients for DTx treatments, even if the DTx company has effectively navigated the regulatory process.”

[Read the full interview](#)

Digital therapeutics reimbursement pricing have gone down significantly when the real world evidence is considered and the economic assessment is made.

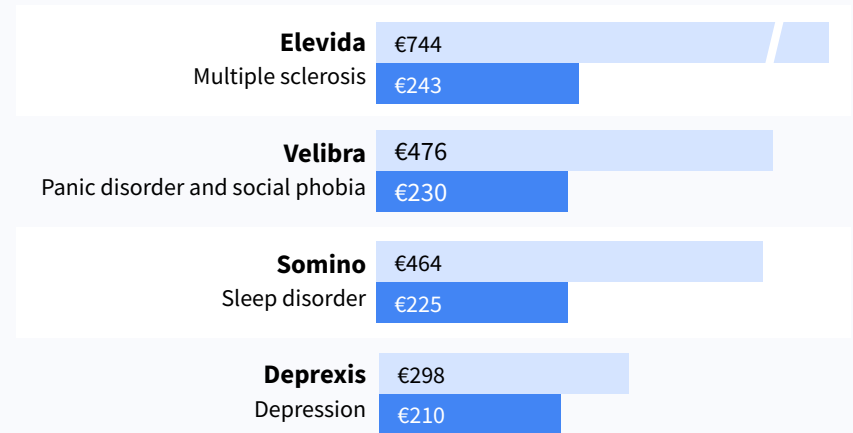
Many **digital therapeutic business models are based on remuneration**, with 50-60% of the pricing of a comparable pharmaceutical treatment ¹.

In Germany, all negotiations between DiGA manufacturers and the GKV-SV (arbitration board) have led to the DTx manufacturers to **accept considerable price reductions**.

Still, when regulation and reimbursement are implemented, **adoption from physicians and patients is needed**.

Difference between price set by DiGA manufacturer and price set by arbitration board. ²

■ Price set by DiGA manufacturer ■ Price set by arbitration board



We fundamentally believe that DTx will become a central tool for providers in an increasingly digitized healthcare system.



Activation of users is an underestimated step in building DTx companies:

you need to convince doctors (through guidelines, training, integration into EMR systems) to drive user engagement by training patients to accept and continue using the DTx, as well as payers to settle the payment for the intervention and take care of the administrative side of billing.

In other words, like in traditional therapeutics, DTx companies need to grow up and **transform from a small Biotech that is focused on drug discovery and market approval into a more Pharma-like company that also can execute on distribution, market access and marketing to capture the true value potential of a DTx.**”

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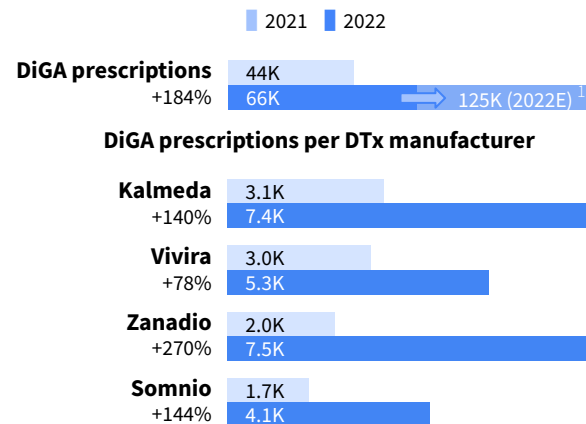


Amanda Stenbaek
Associate



Thijs Cohen Tervaert
Junior Partner

The response from DiGA users (patient and physicians) has been **positive and has increased considerably** in the last year (Digital Health Ventures report):



Source: 1. McKinsey estimation. [E-Health in Germany: The expansion of networked healthcare is proceeding hesitantly.](#)

The largest challenges are the complex regulatory landscape and fragmentation of reimbursement policies across national markets.



Kai Eberhardt
Co-founder & CEO
Oviva



“

Healthcare changes slowly, but over 10-20 years proven better approaches are adopted. In digital therapeutics, there are more pockets of strong evidence and more and more paths to reimbursement for proven products. For those pockets, there will be widespread adoption in the next few years.

