Health Value Evidence Quality:
A Framework to Advance Private Investment That Improves Health Care and Health

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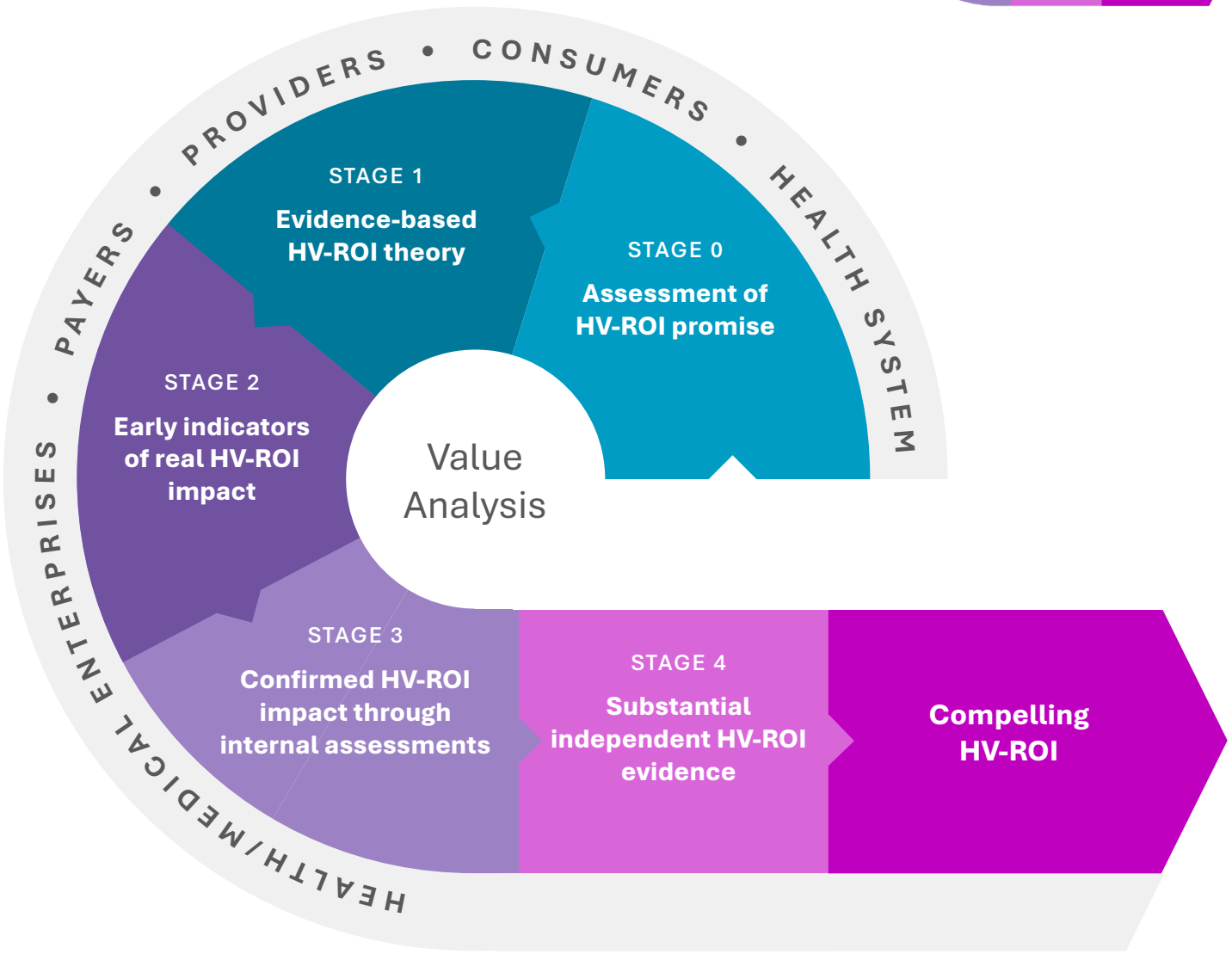

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Disclosure

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Mark McClellan is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

About Duke-Margolis

The Robert J. Margolis, MD, Institute for Health Policy at Duke University is directed by Mark McClellan, and brings together expertise from the Washington, DC, policy community, Duke University, and Duke Health to address the most pressing issues in health policy. The mission of Duke-Margolis is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions. Duke-Margolis catalyzes Duke University's leading capabilities, including interdisciplinary academic research and capacity for education and engagement, to inform policymaking and implementation for better health and health care. For more information, visit **healthpolicy.duke.edu.**

About the Capital Impact Council

The Duke-Margolis Capital Impact Council, co-chaired by FlyteHealth Executive Chair Dr. Cheryl Pegus and Duke-Margolis Director Dr. Mark McClellan, is comprised of mission-aligned venture capital and private equity investors and Duke-Margolis Advisory Board members. The council is dedicated to:

- Advancing use of evidence and establishing best practices for achieving measurable health value improvements through private investment in health care.
- Driving the impact of private investment in health care to improve the lives of people and communities.

