



# Setting a New Standard

Empowering Buyers to Demand Better when Purchasing Digital Health Products

**The digital health industry has a credibility problem.** In recent years, funding for digital health companies has grown from \$4.8B in 2015 to \$29.1B by year end 2021 as the market has increasingly recognized the potential impact digital care can have on outcomes.<sup>1</sup> But the frenzy driving this funding has also given rise to an influx of products that are not clinical grade, leaving patients and business buyers questioning whether or not they can trust the promises they hear from vendors.

At Omada, it is our mission to do right by our members and customers, so we base our programs on clinically validated protocols and seek quality recognition from national accreditors. We believe that rigorous clinical research and

scientific evidence should be at the heart and soul of every digital health offering – because our members deserve care that upholds clinical best practices, and our customers deserve to have confidence in the products they buy.

THE FOLLOW-THROUGH PROBLEM:

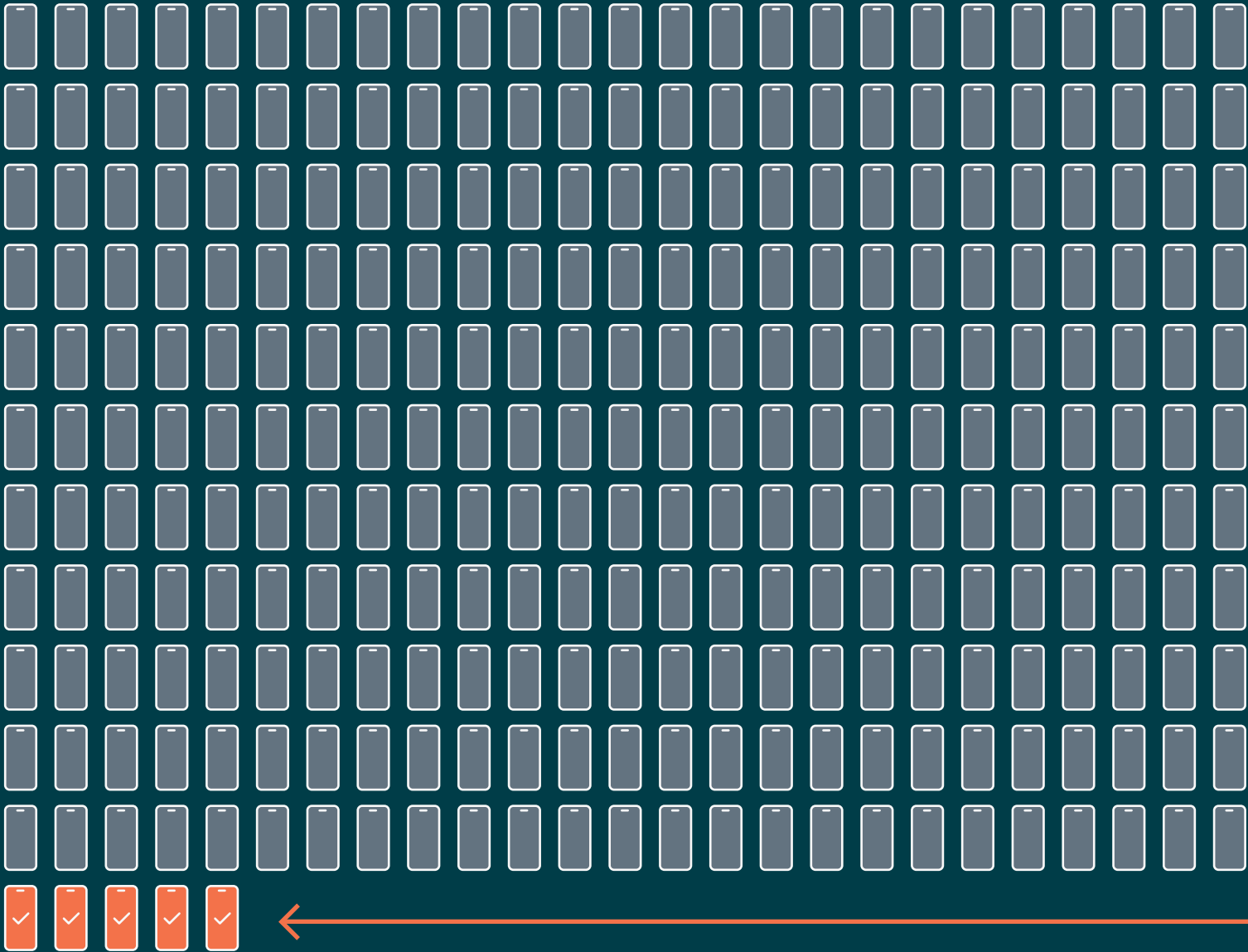
# Digital Health’s Unkept Promises

Although virtual-first care providers are subject to regulations to ensure claims made to consumers are substantiated with competent and reliable scientific evidence, in practice government agencies like the Federal Trade Commission lack the resources to pursue every complaint. As a result, they tend to focus their resources primarily on situations where alleged misrepresentations could directly harm consumers, and give less attention to protecting business purchasers.<sup>2</sup> This reality means the burden of identifying potentially false or fraudulent claims falls upon users or buyers of these products, who may not have the time or resources to distinguish rigorous science from faulty evidence. Understandably, buyers without sufficient resources are left wondering if they can trust that the claims made by vendors are trustworthy.

Omada is committed to helping buyers raise the bar in the digital health industry. Customers and patients deserve better and have the power to demand better. By learning to recognize faulty evidence, buyers can separate real value from empty promises. In this paper, we’ll lay out our view on what customers should look for and what questions they should ask when evaluating digital health offerings.



In one study, 44% of a sample of 224 digital health companies have zero registered clinical trials or regulatory filings<sup>3</sup> and, in a separate study, **of 280 mobile health applications, only 5 were associated with a clinically meaningful improvement in outcomes<sup>4</sup>**