Our market strategy focuses on scaling in countries with DTx reimbursement by statutory health insurance (e.g. German DiGA). Timing is critical. We keep an eye on countries with good market opportunity size and soon to be launched standardised DTx reimbursement pathways to prepare for potential market entry and adoption at scale."

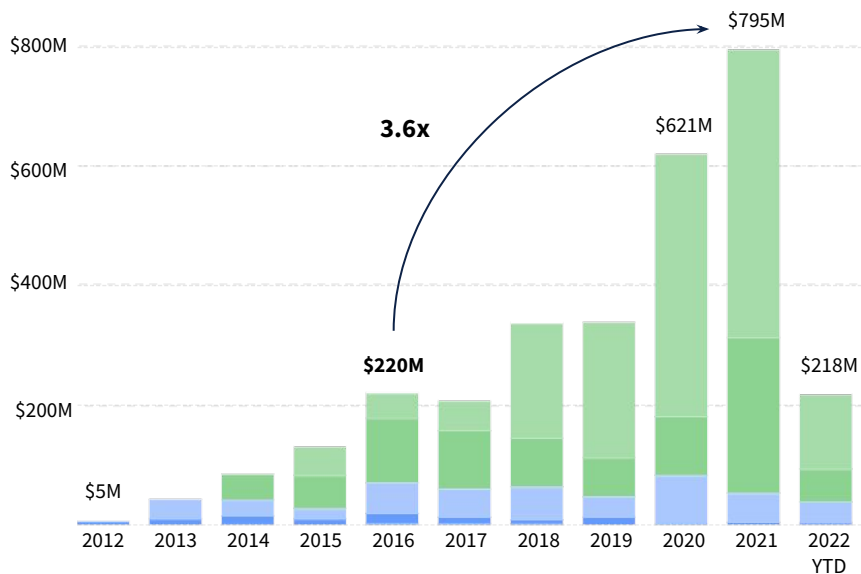
[Read the full interview](#)

In Europe, the growth in early-stage startup investment is even more pronounced compared to the US.

Early stage investment into digital therapeutics startups

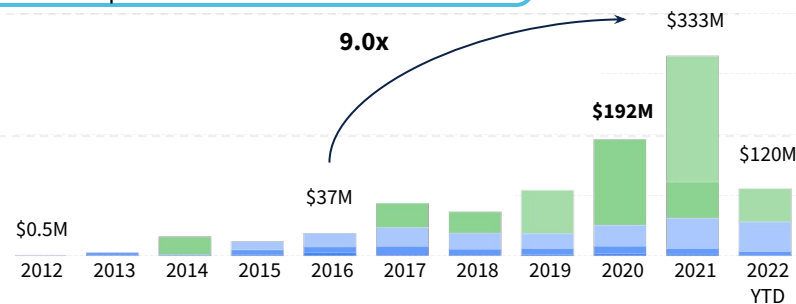
■ \$0-1M (pre-seed)
 ■ \$1-4M (seed)
 ■ \$4-15M (series A)
 ■ \$15-40M (series B)

US-based digital therapeutics [» view online](#)



Europe-based digital therapeutics [» view online](#)

Europe is just a few years behind the US. Early stage VC investment in Europe in 2020 almost equals the US in 2016.

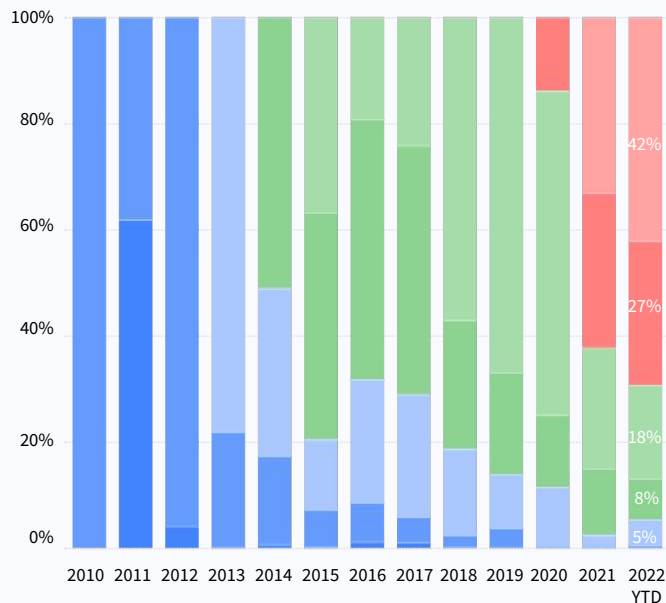


Digital therapeutics is still an emerging field, yet maturing from only early to growth stage rounds now, in both the US and Europe.