Learn more about the Capital Impact Council at healthpolicy@duke.edu/cic.

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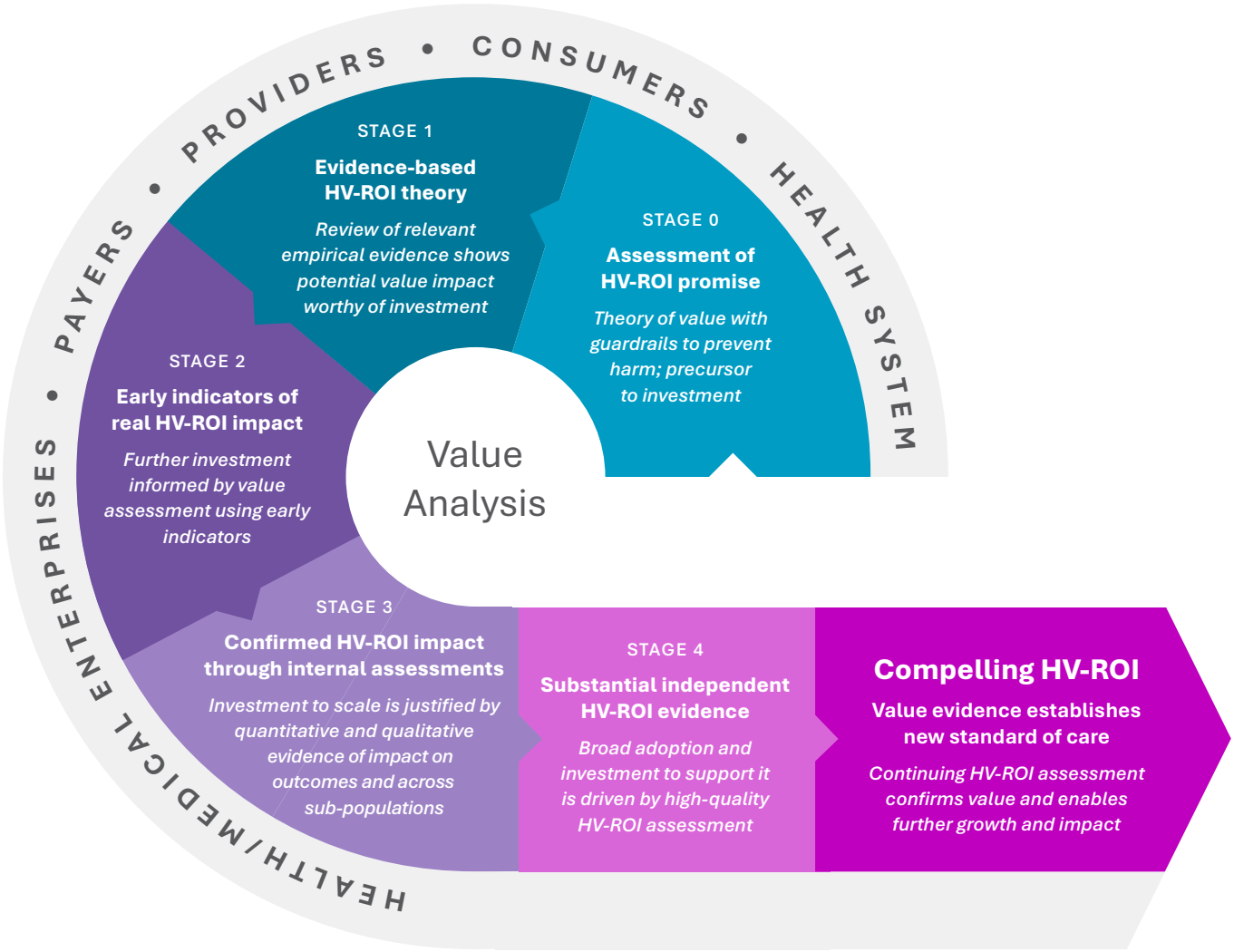
EXECUTIVE SUMMARY

Private for-profit investment continues to play a major role in efforts to improve health care access, affordability, and outcomes. Yet, persistent questions remain about the extent to which this capital is delivering measurable health value to health care. To address this challenge, we present a Health Value Evidence Quality (HV-EQ) Framework designed to help investors and their partners produce more compelling evidence of health value. The HV-EQ Framework draws on prior research on the impact of private investment on medical services, prior frameworks on developing evidence in health care, and recent health investor initiatives.

