



EXECUTIVE SUMMARY

Global Digital Health 2022 • Thematic Report

Clinical Strength in Digital Health

Evidence of Clinical Strength • Drivers of Change

Ecosystem Insights • Partnerships • Global Investment Trends



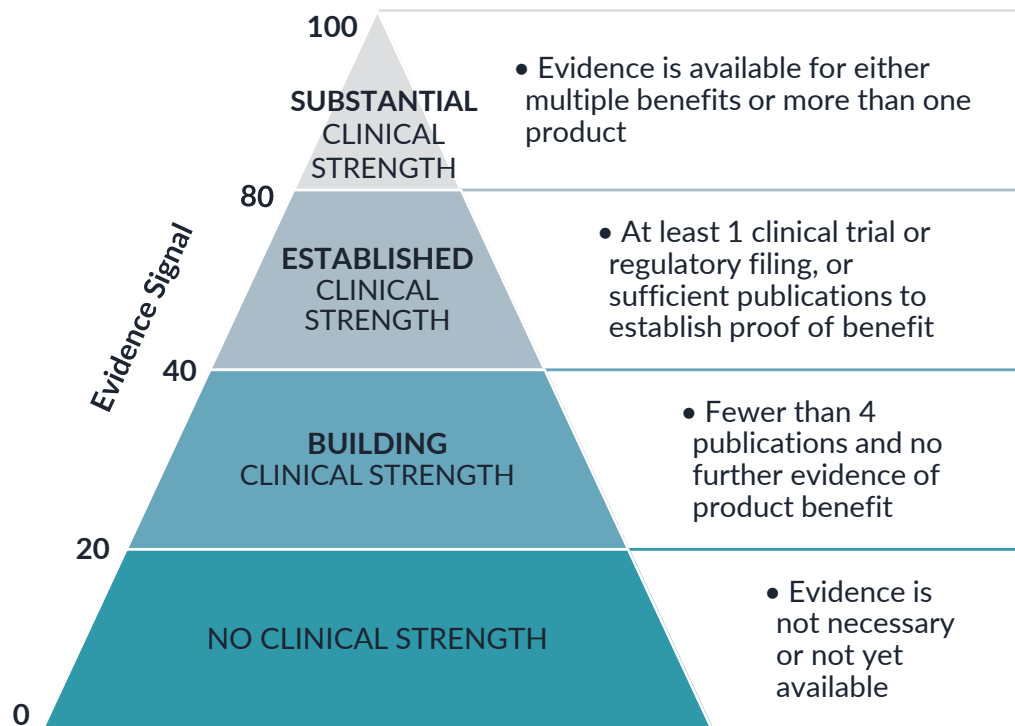
Key Insights

- With the **slowdown of venture funding in 2022**, Digital Health is anchoring back to reality, becoming more focused, and 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 **demonstrate the effectiveness** of their solutions.
- In another first-of-a-kind study, 12,000+ ventures across 5 regional ecosystems have been analysed in this report to reveal that the growth of evidence for Clinical Strength is growing at a **5-year CAGR of 40%**, or 4x the growth of new ventures.
- Galen Growth has introduced the **Evidence Signal** to facilitate the evaluation of the **Clinical Strength** of a venture based on the number of clinical trials, regulatory filings and peer-reviewed publications that a venture has generated as a proof point of the **medical benefit** of its solution to the target patient/consumer.
- Our ecosystem evaluation by Digital Health Clusters shows that over 35% of ventures with solutions in the top 2 clusters: **Medical Diagnostics and Remote Devices**, have established clinical evidence for their solutions, whereas other clusters, such as Health Services Search, have a single-digit share of ventures with established Clinical Strength, as they likely do not require such evidence.
- **Respiratory Diseases and Cardiovascular Diseases** took the top spots for therapeutic areas with the highest share of ventures with established Clinical Strength, at 45% and 40% respectively.
- As venture capital becomes more cautious, ventures that can show evidence that their solution benefits the intended user will be more **attractive for future investment**.



Scope of Clinical Strength for Digital Health Ventures

This report drills into HealthTech Alpha's **Evidence Signal**, which Galen Growth introduced to address the need to focus on Clinical Strength and the exponentially increasing number of clinical trials, regulatory filings and peer-reviewed publications that support the medical claims made by a venture for its Digital Health products. A high Evidence Signal correlates with high Clinical Strength.



