

Global Digital Health Innovation 2023
Executive Briefing

Clinical Strength in Digital Health

Proof Points • Venture Analytics • Drivers of Change
Ecosystem Insights • Partnerships • Global Investment Trends





Foreword by Evaluate

As part of Evaluate's partnership with Galen Growth, we are delighted to bring you this report on the importance of clinical evidence within the digital healthcare space.

While digital healthcare may be a younger part of the market compared to biopharma and more traditional forms of medtech, digital is quickly following a similar path. In recent years, biopharma has seen its share of bubbles across a range of mechanisms of action and therapy areas. While the next big thing might generate much excitement – and initial investment – there comes a time when reality bites, and investors start demanding hard proof of efficacy.

The team at Galen Growth has investigated this trend, one that is being accelerated by the changing regulatory landscape for digital health tools, and published this report with their findings. The bottom line is that investment requires clinical evidence. The funding boom is over, and those companies that try to scale based on a great idea, a vision and a charismatic pitch are going to get left behind.

Enough from us. Read on to learn what the team at Galen Growth has uncovered.

 @EvaluatePharma | @EvaluateVantage

www.evaluate.com

Evaluate Headquarters

Evaluate Ltd., 3 More London,
London SE1 2RE, United Kingdom
T +44 (0)20 7377 0800

Evaluate Americas

EvaluatePharma USA Inc., 265 Franklin,
Suite 1101, Boston, MA 02109, USA
T +1 617 573 9450

Evaluate Asia Pacific

Evaluate Japan KK, Holland Hills Mori Tower 2F
5-11-2 Toranomon, Minato-ku, Tokyo 105-0001, Japan
T +81 (0)80 1164 4754



Galen Growth is pleased to share with you our latest insights on the **Clinical Strength** of Digital Health ventures. We define the boundaries of this important topic and connect the importance of proof points for funding, product development, and partnerships. Our analysis focuses on private ventures and includes **ecosystem growth, most active partners, regulatory approvals** and **venture funding**.

With unmatched, no-bias, no-hype and data driven coverage of the global Digital Health ecosystems, this report is powered by HealthTech Alpha, a Galen Growth proprietary solution, and the global leading Digital Health private market data, intel and insights platform.



TL;DR

18%

Proven Clinical Strength

There is a shift in focus underway in Digital Health to proof points, with Clinical Strength being a priority data point. Across the globe, **18% of all private Digital Health ventures have proven Clinical Strength** through Clinical Trials, Regulatory Filings, or Peer-Reviewed Publications. Approx. half of those ventures with proven Clinical Strength achieved this milestone within the first 5 years after incorporation.

22%

Europe

The regulatory landscape for Digital Health is becoming more favorable across the globe, with the FDA releasing the Digital Health Policy Navigator in January 2022 and the German DiGA program growing to over 50 successful applications. **With 22% share of ventures boasting proven Clinical Strength, Europe takes the top spot**, while the Middle East is the global region in second place for Clinical Strength at 20% share.

1.3x

Partnerships

Digital Health ventures can benefit from partnerships that provide them with access to patients, funding, and medical knowledge. In the top 5 Digital Health Clusters (by % of ventures with Clinical Strength), **ventures with proven Clinical Strength have at least a 1.3x higher share of partnerships** than ventures without proven Clinical Strength.

22%

Digital Health Apps

Navigating health-related apps, software and devices remains a challenge, with healthcare providers and payers requiring proof points of the product's benefit to the intended user. HealthTech Alpha has catalogued over 16,000 products (mobile apps, software, and devices) that have been developed by private ventures focused primarily on Digital Health. **22% of the Digital Health apps were developed by ventures that have proven Clinical Strength.**

81%

Funding Value

Investors are focusing their funds more on ventures that can provide evidence of their solution's effectiveness. Within the Remote Devices Cluster, 64% of Growth- and Late-Stage ventures have proven Clinical Strength. **81% of the cumulative funding value from 2022 – H1 2023 deployed to ventures in this cluster went to ventures with proven Clinical Strength.**

Data & Methodology

Source of Data

Unless otherwise stated, all data are exclusively sourced from Galen Growth's proprietary database **HealthTech Alpha™** – the global leading Digital Health intelligence and analytics on-demand platform. Presently, HealthTech Alpha tracks more than 680M datapoints and has a coverage exceeding 14,000 Digital Health ventures across the globe. For more information visit <https://www.healthtechalpha.com/>



Data Scope

The 2023 Clinical Strength in Digital Health analysis within this report considers ventures and Digital Health products (e.g. apps) across the globe, with selected analysis focusing on six key regions for Digital Health: North America, Asia Pacific, the Middle East, Europe, South America (key markets), and Africa.

- The following scope of analysis criteria must be met in order to be included in this report:
 - The venture was incorporated after 2002
 - The venture has been qualified as being Digital Health i.a.w. Galen Growth's rigorous taxonomy - see slide 32
 - The venture's geographic location is determined by its initial country of incorporation
 - Venture funding includes all stages up to but excluding the exit event
 - Subsidiaries of large corporations (e.g. Microsoft) are excluded
 - The product is developed by a Digital Health venture and is a Digital Health product. Other non-digital products or devices are excluded.

Methodology

Analytics presented in this report are Galen Growth's proprietary algorithms and are explained on slide 33

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*Available
exclusively with a
HealthTech Alpha
Pro or Enterprise
subscription*

ABOUT GALEN GROWTH

Unleash Digital Health Innovation

Our unique combination of data, analytics, specialist team and Digital Health network, enables our clients to outperform their competition

Talk to us



Global Digital Health Ecosystem Coverage

Our unmatched coverage of the world's most innovative Digital Health ventures means more innovation choice and better decisions.

Specialist Team with Decades of Experience

With decades of experience, our team of analysts, decision makers & industry experts extend your team with specialist insights and know how.

Our US, Asia and Europe offices serve our clients worldwide.

Tailored Innovation Solutions

Whatever stage you are at in your innovation journey, we have a world class solution to enable you to succeed. Every solution leverages our unrivalled Digital Health data.

[Create an account](#)

HealthTech Alpha

The world's most trusted Digital Health private market data, intelligence and insights platform

The foundation of our work is our unmatched Digital Health dataset and search, powered by HealthTech Alpha. HealthTech Alpha monitors, aggregates and audits hundreds of millions of data points to efficiently give you the most profound understanding of Digital Health.

Whether you are determining a market entry strategy, fine-tuning Digital Health product development, looking to benchmark and differentiate against your competition or researching future Digital Health innovation, HealthTech Alpha has you covered. Get started with HealthTech Alpha and make better data-driven innovation decisions.

Learn more:

[Find Best-Fit Ventures](#)[Due Diligence](#)[Ecosystem Insights](#)[Competitive Intelligence](#)

HealthTech Alpha Introduces the

Digital Health Product Hub –more than just apps

Consolidated and structured to lead you to the right product - without needing to be a Digital Health industry expert. Why spend days evaluating dozens of ventures, when you can find the solution directly from the HealthTech Alpha Product Hub? The only global, curated hub for Digital Health products.

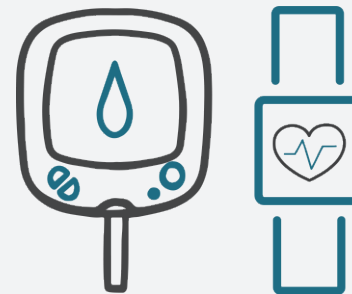
Mobile Apps



Software



Hardware



... and much more



The industry go-to-reference for Digital Health research

We leverage our unmatched data and analyst team to research and publish unique go-to-reference thematic reports on the Digital Health ecosystem.