Figure 1 | Summary of Health Value Evidence Quality Framework



The HV-EQ Framework was developed with guidance from the **Duke-Margolis Institute for Health Policy's Capital Impact Council (CIC),** a group of experienced investors committed to advancing resources, evidence, and published best practices, to help assure investments deliver health value alongside financial returns. This Framework complements the CIC's Health Value Return on Investment (HV-ROI) Framework.

The HV-EQ Framework identifies four stages of evidence quality and demonstrates how an intentional HV-EQ strategy can be incorporated at each stage of an investment's life cycle. We describe the foundations for the framework, its methods and metrics, and provide examples from CIC member experience that illustrate its practical application in health care investments. We identify promising directions to refine the framework and streamline its application in key areas of health care investment through cross-industry collaborations, partnerships with assessment organizations, and by advancing public policies that support health value returns.

Our review of the CIC case examples and the broader evidence landscape on health value in private investment shows that, despite persistent gaps, private capital investors can take meaningful steps to directly and routinely support their portfolio companies' efforts to measure health value. These steps reduce long-term risk and increases their ability to impact health care and health:

- **Define and regularly revisit a core health value question set** to guide a company's care model and strategy throughout the entire holding period, i.e., the time it is owned by an investor
- **Build a forward-looking evidence strategy** that advances as the company evolves
- **Support and disseminate health value assessment best practice**s based on portfolio companies' experiences and prioritize funding for organizations that follow these practices
- **Increase both the supply of and demand for stronger health value evidence** by structuring commercial partnerships that accelerate evidence generation and by leveraging these partnerships to increase market demand for companies with strong health value evidence
- **Collaborate with assessment organizations** to clarify health value evidence pathways in the company's value impact area, reducing risk and increasing efficiency
- **Participate in collaborative platforms for evidence generation,** including those supported by philanthropies aligned with health value creation as well as public-private partnerships that normalize, reward, and scale evidence generation

Building on these strategies, the CIC aims to work with a range of collaborators to advance best practice models for demonstrating health value in private capital investment, and to strengthen and publicize measurement approaches that assess CIC members' own contributions to health value development. At a time when private investment that positively impacts health care is needed more than ever, the HV-EQ Framework can help assure that financial returns align with better health.

BACKGROUND

Health care in the United States is at a crossroads. Health care providers and plans need to invest in new models of care, yet tightening payment rates and rising labor and material costs limit their ability to do so without assistance. Federal, state, and employer budget pressures–driven by high and rising health care costs–suggest that payment rates will continue to tighten, leaving little room to support substantial long-term investments. Consequently, private investment remains a critical driver of health care reform and innovation. Private capital is well positioned to develop and scale new approaches to some of health care's greatest challenges. Private for-profit investment can enable health care organizations to leverage digital technology, AI, diagnostics, and therapeutics that can help prevent or cure diseases, and can support better coordinated and personalized care models that improve access, affordability, treatments, and outcomes. Studies have demonstrated such benefits from both early-stage venture capital investment, which raised $0.9 billion in capital in 2024 across 29 funds, and later-stage private equity investment, which raised $16.9 billion in capital in 2024 across 32 funds.

Despite this need, significant and valid concerns exist about whether private capital is reliably advancing the health care reforms required versus enabling profitable disruptions that do not improve health or affordability. Much of the evidence to date, which focuses primarily on private equity, highlights mixed or adverse consequences in specific sectors or cases, including staff reductions and other cost extractions that may harm access or outcomes, increased spending from higher utilization, and worse performance on broad quality measures, such as readmissions and in-hospital adverse events. Private equity investment also has been linked to recent increases in consolidation with increased prices and spending. With private investment in health care at a critical point, a growing interest exists in integrated investor/CEO strategies to address HV-ROI more intentionally as a pathway to increasing the impact of private for-profit investment on health care transformation.

The **Duke-Margolis Institute for Health Policy's Capital Impact Council** (CIC), a group of experienced venture capital and private equity investors, is dedicated to advancing private capital investment that demonstrates impact on health care outcomes, access, and affordability alongside financial returns. Through its **Health Value Return on Investment (HV-ROI) Framework,** the CIC aims to strengthen and expand the use of effective Health Value assessments to increase the positive impact of private capital investments for patients, health care professionals, communities, entrepreneurs, and investors, and to advance a sector-wide approach for doing so. The framework, released in 2025, synthesizes approaches being used to align and reinforce health value and financial ROI strategies across the spectrum of private for-profit investment to improve care. Previously-released CIC case studies illustrate how the HV-ROI framework can be applied across diverse health care investments, strengthening best practices and making meaningful HV-ROI assessment more effective and routine.