VC investment in digital therapeutics startups by round size

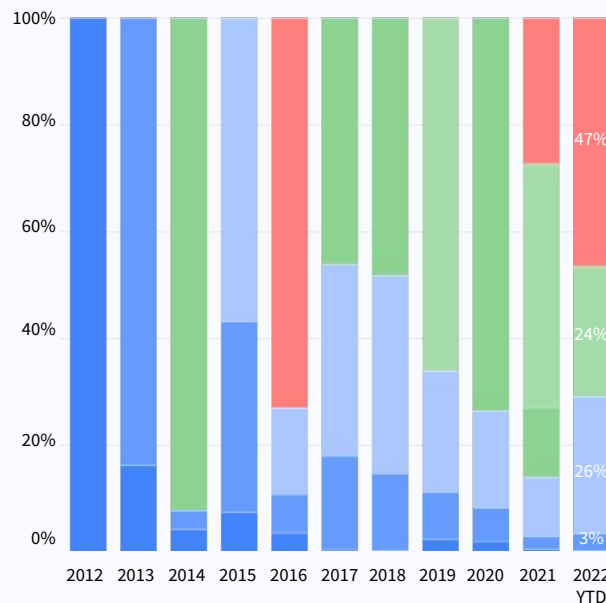
US-based digital therapeutics

[» view online](#)



Europe-based digital therapeutics

[» view online](#)



Except for Germany, the European DTx market is fragmented and hugely lagging behind the US in terms of adoption and health system support / prescription.



Sylvain Piquet
Co-Founder & COO
Five Lives



“

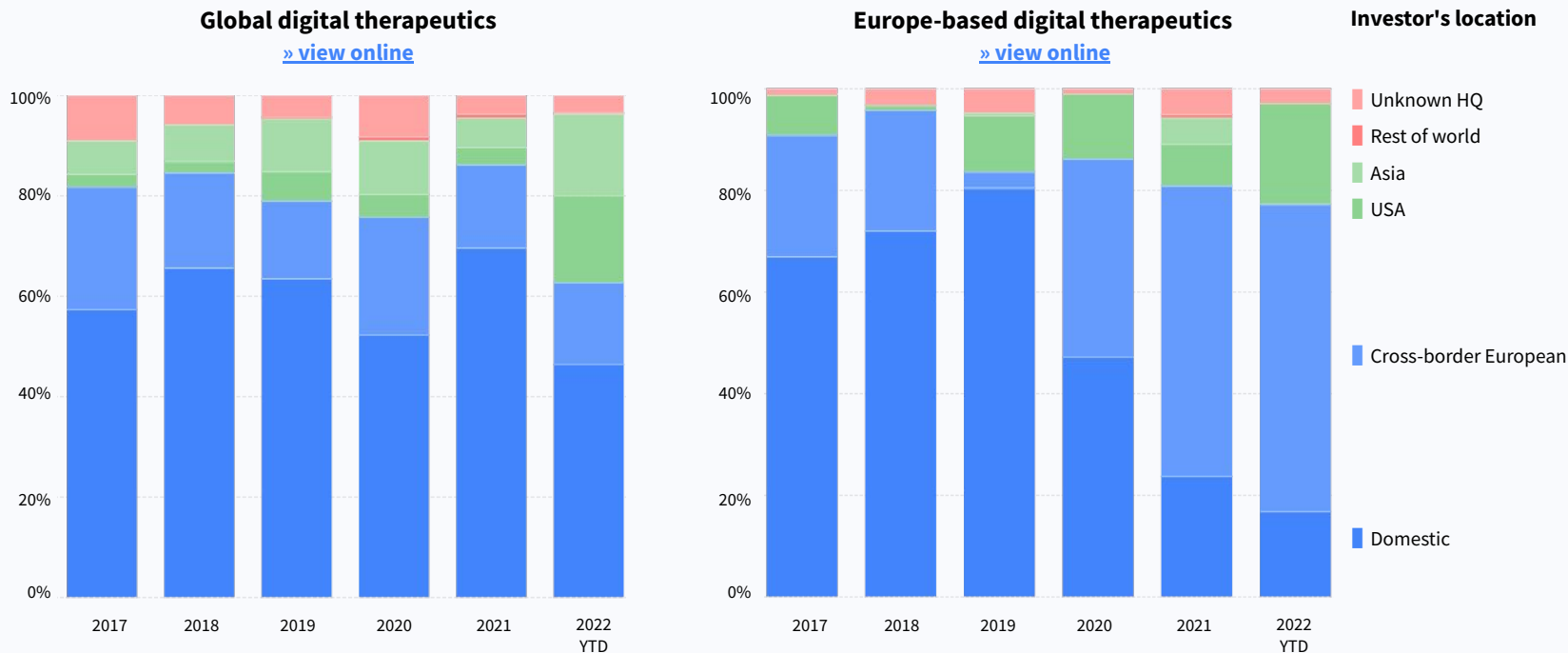
In most countries, except the UK, people are unwilling to buy health products out of pocket (e.g. France, Germany) so certain players are really struggling with market access.