Digital Health in U.S. Health Systems

Digital Health Innovation Ecosystem for Cardiovascular

Global Digital Health Innovation Ecosystem Report on H1 2023 Key Trends

Digital Health Innovation Ecosystem for Oncology

Pharmaceutical Digital Health Innovation Index



CLINICAL STRENGTH

INTRODUCTION



Prove your solution or get left behind

While a great idea and good business acumen have scaled strong Digital Health companies over the past decade, there is finally a shift in focus towards proof points, with Clinical Strength being a priority data point.

There are many reasons for this shift. First, the regulatory landscape for Digital Health is becoming more favorable, with the FDA releasing the Digital Health Policy Navigator in January 2022 and the German DiGA program growing to over 50 successful applications. Second, there is a growing body of evidence that shows that Digital Health interventions can be effective in improving health outcomes. Third, there is a growing demand from healthcare providers and payers for evidence-based Digital Health solutions. Fourth, investors are favoring ventures with evidence.

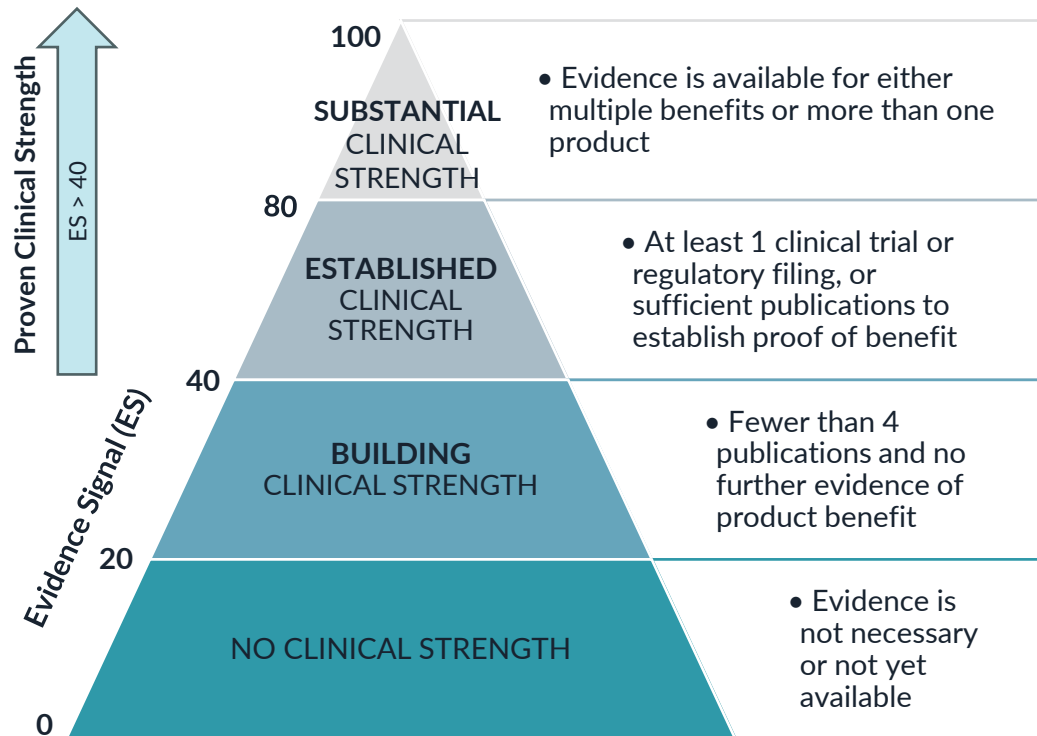
Galen Growth first published its industry-leading research report in 2022 looking at the Clinical Strength of a Digital Health venture by evaluating a venture's clinical trials, regulatory filings, and peer-reviewed publications.

This year's report dives deep into the Global Digital Health ecosystem to continue to demonstrate the importance of proof points for ventures to scale, types of products that have proven Clinical Strength, as well as the growth of proof points and its impact on venture success.



Scope of Clinical Strength for Digital Health Ventures

Galen Growth's **Evidence Signal** in HealthTech Alpha enables the evaluation of a venture's Clinical Strength, or its ability to prove that its products are safe and effective. In particular, the Evidence Signal (ES) considers the number of clinical trials, regulatory filings and peer-reviewed publications that a venture has for its Digital Health products. A high Evidence Signal correlates with high Clinical Strength.



Evidence Signal (ES)

Evaluation of the number of clinical trials, regulatory filings and peer-reviewed publications that a venture has generated to confirm the medical benefit of its solution to the target customer.

Evidence of Solution Benefit



Clinical Trials

Registered clinical trials, not including trials that have been marked as Cancelled



Regulatory Filings

Filings from global regulatory bodies, including but not limited to: United States, Australia, China, United Kingdom, South Korea, Germany, Italy, and Canada



Peer-Reviewed Journal Articles

Journal articles that have been published in peer-reviewed journals. This includes both articles authored or co-authored by a venture employee or studies published that use the venture's device

NOTE: Not all ventures require clinical evidence, and therefore it is not expected for all ventures to reach an Evidence Signal > 40. See slide 33 for top clusters by Evidence Signal.

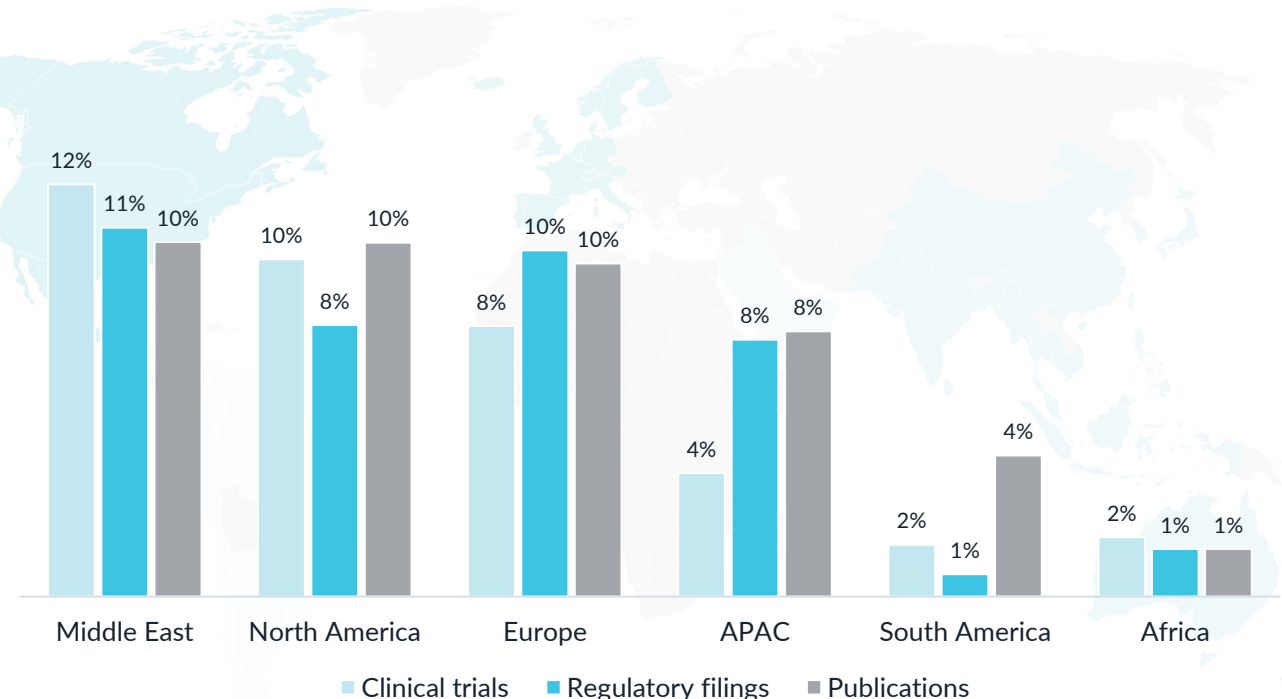
Digital Health Ventures Are Generating Evidence

It is important for Digital Health companies to invest in clinical research and to publish their results in peer-reviewed journals. This will help to ensure that Digital Health products are safe and effective, and that they are used to improve the quality of care for patients.