A key driver of the HV-ROI framework is the development of valid and meaningful supporting evidence across an investment's holding period. While demand for better evidence is growing, generating high-quality evidence is often challenging for individual companies and their investors. The gold standard–prospective randomized controlled trials (RCTs) that utilize reliable, consistent key data and rigorous analytic methods–is costly and time consuming, creating burdens even for late-stage companies with significant capital and revenues. Earlier stage companies may still be refining their business models based on early evidence of financial and health value, resulting in tradeoffs between rapid but imperfect evidence versus more robust studies that are more costly and may not remain relevant. Evidence development also requires coordination with clients who must be willing to share reliable data and participate in methodologically sound evaluations, adding further complexity.

However, industry trends and growing experience by investment groups suggest that health value evidence generation is becoming more feasible. Advances in electronic data capture and exchange (supported through application of the TEFCA framework, Bulk FHIR adoption, and the Center for Medicare & Medicaid Services (CMS) Health Technology Ecosystem initiative), more reliable real-world data, rapid learning networks and platforms that make it easier to develop needed evidence at scale (such as, LHS E-StaR Centers and Health Care Payment Learning & Action Network (HCP-LAN), among others), along with assessment frameworks and independent analyses are enabling easier and more routine health

value evidence development. While randomized studies remain the gold standard, increasing experience and best-practice guidance exists for robust observational studies when randomization is not feasible, as well for pragmatic, real-world, randomized studies using data from within routine care delivery settings, that assess products and services under conditions and in populations close to usual conditions of use. These developments create unprecedented opportunities for advancing meaningful health value evidence on private health care investment.

CIC members and collaborators are leveraging the progress in data, methods, and expectations for evidence on value. These steps can create more practical and scalable approaches to needed evidence development and help improve business models to enable greater health impact. Early-stage companies that incorporate a HV-ROI Framework into their strategy can leverage it to generate leading evidence and a clearer roadmap to more substantive HV-ROI evidence as their business case evolves. We hypothesize that a forward-looking strategy that embeds best practices throughout the full holding period of an investment can reduce the cost and time required to generate evidence and increase both financial and health value returns. Further, growing opportunities for collaboration across health care organizations, health plans, and philanthropically supported platforms can create ongoing support for timely health value evidence development and health care transformation, particularly in areas of public-private interest such as digital health, AI, primary care, and population health.

In this paper, drawing on CIC experience and expertise, we review key challenges and progress in developing HV-ROI evidence, including examples from specific for-profit health care investments. Based on our analysis, we propose and apply a framework with practical steps that individual investors and collaborative efforts can undertake to accelerate development of valid HV-ROI evidence–with the goal of high-quality HV-ROI generation becoming a routine, practical element of health care investment.

Literature Review: Relevant Frameworks for Assessing and Advancing Health Value Evidence Quality

We conducted a literature search, supported by informal expert interviews, to review approaches used to develop health value evidence. We found a range of widely used frameworks for assessing health care innovations, as well as frameworks for evaluating the social value of investments and companies. Few, however, provide detailed guidance for developing evidence on the health value impact of private investment through the full investment life cycle.

We identified four major categories of existing frameworks relevant to improving evidence on health value:

- Health technology assessment
- General private investment evaluation
- Real-world evidence (RWE) quality
- Routine and reusable learning/evidence platforms

Drawing on these frameworks, along with our case examples of the use of evidence in private health care investment, we identified the following key dimensions required for an HV-ROI evidence framework in private health care investment:

- Investment Stage–How firmly developed and scaled is the investment?
- Key Dimensions of Health Value – What aspects of value to patients, providers, payers, and society is the investment expected to impact?
- Data Quality–Are the data used in the value assessment strategy "fit for purpose" to support evidence generation?
- Methods Quality–Are the methods used in the analysis "fit for purpose" and likely to produce unbiased, informative results relevant to th stage of investment?
- Evidence Potential–Does the investor or firm have a forward-looking strategy that will generate stronger evidence on value, and on increasing future value, as the investment progresses?