# What to Look for when Purchasing a Digital Health Offering

Understanding the following key indicators of clinical rigor will allow customers to make an informed purchasing decision.

## Seek out digital health offerings that:

### 1. Are evidence-based and follow clinical practice guidelines

A clinical-grade program is one that is evidence-based, meaning it leverages the latest clinical practice guidelines published by accredited organizations, such as the American Diabetes Association. Additionally, a clinical-grade program will have its outcomes and claims validated through research published in credible peer-reviewed journals.



**Putting it into Practice:** Ask your vendor if their claims are validated through publications in credible peer-reviewed journals and if they invest in randomized controlled trials to demonstrate outcomes and validate claims.

### 2. Track against gold-standard metrics

Gold-standard metrics, derived from clinical practice guidelines, are the trusted and well-known outcomes metrics utilized by providers in the medical community and researchers in academia. When measuring outcomes, metrics and the measuring technique matter.



**Putting it into Practice:** Some companies may utilize convenience metrics like estimated Hemoglobin A1c, which is an estimation of the true A1c value. Convenience metrics are a shortcut to measuring the true value and may falsely inflate outcomes and cost savings. Ask the company if their metrics are aligned with clinical practice guidelines and utilized by healthcare providers.





### 3. Deliver a trustworthy ROI analysis

When it comes to ROI calculations, methodology matters. A strong ROI analysis should:

**A.** Utilize total cost of care as opposed to selected costs that make the program ROI look better than what it truly is



**Putting it into Practice:** An ROI analysis that includes the savings on medical spend resulting from the program but excludes increased spend in other areas of health care, such as spend on medications due to better adherence, will overstate program ROI. Ask vendors about which costs were, and were not, included in their ROI calculations.

**B.** Use a representative study population and an adequately-matched cohort



**Putting it into Practice:** An ROI analysis that selects a study comparison group that is sicker than the control group will falsely overstate program savings. Ask companies to walk you through their study and control group characteristics to help you understand if they are comparable on key factors such as demographics, health status and social determinants of health. Be sure the program is helping entire populations get healthier, not just those most affected by a condition.