The Middle East leads the global regions for the largest share of ventures with Clinical Trials and Regulatory Filings, while North America and Europe follow closely behind. Europe boasts the overall highest share of ventures with proven Clinical Strength (see full report).

In South America and Africa, there is a notable lack of Clinical Evidence, which can be directly related to the lack of funding that makes it difficult for Digital Health ventures in the regions to conduct Clinical Trials, as well as the lack of regulatory support and framework for approvals and structured clinical trial procedures.

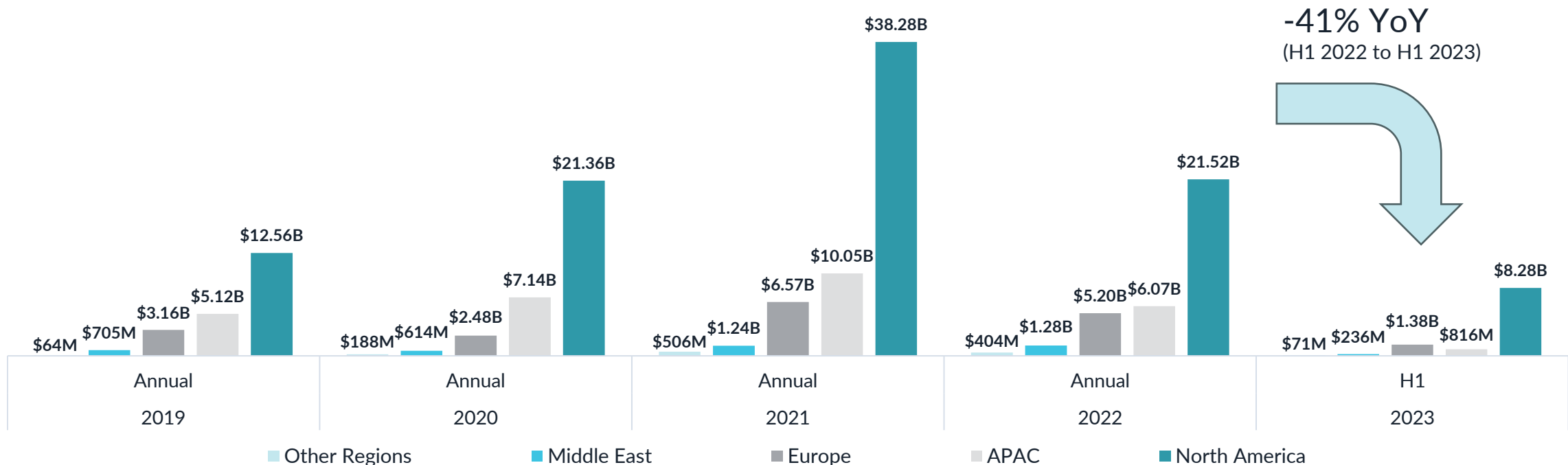
Share of Digital Health Ventures with Evidence of Clinical Strength, by Region and Type



The Digital Health Venture Funding Boom Has Ended

With the return to normal for venture funding in 2022, Digital Health investors are anchoring back to reality. Funding remains strong for new ventures, while investment in Growth- and Late-Stage funding deals has become more focused and is demanding more verification that ventures are offering solutions that will bring value to the Digital Health ecosystem. To meet these demands, ventures should be prepared to show Clinical Evidence to support the effectiveness of their solutions.

Global Digital Health Venture Funding Value (excludes exits)

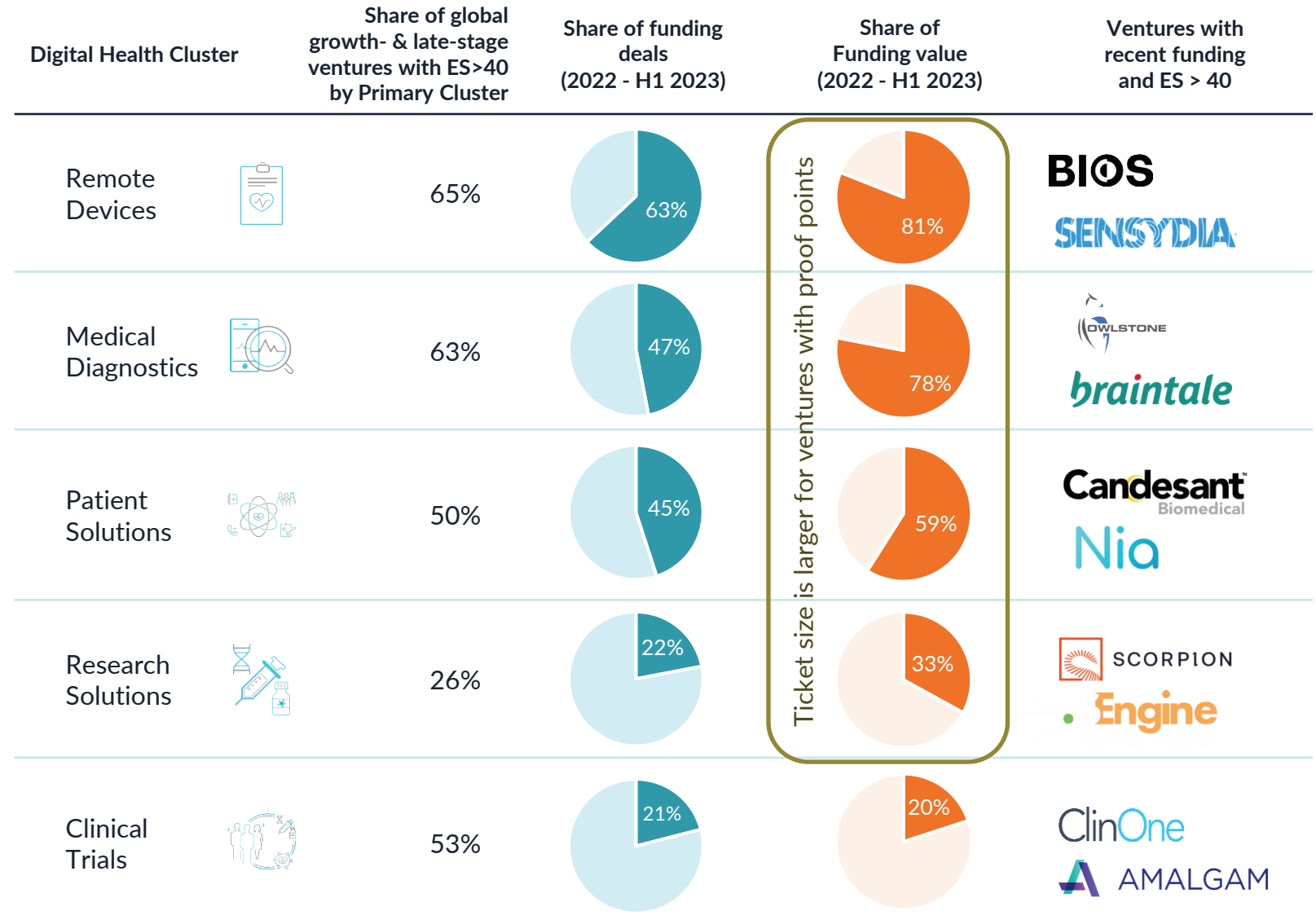


INTRODUCTION: CLINICAL STRENGTH

Clinical Evidence Increases Ticket Size

In the current funding drought in Digital Health, investors are focusing their funds more on ventures that can provide evidence of their solution's effectiveness. Galen Growth considers peer-reviewed publications, clinical trials, and regulatory approvals in the Evidence Signal (ES). Considering funding deployed in 2022 and H1 2023, the top 5 clusters with the highest share of Growth- and Late-Stage ventures with ES > 40 capture a significantly higher share of funding value compared to their corresponding deal share.