Table 1 | Summary of Relevant Frameworks

	Health Technology Assessment (e.g., PHTI)	Private Investment Evaluation (e.g., NESTA)	Real-World Evidence Quality (e.g., FDA and frameworks)	Learning/Evidence Platforms (e.g., many public-private and private collaboratives)
Investment Stage	**Later-Stage**	**All Stages**	**All Stages**	**Mid- to Late-Stage (Scaling)**
Dimensions of Health Value	Clinical Impact: user experience, safety and effectiveness, health equity; Economic (Financial) Impact: cost, spending by payers and patients	Impact on well-being of populations served, with focus on investments in social innovations that improve children's health and reduce obesity	Developed with focus on clinical outcomes (benefits and risks) but applicable to other dimensions	Developed with focus on clinical outcomes (benefits and risks) but applicable to other dimensions
Data Quality	Presumes reliable and accurate data as evidenced by peer-reviewed, published high-quality studies	Depends on stage of investment – more qualitative and limited data at early stages; expectation of larger-scale and more complete data at later stages	"Fit for purpose" data framework describes key "real-world" data features needed to avoid bias and support a particular type/level of study	"Fit for purpose" data framework describes key "real-world" data features needed to avoid bias and support a particular type/level of study
Methods Quality	Emphasis on peer-reviewed, randomized, prospective studies, as assessed by independent experts	Depends on stage of investment – more limited analyses (before/after, nonrandomized) may be sufficient at earlier stages; randomized or otherwise more rigorous evidence at later stages	"Fit-for-purpose" methods framework describes study design considerations for confident causal analysis in real-world settings, including randomized and non-randomized well-controlled studies	"Fit-for-purpose" methods framework describes study design considerations for confident causal analysis in real-world settings, including randomized and non-randomized well-controlled studies
Evidence Potential	Point-in-time assessment of evidence certainty, based on overall quality of the body of evidence; aims to provide clear standards for further evidence that companies should develop by the time they go to market at scale	Provides strategic planning framework for improving investment and generating high-quality evidence on social impact by the time that it is ready to scale	Informs strategic planning for evidence generation to improve investment and support scaling	Informs strategic planning for evidence generation to improve investment and support scaling

Health Technology Assessment Applied to Private Health Care Companies: Health technology assessment (HTA) tools and approaches have been applied extensively in the U.S. and globally, particularly to evaluate the value of drugs, devices, and other specific medical interventions. More recently, assessment organizations have applied these established methods to evaluate the health value of the products and service sets of privately financed innovative health care companies. For example, the Peterson Health Technology Institute (PHTI) conducts comprehensive reviews of companies that have developed digital health solutions (a company's set of products and services). Applying HTA methods, ratings are based on secondary reviews of published literature, performance data, and proprietary or non-public data submitted directly by companies.

Dimensions of Health Value. PHTI focuses on evidence of impact across two main dimensions of health value:

1. **Clinical Impact –** Health outcomes that matter to patients. For diabetes management solutions, for example, primary outcomes include glycemic control with secondary outcomes such as body weight, blood pressures, and total cholesterol.
2. **Economic Impact –** Cost, resource use, and utilization. For example, for diabetes solutions, pricing was compared to expected medical cost savings from avoided care.

PHTI focuses on clinical and economic outcomes rather than early indicators, such as patient engagement and persistent use. Solutions are rated as having a positive, moderate, or negative impact based on a value-weighted integration of the impacts on clinical and economic outcomes.

Quality of Evidence (Data and Methods). PHTI assesses the certainty or confidence in the evidence based on factors that reflect best practices in HTA. Strength of evidence reflects both the magnitude of the difference in net health benefit (the balance between benefits and risks or adverse effects) between a therapeutic agent and its comparator, and the level of certainty around the best point estimate of that benefit.

PHTI evaluates data quality and representativeness, which are factors in peer-reviewed publication decisions and therefore, carry substantial weight in its review. PHTI also emphasizes on methods quality, prioritizing randomized, prospective studies because HTA literature consistently shows they are most likely to yield unbiased and credible results. Published, peer-reviewed observational studies are considered, with careful review as they are more likely to be subject to bias. For example, prospective studies with well-matched populations and/or clear methods to control for potential unmeasured differences. Press reports and other non-peer reviewed products are heavily discounted.

Accounting for Stages in the Innovation Process: Evidence assessments, like those conducted by PHTI, focus on evidence available at a specific point in time, including gaps that companies and their investors aim to fill. Recognizing that evidence will evolve as an innovator matures, NESTA–the UK's "innovation agency for social good"—supports the design, testing, and scaling of innovative solutions to major social problems. Its work is not limited to health care–indeed, many of its focus areas, such as improving child well-being and reducing population obesity, involve non-medical innovations. It is also not limited to private for-profit investment. Its evidence assessment considers both key dimensions of value (impact on outcomes that matter and cost) and evidence quality. Importantly, NESTA's value assessment methods can be applied both to mature solutions and also to advance a more efficient and predictable innovation process that leads to scaled social value creation. For this reason, NESTA's framework explicitly incorporates consideration of the stage of investment.