Evidence Signal

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



Regulatory Filings

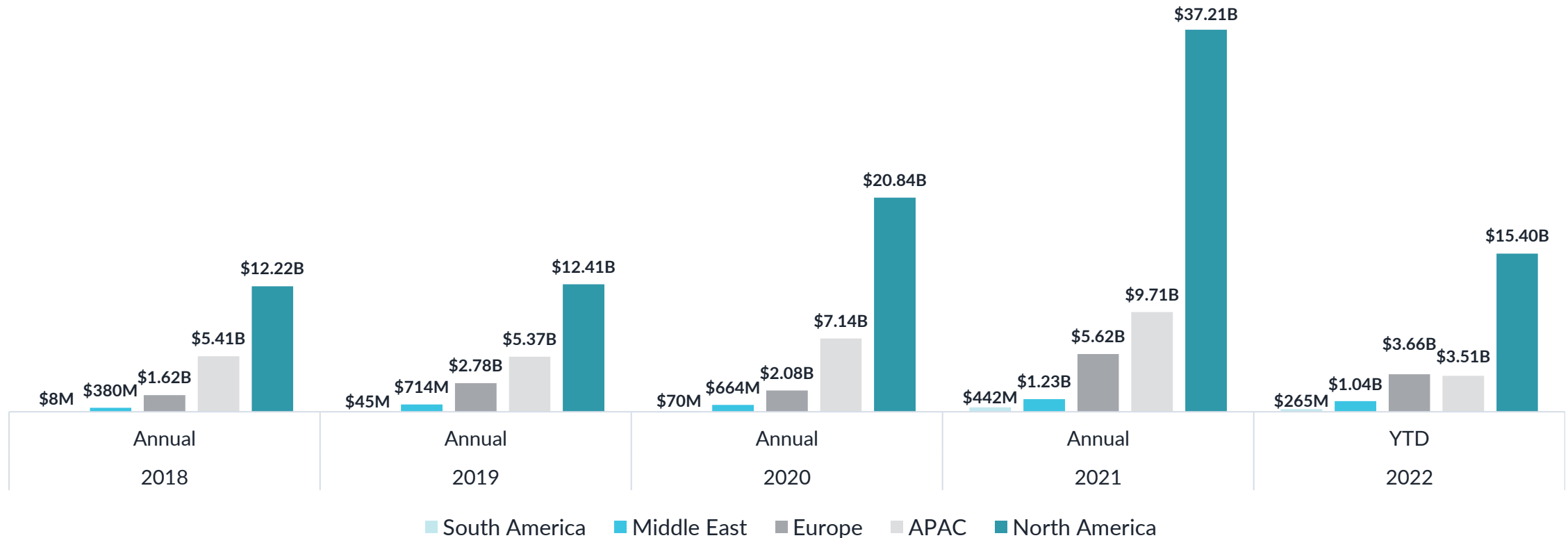


Peer-Reviewed Journal Articles

NOTE: Not all ventures require clinical evidence, and therefore it is not expected for all ventures to reach an Evidence Signal > 40

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 stages 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.



Digital Health Ventures Are Generating Evidence

Expanding on the methodology developed by Day et. Al¹, Galen Growth considers a venture's clinical trials, regulatory filings, and peer-reviewed publications to measure a venture's clinical strength, or put another way, the amount of evidence that is available to indicate that the venture's solution can deliver the expected medical results.

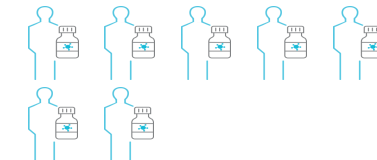
Clinical trials and regulatory filings, while necessary to assess clinical strength, are only a subset of evidence showing the effectiveness of a solution. Scientific publications that are verified through peer review indicate rigorous scientific methodology and build credibility for a venture.

Partnerships between industry and Digital Health ventures can accelerate evidence generation. Partnership trends and a ranking of the top partners are revealed in the full report.