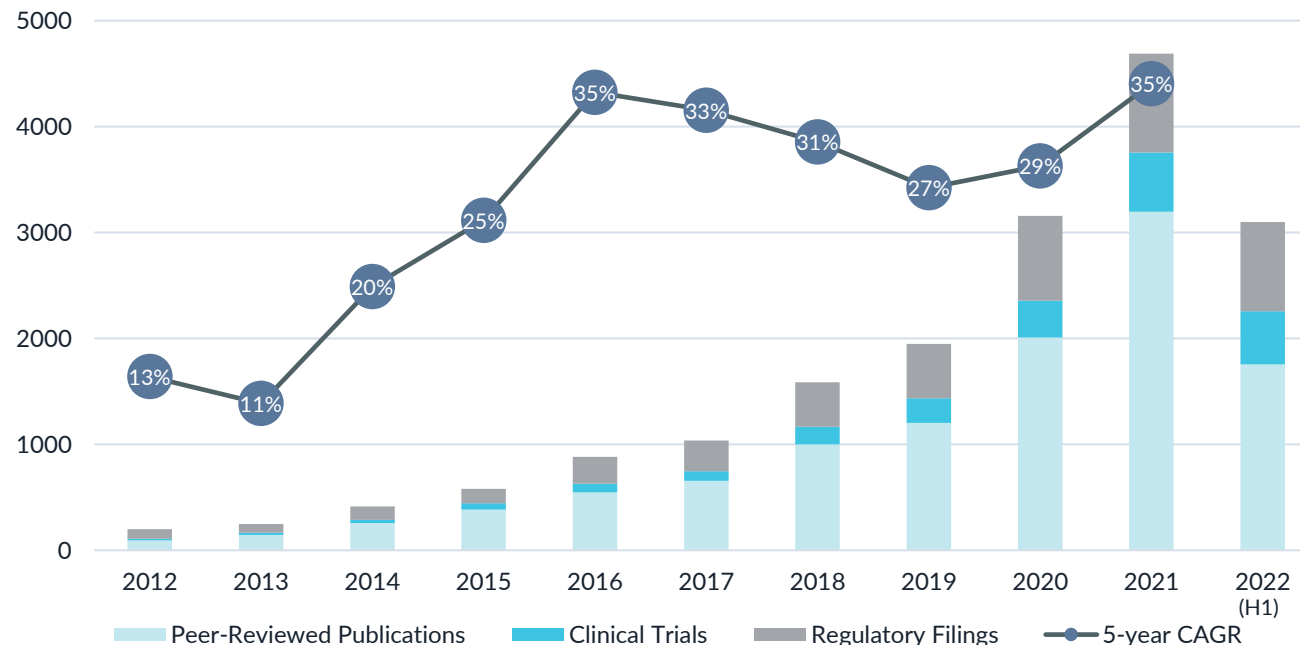
Growth- & Late-Stage Ventures with Evidence Signal > 40



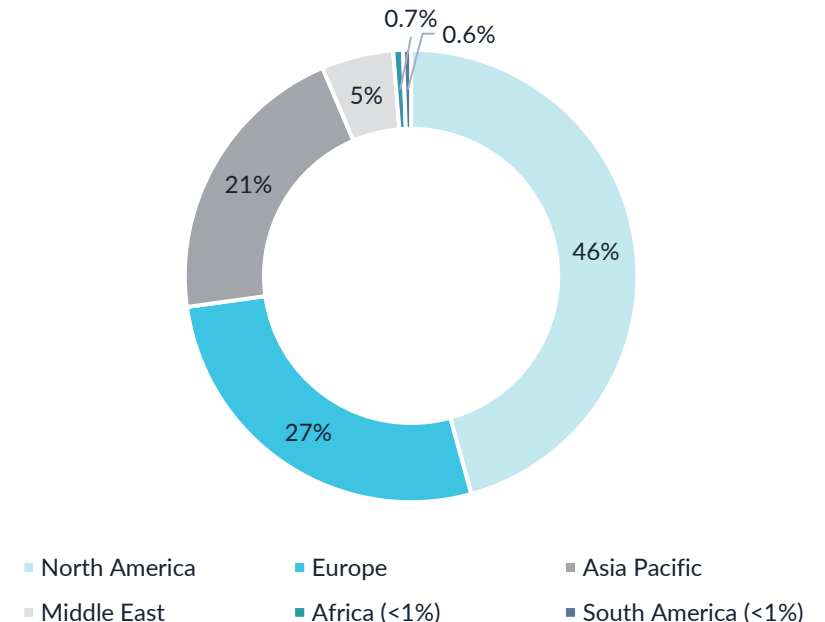
The Pandemic Delayed Clinical Trials and Research; Publications in 2022 Suffered

The growth of evidence for Digital Health ventures was growing at 5-year CAGR of 35%, until it dropped sharply in 2022. This drop in peer-reviewed publications is likely due to a number of factors, including the COVID-19 pandemic, which disrupted clinical trials and thus the publishing of results, as well as the economic downturn, which is making it more difficult for Digital Health startups to secure funding.

Growth of Evidence for Clinical Strength



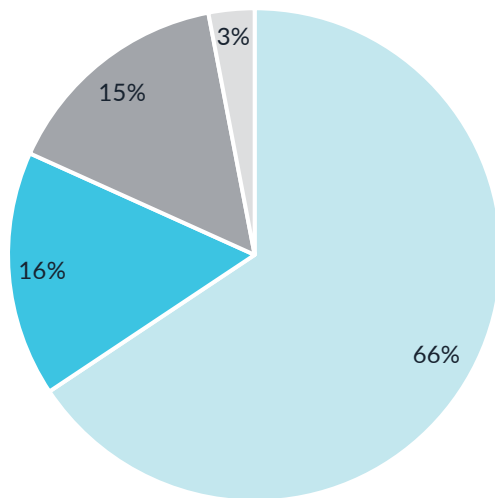
Regional Distribution of Digital Health Evidence (2018 – H1 2023)