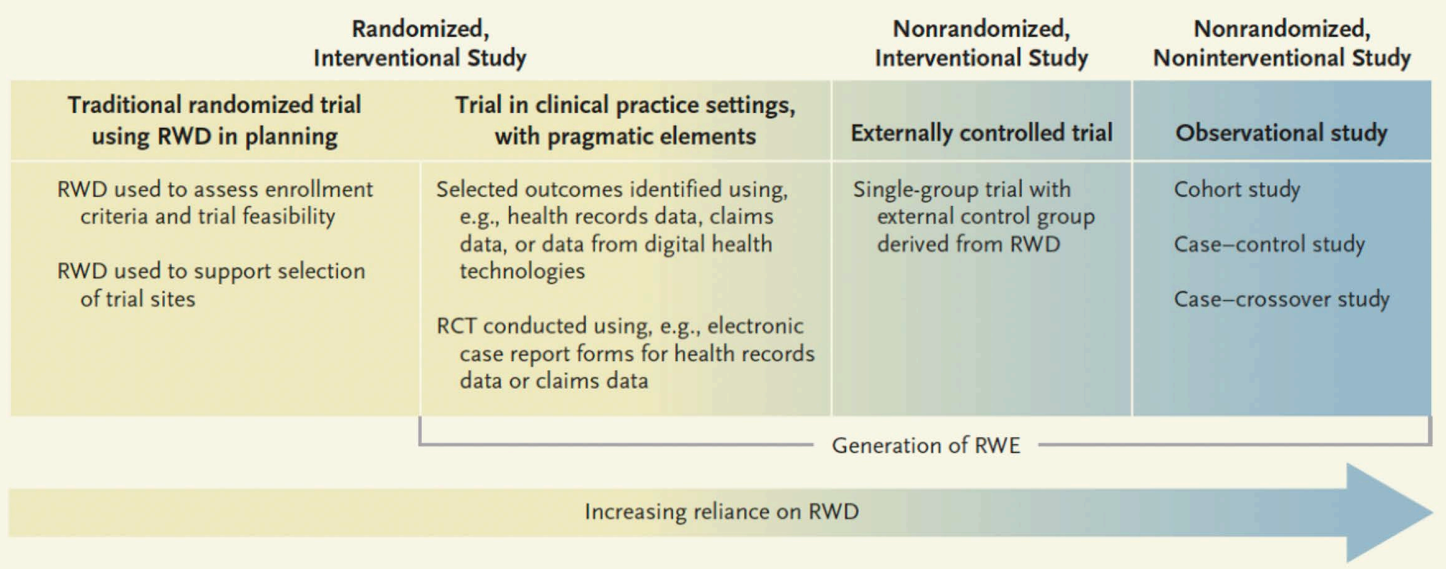
Stage of Investment. NESTA's framework notes that early-stage innovation investments are generally informed by internal, often non-public data that suggest positive impacts. In contrast, later-stage, more mature companies are expected to demonstrate clear impacts on key dimensions of social value. Similar to high-quality HTA evidence, substantiating such impacts requires using a control or comparison group and, eventually, independent third-party evaluations. Unlike PHTI, however, NESTA does not require randomized, prospective studies to reach its highest level of evidence. This allowance may reflect that such randomized studies are often less feasible for social programs and complex interventions in diverse settings (e.g., community social care reforms versus a specific drug dosage in a defined patient population). The substantial cost of such a study is typically justified only when a product or service is mature, well-defined, and expected to be scalable in its current form.

Real-World Evidence (RWE) and RWE Quality: Because of the feasibility challenges associated with traditional clinical trials, HTA organizations, expert groups developing practice guidelines and recommendations, and health care purchasing organizations increasingly rely on **real-world data (RWD) and real-world evidence (RWE)** to inform decisions about the value and use of products and services. As electronic health-related data and its interoperability has expanded, published studies using RWE have grown rapidly, prompting development of frameworks to assess its quality. These frameworks focus on both the reliability and appropriateness of the RWD used in the analysis and the quality of the methods applied to draw causal inferences about the impact of a medical product or other intervention.