### C. Focus on long-term (12+ months) return



**Putting it into Practice:** An ROI analysis that only shows short-term program benefits but not long-term (12+ months) benefits may indicate that the program does not improve long-term outcomes. Ask vendors about both short-term and long-term ROI to fully understand a program's impact.

## 4. Operate as a health care provider

An organization that operates as a health care provider will be a HIPAA Covered Entity. Health care professionals should be licensed where that is the standard for the practice of care, and be credentialed as applicable.



**Putting it into Practice:** Watch out for companies that claim to be a digital health provider but are really just tech companies with a healthcare product and a robot interface. These companies may not be required by HIPAA to protect the privacy or security of your employees' data. Ask vendors whether or not they are a HIPAA Covered Entity and understand what types of healthcare credentials their staff hold.





# Omada’s Clinical-Grade Approach

Omada Health, a virtual-first care provider with **human-led coaching services**, is built upon a foundational commitment to clinical rigor and precision, which is evidenced through the company’s 24 peer-reviewed studies, including the largest **randomized controlled trial** of a virtual diabetes prevention program. Omada’s products are developed based on evidence-based programs and accredited by credible external parties – for example, our programs for Diabetes Management and Diabetes Management + Hypertension are **accredited by the NCQA**. Omada prides itself in starting with science and insisting on outcomes because we know that this approach translates directly into long-term benefits for both our members and our clients. For financial projections, Omada’s preferred method for calculating ROI is to conduct a claims analysis using longitudinal data of annual health care claims. We use employer data to construct a comparison group that is matched to the study group, then evaluate these groups for clinical outcomes and claims costs.

For more information about Omada Health’s approach to clinical rigor, visit [omadahealth.com](https://omadahealth.com) or contact [press@omadahealth.com](mailto:press@omadahealth.com).

## 24 Peer-reviewed Studies

Validation Against CDC Standards	Performance Compared to In-Person Programs	Projection of Reduced Diabetes Incidence	Long Term Benefits	Success with Seniors Economic Impact
Program Adaptability	Medicare Success	Efficacy in a Nationwide Workforce	Validated 3-Year Outcomes	Medicaid Receptiveness
Superior Engagement	Medicaid Success	Randomized Controlled Trial Protocol	Medicare Economic Outcomes	Workforce Healthcare Savings
Reduced Risk in a Workforce	Meaningful Outcomes for People Living with Diabetes	Cost of Implementing Digital DPP	Population Health Management Approach	Patient-Provider Relationships Drive Meaningful Outcomes in MSK
	Clinical Outcomes Compared to In-Person Care	Blood Pressure Reduction in Hypertension Population	Success in Digital Physical Therapy	Impact of a Digital Diabetes Program on Medical Costs and Diabetes...





## CUTTING THROUGH THE NOISE: A Buyer's Quick Guide to Demanding Clinical Rigor in Digital Health Offerings

When evaluating digital health offerings, keep the following questions in mind to help ensure the product being purchased is a rigorously-tested, clinical-grade digital health program.

1

### Do they follow clinical best practices?

Clinical best practices include leveraging clinical practice guidelines and validating outcomes and claims through peer-reviewed journal publications.

2

### Do they track against gold-standard metrics?

Gold-standard metrics, which are derived from clinical practice guidelines, are the trusted and well-known outcomes metrics utilized by providers in the medical community and researchers in academia.

3

### Do they use reasonable assumptions and long-term methodology in their ROI calculations?

When analyzing a company's ROI, ensure that it is based on total cost of care, utilizes a comparison group that is representative of the study population, and shows long-term (12+ months) ROI.

4

### Do they operate as a clinical provider?

An organization that operates as a clinical provider will be a HIPAA-covered entity and will employ properly credentialed or licensed staff.





## Ready to get started?

Schedule a call with an Omada representative today:

Contact Omada Today

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## References

- 1 <https://rockhealth.com/insights/h1-2022-digital-health-funding-two-sides-to-every-correction/>
- 2 <https://www.ftc.gov/about-ftc/mission/enforcement-authority>
- 3 <https://rockhealth.com/insights/assessing-the-clinical-robustness-of-digital-health-startups/>
- 4 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6550273/>