Partnerships Can Accelerate Generation of Proof Points

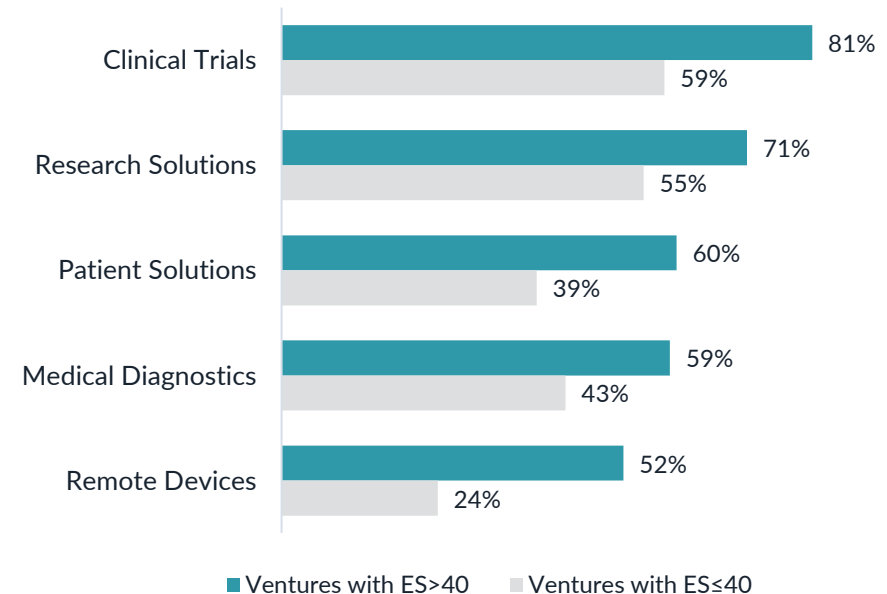
Digital Health ventures can benefit from partnerships that provide them with access to patients, funding, and medical knowledge. In the top 5 Digital Health Clusters (by % of ventures with ES>40), ventures with proven Clinical Strength have at least a 1.3x higher share of partnerships. Clinical Trials tops the list, with 81% of ventures having proven Clinical Strength active in partnering. Ventures founded in N. America are most active in partnering, capturing 66% of global partnerships for ventures with proven Clinical Strength.

Geographic Distribution* of Partnerships for Ventures with Proven Clinical Strength



■ North America
 ■ Asia Pacific
 ■ Europe
 ■ Middle East

Share of Ventures Active in Partnering, by Cluster
(Top 5 Clusters by % of ventures with proven Clinical Strength)

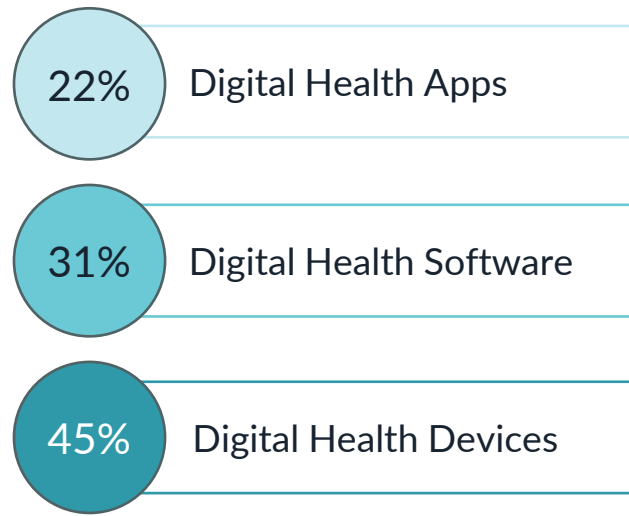


■ Ventures with ES>40
 ■ Ventures with ES≤40

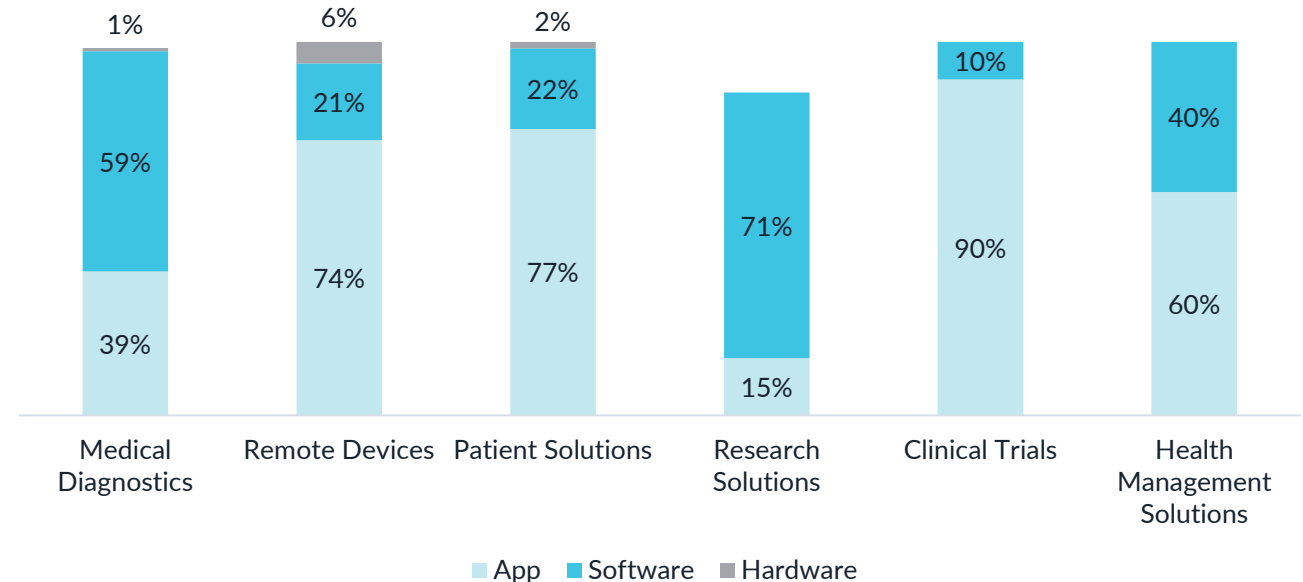
Patients, Providers and Payors Rely on Products with Proof Points

Navigating the numerous “health-related” apps, software and devices remains a challenge, and in addition, stakeholders such as healthcare providers and payers are requiring proof points of the product’s benefit to the intended user. HealthTech Alpha has catalogued over 16,000 products (mobile apps, software, devices, and more) that have been developed by private ventures focused primarily on Digital Health. 25% of these products were developed by ventures that have proven Clinical Strength.

Share of products developed by Digital Health ventures with ES > 40, by product type