The main challenge we have is the different timescale required/compatibility between fast moving consumer tech (needs fast proof of traction) and the lengthy clinical validation process. The most interesting trend I observed are selective contracts signed between big German insurers (e.g. TK) and DTx players. It goes beyond DiGA and incentivizes PCP/GP with significant referral fees for each prescription (30/40€), which makes a real difference."

[Read the full interview](#)

Global digital therapeutics VC funding is dominated by domestic investors. Still, European startups are increasingly attracting capital from cross-border European investors.

Investment into digital therapeutics startups by investor's location



Digital therapeutics-focused investors.

Pre-seed and seed

 Speedinvest

Second Nature, Five Lives, Juli, Charles.co



Feel, Flow Neuroscience, Braingaze

 ANANDA Impact Ventures

Mika, Ieso Digital Health, Caspar

 High-Tech Gründerfonds

Kranus Health, Selfapy, M-sense



Second Nature, Bold Health, Limbix



Quit Genius, Cohero Health

Early stage





Vira Health, Big Health, Quit Genius



SWORD Health, Hello Heart, Flow Neuroscience



Sidekick Health, Koa Health, Cara Care





Biofourmis, Virta Health, Vibrant



Quit Genius, Hinge Health

Late stage


Oviva, Koa Health

 
Omada Health, Dopavision, Pear Therapeutics, NuvoAir,
Holmusk


Vira Health, Kaia Health, Holmusk


AppliedVR, Oviva


Sidekick Health, Koa Health


Kaia Health, Bioserenity


Oviva, Akili, Pear Therapeutics

Digital therapeutics combine the power of technology with evidence-based treatments tailored to an individual's needs, allowing healthcare providers to monitor progress and adjust treatments as needed.