RWD are data collected as part of the routine delivery of health care from a growing variety of sources, including Electronic Health Record (EHR) data, claims data, data collected from digital health technologies (wearables, in-home monitors, etc.), and data on health-related social needs and steps to address them. Data quality includes completeness, accuracy, and provenance, all of which contribute to reliability. Whether RWD are **fit-for-purpose** involves an assessment of whether they are representative of the population being studied, and whether the data quality is adequate to capture relevant outcomes, exposures (treatments), and covariates that also impact treatment and outcomes.

Existing frameworks, including those developed by Duke-Margolis and the U.S. Food and Drug Administration (FDA), emphasize the importance of fit-for-purpose data and methods in generating credible RWE. The validity of RWE derived from RWD, in turn, depends on whether the research methods are fit-for-purpose. That is, the methods should enable confidence that the estimated effect of the intervention of interest–here, the products and services delivered by the innovative company–is sufficiently precise (adequate power) and unbiased (adequate controls for potential covariates, other treatments, and environmental factors) to inform key decisions its use. FDA's approach to characterizing RWD and RWE is summarized in **Figure 2**.

Figure 2 | FDA's Real-World Evidence Framework



Reliance on RWD in Representative Types of Study Design
RCT denotes randomized, controlled trial; RWD real-world data; and RWE real-world evidence.

Source: https://www.nejm.org/doi/abs/10.1056/NEJMp2200089

Whether real-world data and methods are fit for purpose depends on the evidence question at issue. Because evidence is costly to generate, what constitutes fit for purpose varies by context. At earlier stages, when a company's strategy is still evolving, shorter-term, before-after observational studies that involve early indicators of impact within an HV-ROI framework such as patient engagement may be sufficient to justify further investment in refining or piloting the company's activities, particularly if the effect size is large. At later stages, when a mature product has already demonstrated considerable evidence but not enough to justify adoption on a broader scale by providers, payers, purchasers, or patients, more costly and rigorous data and methods become appropriate. In practice, the threshold for RWE rigor is not fixed: payers, regulators, and health systems must calibrate expectations based on the stakes of the decision, including whether to continue piloting, expand coverage, or adopt at scale.

Learning Networks and the Evolution of Better Evidence–and Better Investments: Given the importance of health care interventions for outcomes, costs, and other dimensions of value–and the evolving nature of many medical products and services developed by innovative private companies–growing interest and capabilities exist in generating better evidence on how to improve innovations and their application in particular settings. This trend is reflected in the growth of learning health systems and learning networks supported by increasingly rich data and analytic capabilities. Large health care organizations typically have internal methods for reviewing available evidence on a product and conducting their own real world assessment before adopting it across the organization. Private and public organizations also collaborate to enable more rapid and reliable evidence on value.

One example is Project ECHO (Extension for Community Health Outcomes), a learning network that connects specialty experts at academic medical centers with general practitioners in underserved or rural areas for real-world testing and diffusion of best practices. Another example includes the FDA's Sentinel Initiative, a national learning network that enables broad, aligned analyses of electronic health data across multiple health systems, allowing regulators, payers, and providers to generate real world evidence on product safety and effectiveness more rapidly and without requiring data to leave local institutions.

The Center for Medicare and Medicaid Innovation's recent Rapid Cycle Innovation Program (RCIP) aims to enable accountable care organizations (ACOs), and potentially other organizations in value-based payment arrangements, to generate timely evidence to improve care and reduce costs. The RCIP helps ACOs identify and evaluate high-priority interventions and products through a shared platform to facilitate real world, prospective randomized data collection and analysis. These and similar rapid learning collaborations share common features:

1. A process for identifying interventions with promising evidence that is not yet definitive enough for large-scale adoption.
2. An infrastructure for technical guidance and collaboration that makes real-world evaluation feasible and timely.
3. Sufficient interest across participating organizations to cover the incremental organizational effort and cost required to conduct the analysis.

For example, RCIP members assess whether a site-randomized pilot is worthwhile based on generating enough evidence at low enough cost to inform decisions about scaling, modifying, or discontinuing an innovation. Assessment proceeds if critical mass exists.

Several pediatric care learning networks demonstrate the potential of this model, including the Ohio Solutions for Patient Safety (SPS), which has supported adoption of innovations that achieve measurable improvements in children's health, including reductions in surgical site infections and adverse drug events. Similarly, the Learning Health System Embedded Scientist Training and Research (LHS E-StaR) Centers, supported by the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI), embeds scientists within health systems to generate evidence internally and act on it in real time to accelerate improvements in care.

Sustaining and scaling such learning networks requires ongoing support, including payment incentives or infrastructure cost supports, interoperable data infrastructure, and technical assistance, to keep the incremental financial costs and effort of each study low. This support can occur through payment incentives such as CMS's Coverage with Evidence Development (CED) policy, which provides a financing mechanism that links Medicare coverage of certain new medical devices to participation in studies or registries so that initial payment supports the generation of RWE needed for safer, more effective use and more informed long-term coverage decisions.