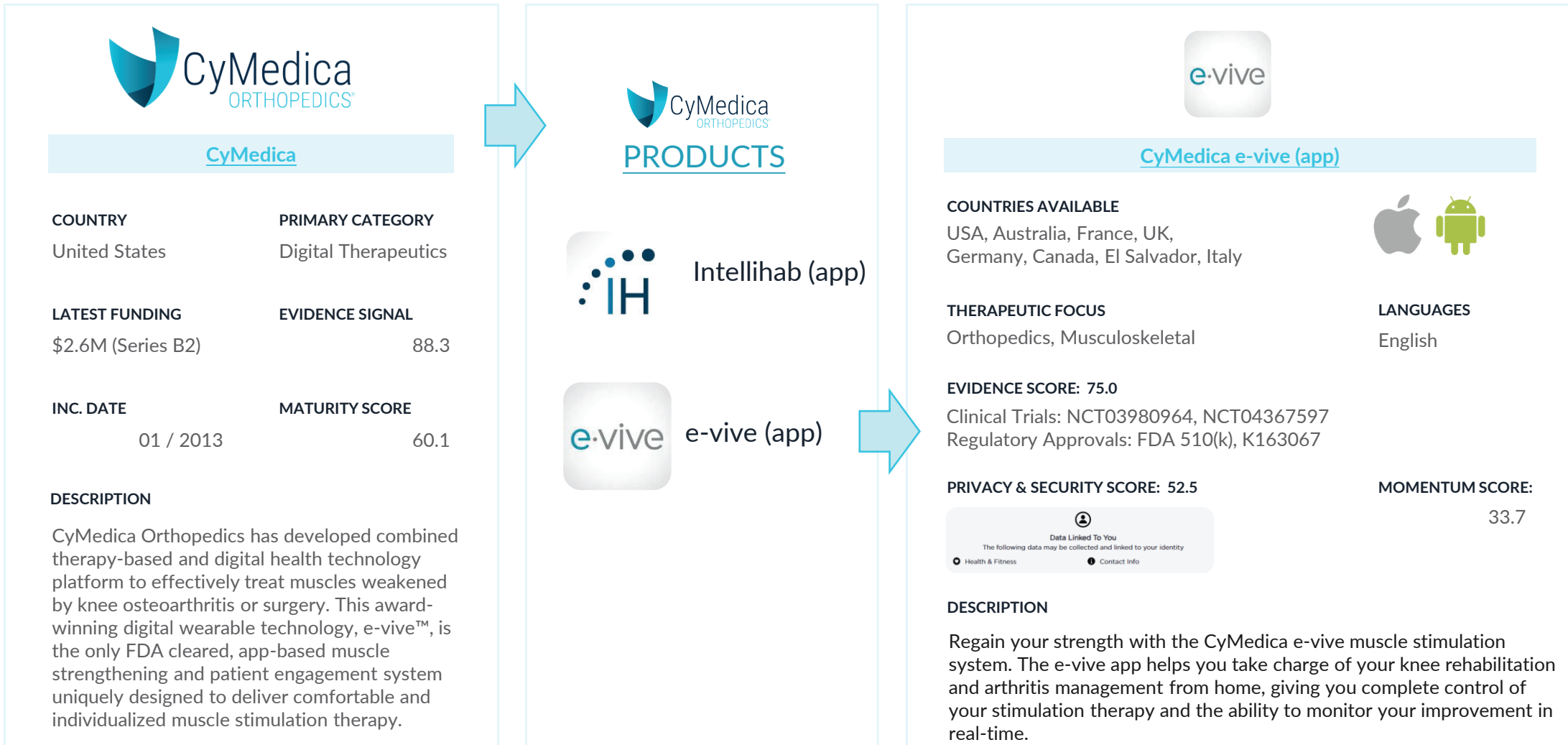


Share of products* developed by ventures with ES > 40 in each Digital Health cluster, by product type



INTRODUCTION: CLINICAL STRENGTH

Products with recent regulatory filings



Products with recent regulatory filings



[Neurophet \(뉴로핏\)](#)

COUNTRY

South Korea

PRIMARY CATEGORY

Medical Imaging

LATEST FUNDING

\$16M (Series B)

EVIDENCE SIGNAL

70.8

INC. DATE

03 / 2016

MATURITY SCORE

71.4

DESCRIPTION

Neurophet has specialized in developing solutions for diagnosis support, treatment guides, and treatment devices targeting brain diseases based on cutting-edge artificial intelligence (AI) technology.



[PRODUCTS](#)



neurophet AQUA



neurophet AQUA

[Neurophet AQUA](#)

COUNTRIES AVAILABLE

South Korea, Japan, United States, Europe

THERAPEUTIC FOCUS

Neurology, Stroke, Oncology

LANGUAGES

English

EVIDENCE SCORE: 53.7

Regulatory Approvals: FDA 510(k), K220437, MFDS 20-4771 (Class 2)

PRODUCT TYPE

Software

DESCRIPTION

Neurophet AQUA is an artificial intelligence-based degenerative brain disease assistant software that helps clinicians to diagnose brain MRI data through quantitative analysis.

Caution: Not All Proof Points Are Created Equal

While the evidence base for Digital Health solutions is expanding, several notable Digital Health companies that appeared to have adequate proof points have collapsed in 2023. When assessing a venture's Clinical Strength, the following cautionary words should be remembered:

- Leveraging non-peer reviewed publications may be unsuitable. These publications are not subject to the same level of scrutiny as peer-reviewed publications, so they may contain errors or omissions.
- Peer reviewed by association is a strategy that some companies use to boost their credibility. This involves hiring a scientific advisory board or other experts who have published peer-reviewed research. The idea is that by association, the company's own research will be seen as more credible.
- Patients are increasingly using newer technology in their everyday lives. If a clinical study uses outdated technology, it may not be relevant to the experiences of many patients.
- The standards for conducting clinical trials in Digital Health are becoming increasingly rigorous and new regulatory are being developed to address the unique challenges of Digital Health research. Using outdated protocols and data may make it difficult to meet these standards.

Relevant publications: "Rigorous and rapid evidence assessment in digital health with the evidence DEFINED framework", npj Digital Medicine (2023) 6:101 ; <https://doi.org/10.1038/s41746-023-00836-5>
"Confidence in Research: researchers in the spotlight", Economist Impact (2023); <https://impact.economist.com/projects/confidence-in-research/>



Pear Therapeutics

Founded in 2013
Went public in Nov 2021 via \$1.6B SPAC deal
Filed for bankruptcy in April 2023
Was sold into 4 main parts at auction in May 2023



Babylon Health

Founded in 2013
Went public in October 2021 via \$3.5B SPAC deal
Acquired Higi in Jan 2022, Sold Higi in May 2023
Plans to be merged with MindMaze collapsed in H2 2023