Magdalena Plotczyk

Investment Associate

MTIP



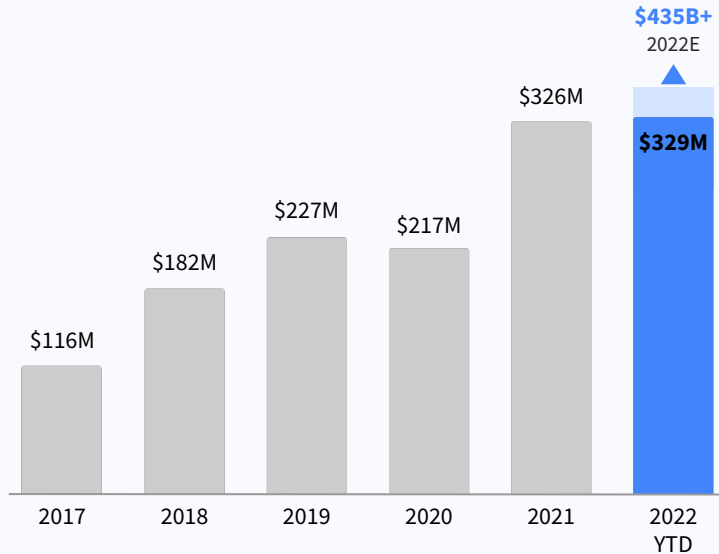
“

At MTIP, we recognize the complexity of the ecosystem and want to support teams with a deep understanding of the current challenges to the broader **market adoption**, including the **still-evolving regulatory environment** and the need for **appropriate data protection and robust clinical trials to prove clinical efficacy**.

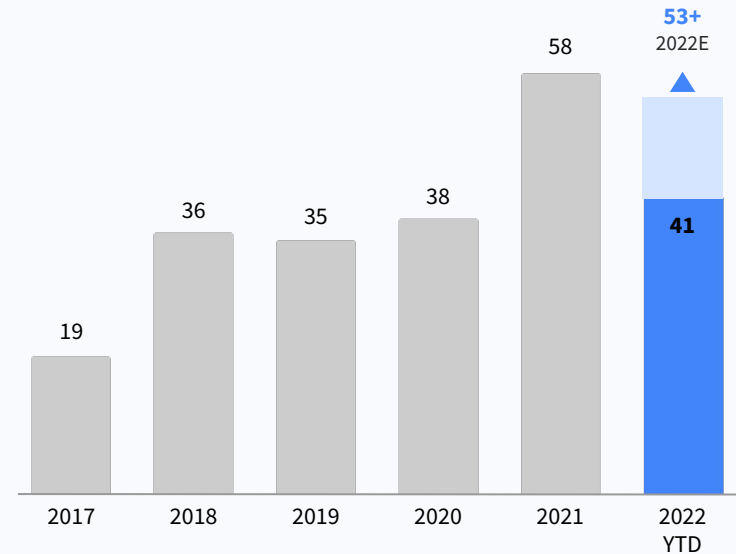
We look for market strategies that align incentives across healthcare stakeholders to ensure benefits to all parties involved, from greater patient engagement and improved health outcomes to reduced medical costs and optimized clinical workflows.”

Corporate VC investment in digital therapeutics has reached \$329M in 2022, tripling 2016 levels and on track to surpass 2021.






