Share of Global Digital Health Ventures with Evidence of Clinical Strength

7%

Clinical Trials



9%

Regulatory Filings



10%

Peer-Reviewed Publications



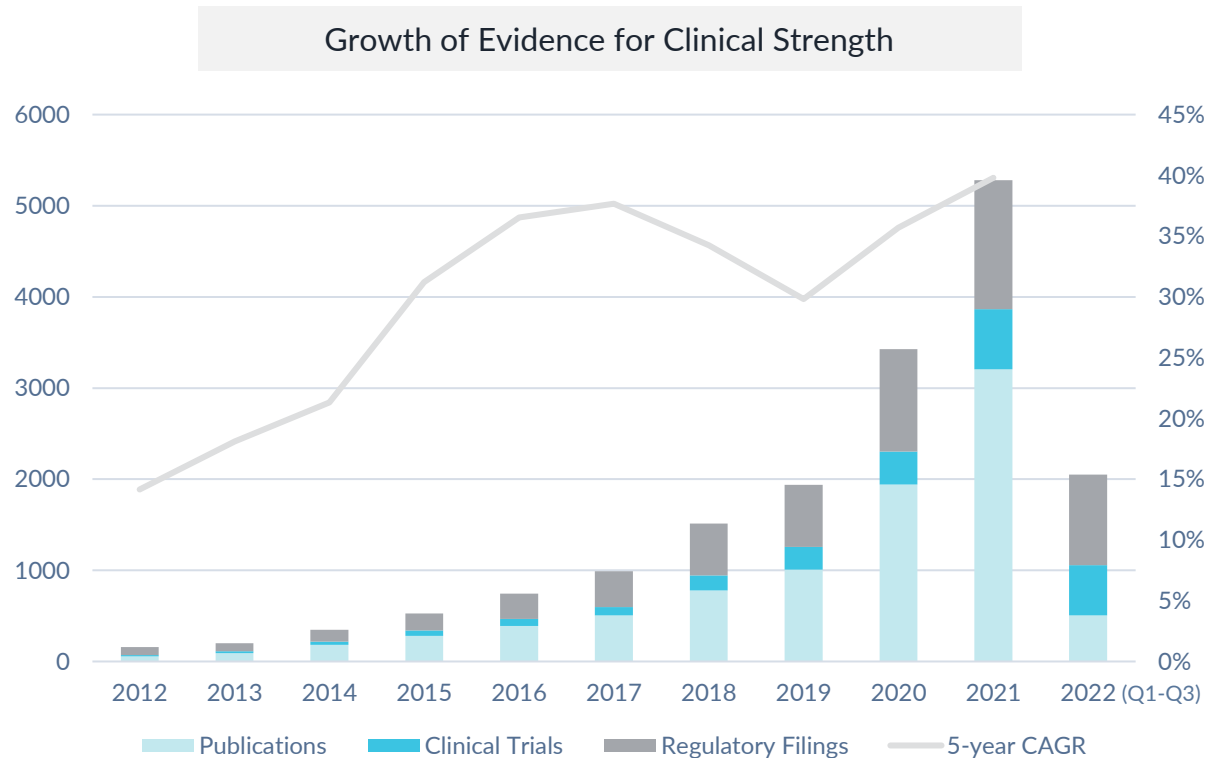
Note: A single icon represents 300 items

Reference:

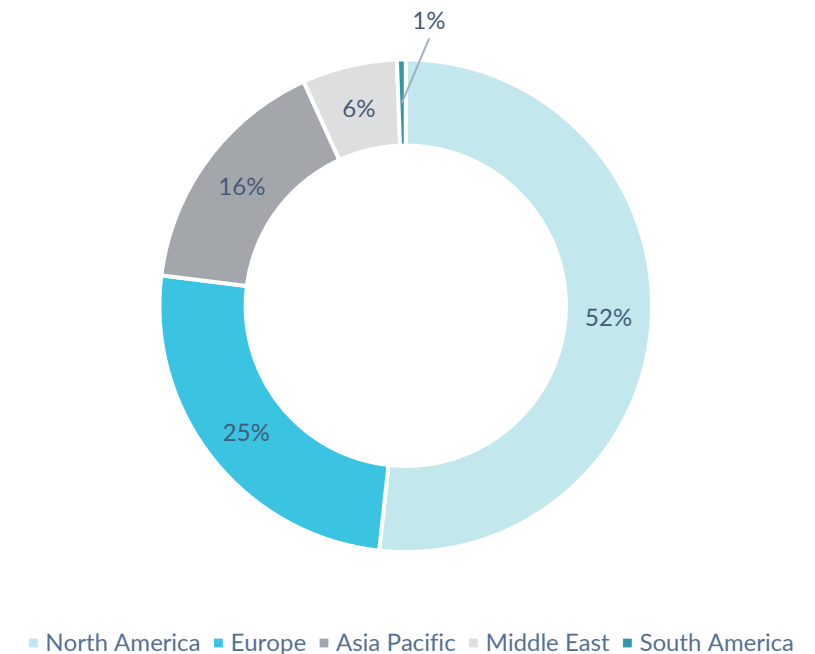
1. Day S, Shah V, Kaganoff S, Powelson S, Mathews SC Assessing the Clinical Robustness of Digital Health Startups: Cross-sectional Observational Analysis J Med Internet Res 2022;24(6):e37677

Clinical Strength for Digital Health Ventures

While the number of Digital Health ventures globally is increasing at a 5-year CAGR of 7%, the growth of evidence for clinical strength is growing at a 5-year CAGR of 40%, far outpacing the growth of new ventures. The majority of the evidence is being generated by ventures in North America. This report dives into the North American ecosystem, to uncover the Digital Health clusters with the most ventures with established clinical strength.