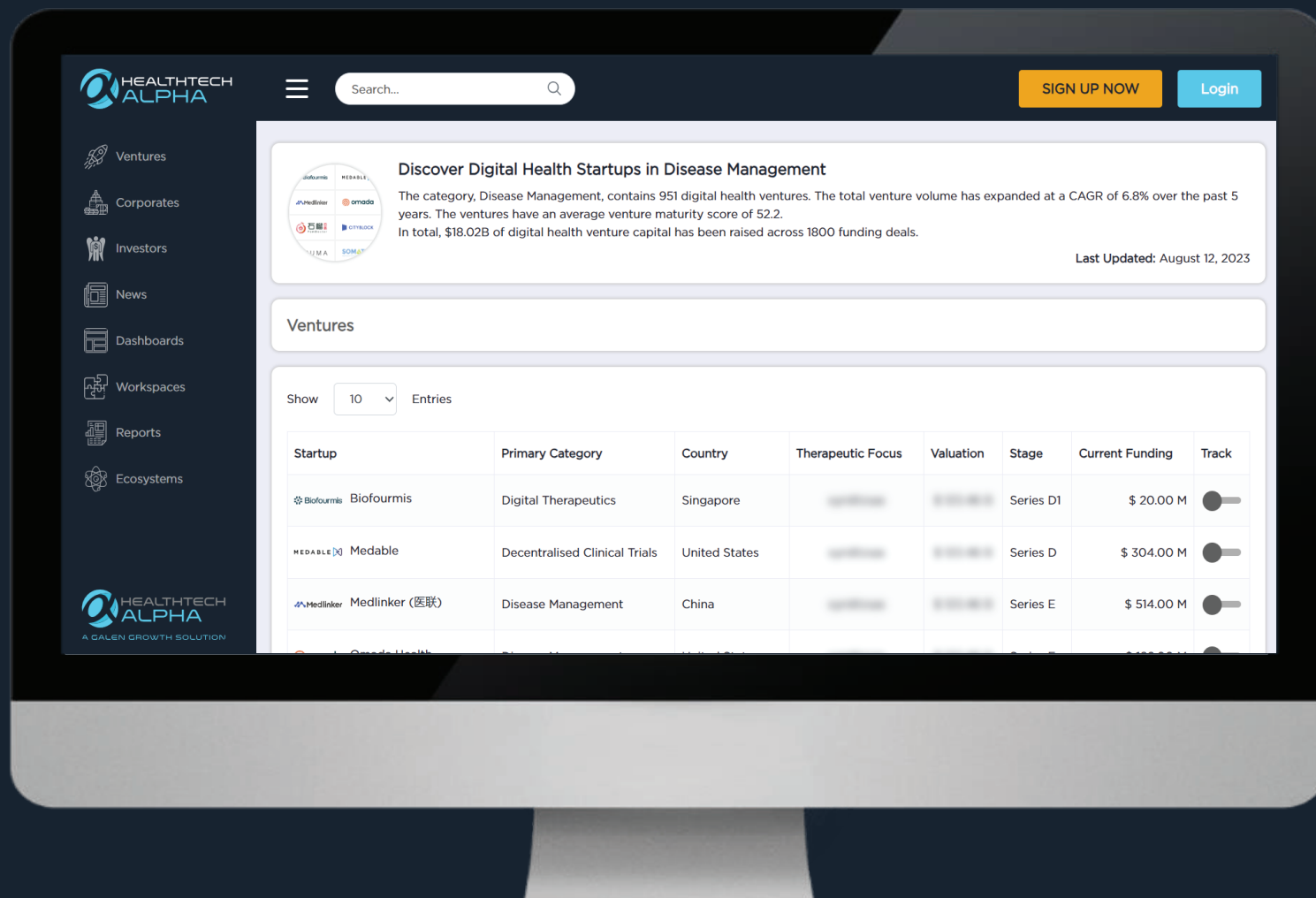
Mindstrong Health

Founded in 2016
Hired all-star executive team in 2019
Ended patient care in Jan 2023
Acquired by SonderMind in Mar 2023



Access all the data
behind this report and
conduct your own
analysis

Get started



Clinical Strength

ECOSYSTEM INSIGHTS

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DEEP DIVES

REGIONAL FOCUS



NORTH AMERICA



EUROPE



ASIA PACIFIC



MIDDLE EAST

Get in contact for the full report

NOTEWORTHY

KEY INFORMATION

KEY INFORMATION

Key Information

SCOPE OF REPORT

This report covers Digital Health ventures with incorporation date after 2002. The data is valid as of 01 July 2023.

Digital Health is defined as the intersection between healthcare and technology, and is also referred to as HealthTech. Digital Health does not include Biotech (protein research or pharmaceuticals), MedDev (devices that are mechanical and electronic in nature), neuro-stimulates, opioids and minimal-invasive instruments. We recommend reviewing our taxonomy on the next page for further details.

DATA SOURCING AND TRACKING

Galen Growth tracks a comprehensive inventory of key data points ranging from company demographics, funding and valuation to in-market capabilities on a continuously growing and curated list of HealthTech ventures drawn from global markets. Data is collated from primary research, public domain sources (press releases, news, public filings), proprietary analytics and from its unique network.

The information is:

- Disclosed and undisclosed by nature
- Continuously updated with the latest data
- Curated from both direct and indirect verified sources
- Augmented with our proprietary algorithms

Each HealthTech Alpha Index and Score is calculated using proprietary algorithms and data points drawn from our carefully curated HealthTech Alpha database. We recommend reviewing the Data & Methodology section for further insights.

KEY TERMS AND DEFINITIONS

BASE CURRENCY	USD
EARLY STAGE	All deals up to Series A stage
GROWTH STAGE	All deals at Series B & C stage
LATE STAGE	All deals at Series D & Beyond stage
EXIT	IPO, SPAC and M&A deals
HTA	HealthTech Alpha

IMPORTANT INFORMATION

This report is provided solely for informational purposes and was prepared in good faith on the basis of public information available at the time of publication without independent verification. Numbers will be updated from to time to reflect information identified after the event.

Galen Growth does not guarantee or warrant the reliability or completeness of the data nor its usefulness in achieving any particular purposes.

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RESEARCH INQUIRIES

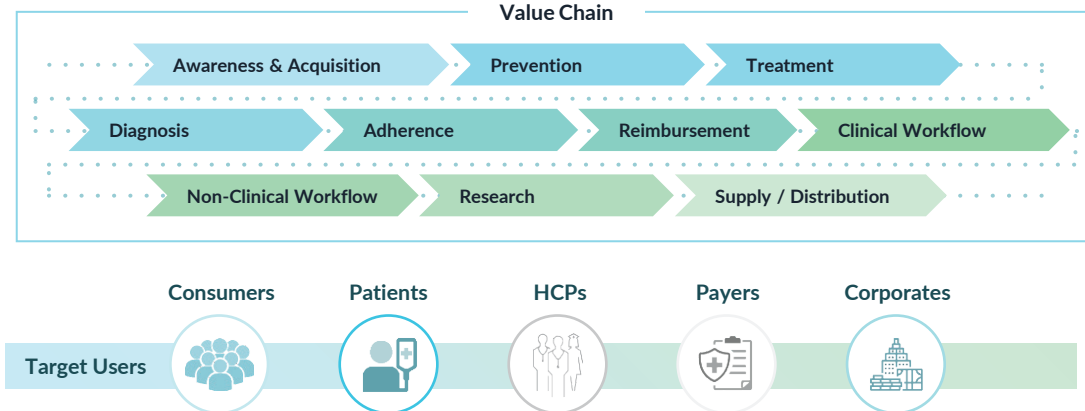
For more information about data, research and Galen Growth's proprietary algorithm contact: research@galengrowth.com for more information.



With 68 Digital Health categories across 18 clusters, Galen Growth's comprehensive taxonomy streamlines venture discovery and analysis.



Further classification of target users and value propositions



Data & Methodology

The Alpha Score is a 360° Venture Maturity assessment that aggregates four distinct and independent Alpha Indices

Momentum index: evaluates the present performance and fitness of the venture relative to its ecosystem peers.

