JUN 28

Rajiv Leventhal

Digital health startups are generating billions, but they aren't producing clinical outcomes

Article

The news: Most digital health startups fail to demonstrate robust clinical evidence for their products, according to a new study published in the Journal of Medical Internet Research

(JMIR).

- Researchers analyzed 224 venture-backed digital health startups that have raised more than $2 million in funding, according to a funding database from Rock Health.

Digging into the data: Each company received a “clinical robustness” score from 0 to 10 based on their FDA filings and registered clinical trials.

- Note, a score of 10 is the highest possible score.
- Of the 224 startups included in the study, **98 (43.8%)** had a **clinical robustness score of 0.** The **average score was 2.5**.
- **20%** of the companies evaluated **received a mark of 5+**, and **just 13 (5.8%) earned a 10.**
- Startups that sell their solutions to employers received an average clinical robustness score of **3.1—15% higher** than those that target providers (**2.7**).

Why it matters: The companies in the study have collectively raised $8.2 billion in VC funding and have been around for an average of 7.7 years.

While some newer firms wouldn’t be expected to generate a high clinical evidence score, many companies in this review are well-funded and older.

Breaking down the marketing hype: Researchers also studied how many companies made claims on their websites about their solutions’ clinical, economic, and engagement outcomes.

- **32 companies (14.3%) posted one or more claims about clinical effectiveness** on their websites despite having a **clinical robustness score of 0**.
- 43% of the startups examined made no such claims on their websites.

The problem: The technological advances made in healthcare continue to impress, particularly as better access to care is a huge need. But if digital health companies can’t validate their products’ efficacy, will they impact patient care?

This study isn’t the first to underscore the lack of clinical evidence generated by digital health companies. But investments into health tech entities have soared in recent years, putting the onus on these startups to deliver outcomes.

- US digital health venture funding nearly doubled from 2020 to 2021, and startups in this space have raised nearly **$77 billion in total since 2011**, per JMIR.

- The FDA regulates medical devices, but the agency's oversight of digital health products is a huge gray area. These companies typically don't have to meet the highest standard of requirements.
- Digital health startups' customers—typically employers, insurers, and providers—will need "to demand greater validation for the products and services they purchase," according to the study's researchers.

The bottom line: Digital health startups have an opportunity to distinguish themselves by standing up to the test of clinical rigor and proving that their high valuations are deserved.

Digital therapeutics companies, for example, must demonstrate real-world evidence through randomized controlled trials to get employers and payers to cover their products.