Regional Distribution of 2022 Digital Health Evidence



Clinical Strength for Digital Health Ventures

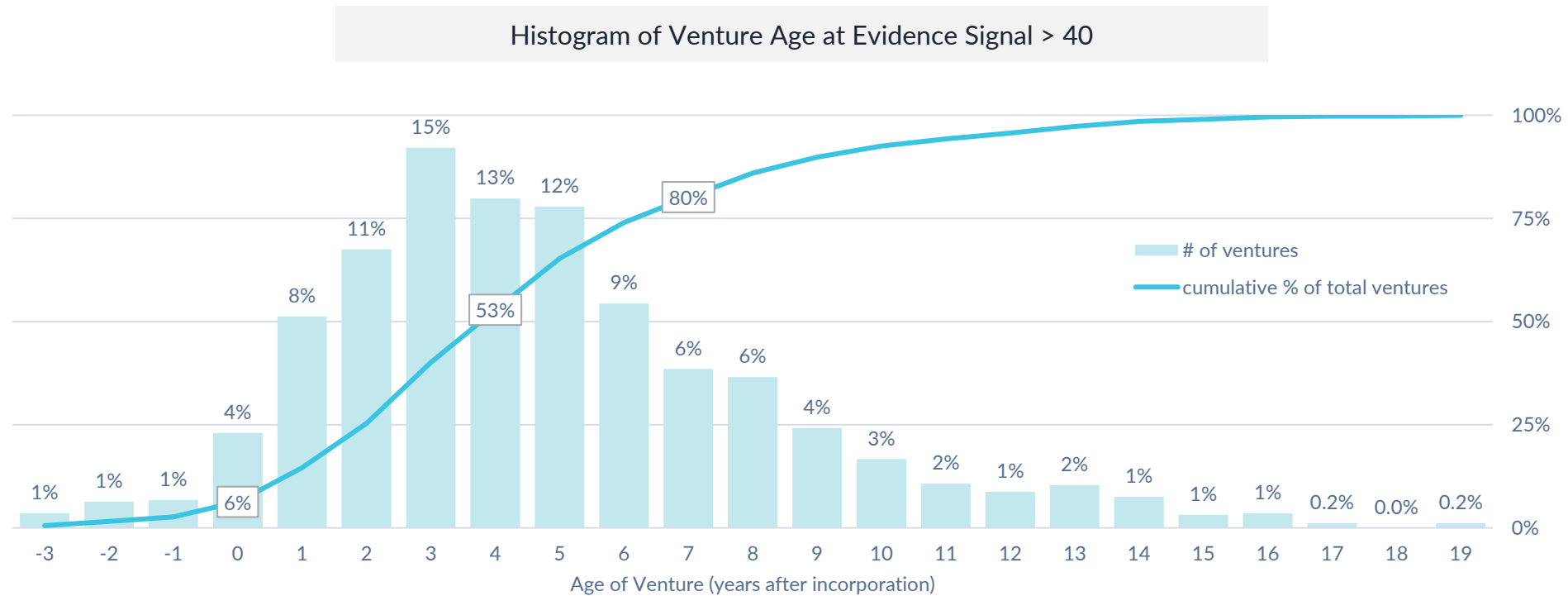
Using Galen Growth’s Evidence Signal and setting 40 as the minimum score at which a ventures is considered to have “Established” clinical strength (see slide 3), the distribution of scores for the Evidence Signal indicates that most ventures require time to build evidence after the incorporation date. The distribution of scores across venture funding stages and geographic regions is highlighted in the report.

Distribution of Venture Evidence Signal (status August 2022) by Incorporation Year

Evidence Signal	Venture Incorporation Date													
	< 2010	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
80 to 100	5%	4%	3%	3%	3%	2%	1%	1%	1%	1%	0%	0%	0%	0%
60 to 80	13%	9%	8%	8%	8%	7%	6%	6%	7%	3%	3%	3%	2%	0%
40 to 60	10%	9%	8%	8%	7%	8%	8%	7%	9%	9%	7%	5%	3%	2%
20 to 40	6%	4%	4%	5%	6%	5%	3%	4%	4%	3%	3%	3%	1%	2%
0 to 20	66%	73%	76%	75%	77%	77%	82%	82%	79%	84%	87%	89%	94%	96%

Digital Health Venture Age for Establishing Evidence

Distribution of ventures (including ventures that have exited) by age at which the venture reached the criteria for having established clinical strength (Evidence Signal > 40) indicates that 6% of ventures already had established clinical strength before the venture was incorporated. Example scenarios could include university spin-offs that have published results or spin-offs from larger organisations. Half of the global Digital Health ventures have attained established clinical strength by 4 years of operations, and 80% of ventures have reached this milestone by 7 years of operations.





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