Corporate VC amount invested in global digital therapeutics



Corporate VC rounds in digital therapeutics

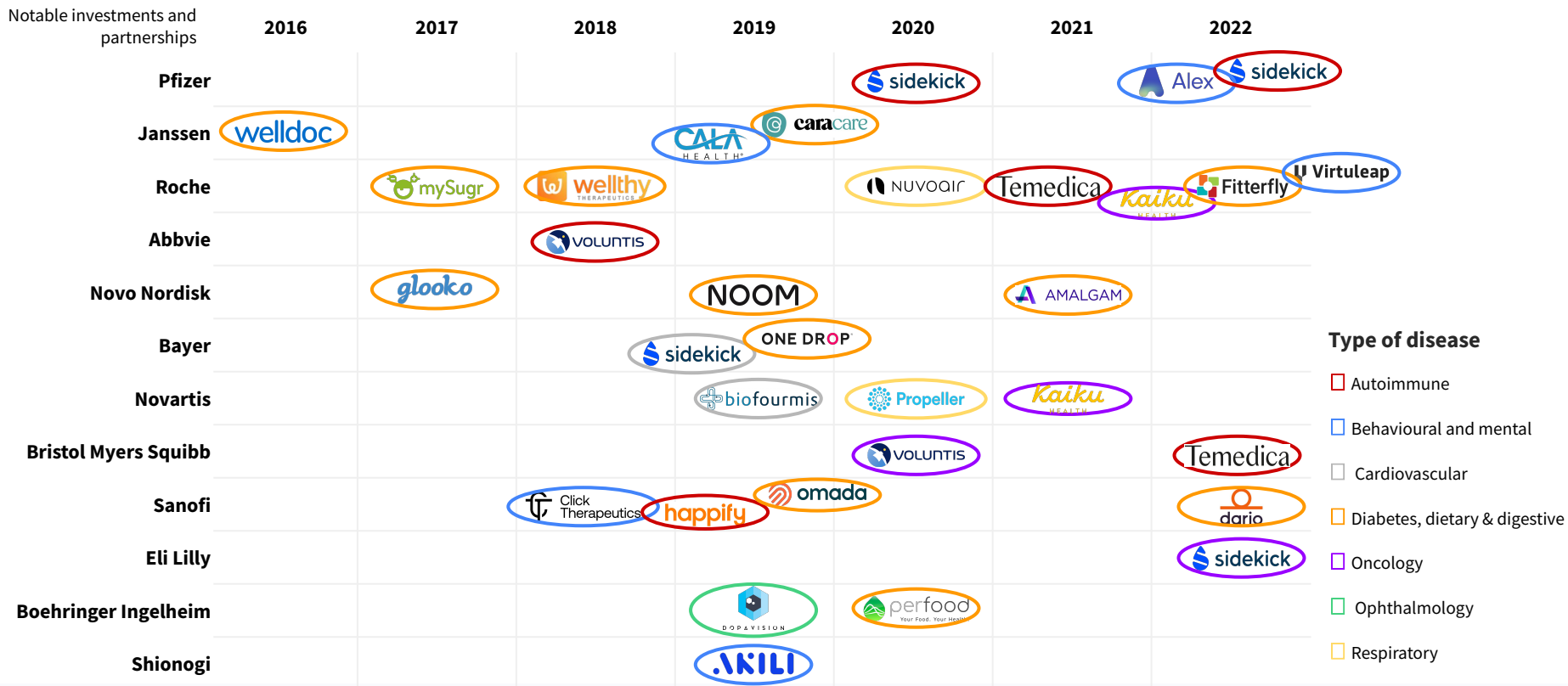


Active corporate VC investors in digital therapeutics.

Corporate VC	Target	HQ	Transaction	Funding date
  	 Chronic care		\$320M Series D	Aug 2022
  	 Chronic care		\$110M Series D	May 2021
  	 Neuroscience		\$110M Series D	May 2021
	 Musculoskeletal		\$75M Series C	Apr 2021
	 Mental health		\$53M Series B	Nov 2021
 	 Behavioural health		\$52M Series B	Oct 2021
 	 Chronic gastrointestinal		€7M Early VC	Jun 2022

Pharma is getting involved in digital therapeutics to enhance their value proposition and improve patient care.

Notable investments and partnerships



Despite the challenges of time and cost, the randomised controlled trial (RCT) remains as the gold standard for determining whether any given intervention does better than placebo.



Oliver Harrison
Founder & CEO
Koa Health



“

But the question of what “controlled” really means to be continued with some recent opposition to waitlist controls.

Some journals no longer accept evidence from waitlist-controlled studies for the assessment of psychotherapies, and now it looks like this perspective is shared by some regulatory bodies, although a new draft UK regulatory framework suggests that waitlist trials may be adequate.

As digital health technology continues to emerge, these issues have become complex, and Koa is working with a range of international experts to generate consensus in regard to the best practice design of clinical trials and regulatory pathways to make research, development and evidence generation more efficient.”

[Read the full interview](#)

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» Visit the platform



The screenshot shows the Healthtech Database website. At the top, there is a search bar with the text "Search for companies, investors, people, lists & innovations". Below the search bar is a navigation menu with "OVERVIEW", "CURATED CONTENT", and "NEW STARTUPS". The main content area features a large banner with the text "Explore the Healthtech & Biotech ecosystem" and "The world's most comprehensive Health & Biotech ecosystem database". Two large statistics are displayed: "46,868 STARTUPS" and "55,403 ROUNDS". Below the banner, there are four search categories: "TECH FOR PATIENTS", "TECH FOR BIOTECH & PHARMA", "TECH FOR DOCTORS", and "TECH FOR HO". Each category has a representative image and a list of search results. For example, "TECH FOR PATIENTS" includes "Digital health for patients", "Femtech", and "Health savings accounts (HSA)".



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