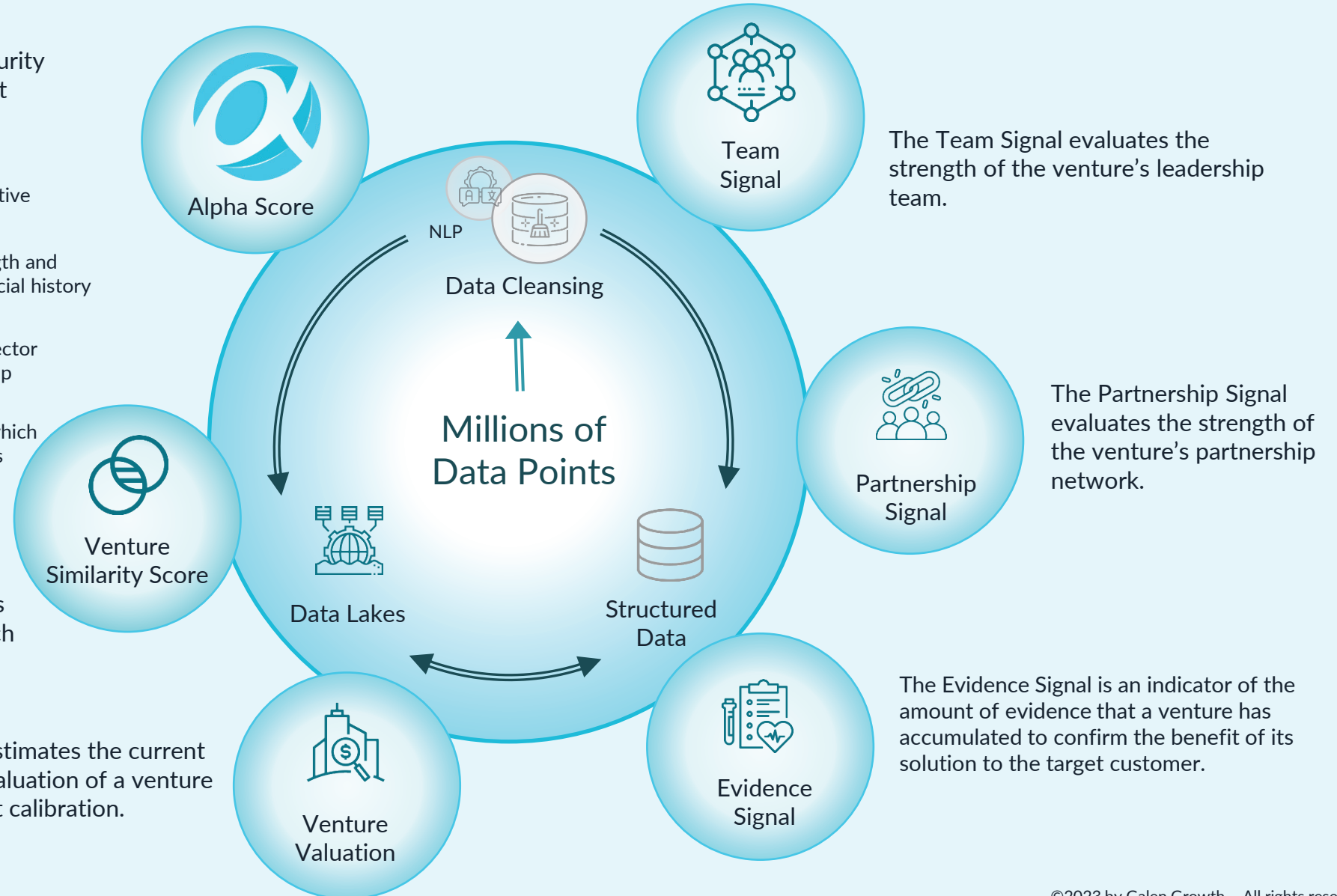
Money index: quantifies the financial strength and wellbeing of the venture based on its financial history and investor quality.

Market index: evaluates the health of the sector category and sub-category in which a startup competes

Innovation index: evaluates the degree to which the venture is solving healthcare pain points

The Venture Similarity Score indicates the commonality of existing data points between startups within the HealthTech Alpha database.

The Venture Valuation estimates the current and next funding stage valuation of a venture based on mark-to-market calibration.





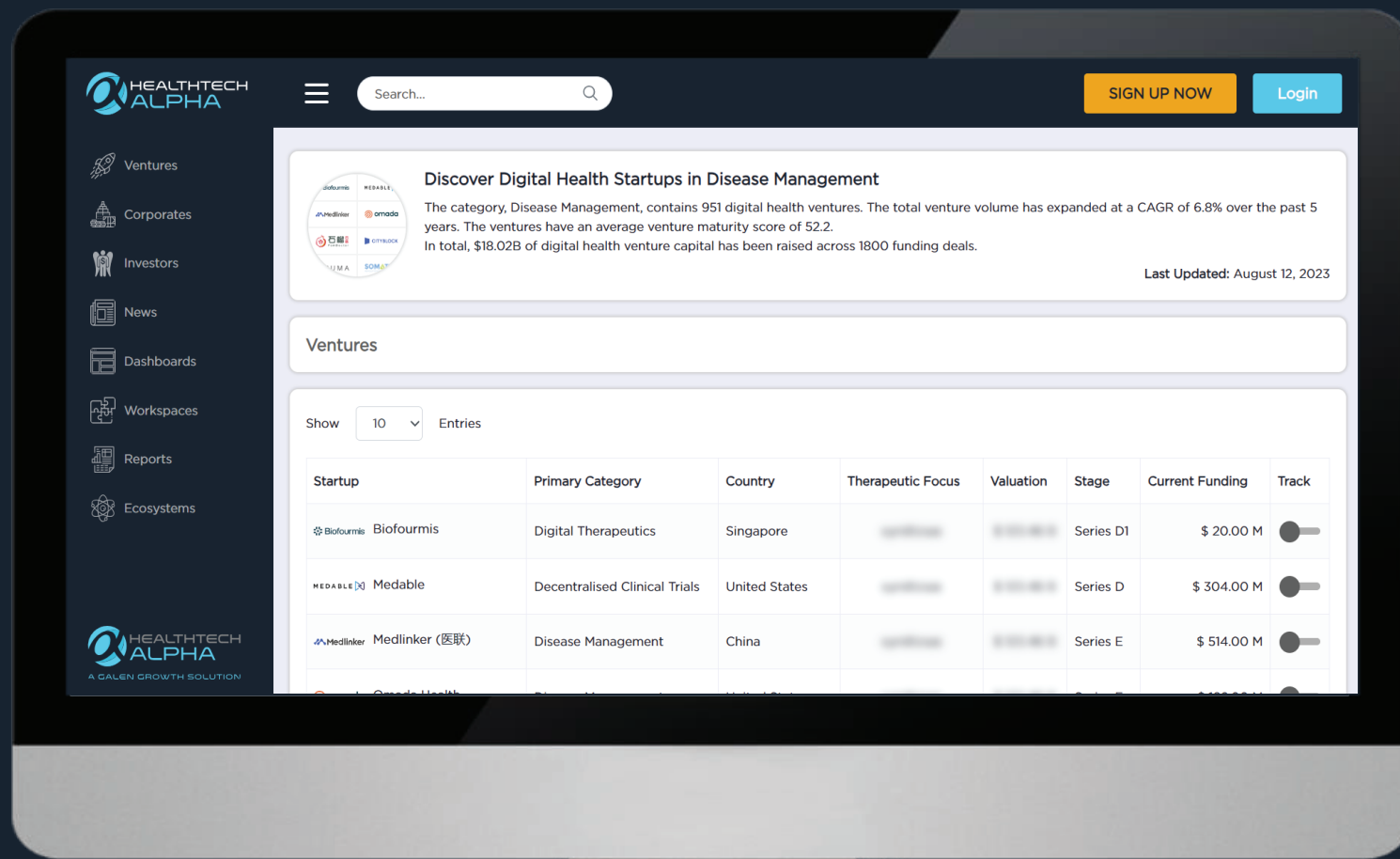
Explore the key themes driving the Digital Health ecosystem

Research

Telemedicine

Oncology

Neurology





Create your HealthTech Alpha account today

Better informed Digital Health innovation choices are just a click away with our best-in-class, private market data, intel and insights platform. Our comprehensive specialist data gives you all the information you need to make winning decisions.

Get started



Let's Discuss How We Can Deliver Your Strategic Healthcare Goals

Galen Growth Inc
United States

Galen Growth Asia Pte Ltd
Singapore

Galen Growth GmbH
Switzerland

Contact Us

Galen Growth USA

Boston, MA, USA

+1 (847) 456 8307

lawrence.wurtz@galengrowth.com



Lawrence Wurtz

Lawrence leads Galen Growth in North America with over 20 years of experience in high-growth healthcare companies.

Galen Growth Europe

Basel, Switzerland

+41 79 610 1764

julien.desalaberry@galengrowth.com



Julien de Salaberry

Julien is the CEO and leads Galen Growth's in Europe, leveraging over 30 years of experience in healthcare.

Galen Growth Asia

Singapore, Singapore

+65 9814 9018

ana.kollcaku@galengrowth.com



Ana Kollcaku

Ana leads our relationships with our Asia located clients and brings a wealth of management consulting experience in healthcare.