Our framework for Health Value Evidence Quality integrates key features of all these frameworks.

CIC Evidence Quality Framework

Drawing from the most relevant components of existing frameworks and incorporating the distinct considerations for private investment in health care, we developed the Health Value Evidence Quality (HV-EQ) Framework. As summarized in **Figure 3**, it provides a pathway for investors, in collaboration with their portfolio companies and clients, to improve evidence generation on an investment's health value. The framework proposes four stages of evidence development that can be applied across progressively more mature investments, each with fit-for-purpose data and methods applicable to a variety of health care companies and solutions. We describe how evidence generated at each stage provides insights for advancing and expanding HV-ROI through private investment. In parallel, we propose several critical decision points for investors and portfolio companies to assess the feasibility and value of evidence generation.

Figure 3 | Health Value Evidence Quality Framework

Stage 0

Assessment of HV-ROI Promise

Theory and logic model for financial and health value preceding investment, including guardrails.

Stage 1

Evidence-Based HV-ROI Theory

Methods: Literature review and summary of prior evidence of potential impact on key populations and users including key outcome measures and magnitude of expected impact.

Measures: Existing published literature, not published by the portfolio company and not necessarily representative or complete, and early qualitative or quantitive experience with expected products or services.

Investment Insights: Clear, empirically based reasoning for why the portfolio company has the potential for substantial HV-ROI impact that is worthy of initial investment.

Stage 2

Confirmed HV-ROI Impact Through Internal Assessments

Methods: Internally-performed, descriptive analyses or case studies (e.g., before/after studies in early sites or less formal comparisons with non-implementing sites), augmented by qualitative assessments; often conducted in collaboration with the portfolio company's early clients or collaborators and potentially guided by expert consultants.

Measures: Reasonably standardized, early quantitative results on relevant indicators of key outcome measures, and early results on impacts on outcomes where available (e.g., short-term outcomes).

Investment Insights: Early indicators demonstrate that the portfolio company is achieving real impact and thus is likely to achieve significant HV-ROI impact, and/or empirical insights into how to improve products and services, justifying further investment for refinement and initial scaling.

Stage 3

Confirmed HV-ROI Impact Through Internal Assessments

Methods: Observational studies (e.g., before/after cohort studies) or short-term real-world "rapid learning" assessments with comparison groups (e.g., comparisons of early-adopting sites with "control" sites) in collaboration with a growing set portfolio company's clients, with well-defined methods and formal statistical evaluation, including analyses of key subpopulations. Prospective studies should be considered, and quantitative studies augment qualitative assessments. Studies generally conducted internally but may be guided or augmented by independent experts.

Measures: Well-characterized data with clear data protocols and detailed population information (size, demographics, and selection/exclusion criteria) sufficient to provide clear evidence on key outcome metrics for HV impact and to provide a foundation for compelling Stage 4 evidence.

Investment Insights: Significant evidence of HV-ROI impact through internal quantitative and qualitative assessments supports significant investments for scaling.

Stage 4

Significant Independent HV-ROI Evidence

Methods: **4a**: Independent observational studies or non-randomized controlled trials, with limited or no contemporaneous control groups. Prospective studies preferred.

4b: Independent prospective randomized controlled trials or more advanced observational studies with contemporaneous and well-matched comparison groups. Studies conducted by external expert evaluators, with peer-reviewed publication preferred.

Measures: Standardized data including key outcomes, collected as part of the routine delivery of health care and/or augmented using well-defined methods, with fit-for-purpose data quality and relevance to the population(s) being served, assured by independent evaluation.

Investment Insights: High-quality independent evidence drives broad adoption and any further investment needed to support it.

Compelling HV-ROI

Value Evidence Establishes New Standard of Care

Continuing HV-ROI assessment confirms value and enables further growth and impact

Stage 0 Assessment of HV-ROI Promise

This foundational stage establishes how a company will achieve both health value and financial returns. This assessment should consider potential adverse consequences of its innovations in products and services for access, outcomes, and affordability, identifying where guardrails and monitoring may be needed to safeguard against potential harm.

Stage 1 Evidenced-Based HV-ROI Theory

Through review of published literature and existing empirical evidence of the potential impact on key populations and users, the company should develop a concise, preliminary HV-ROI model. The evidence base at this stage is generally not from the portfolio company but focused on similar interventions and their supporting evidence, including early evidence on products and services that will be included in the company. Available data may be non-representative or incomplete, but should include key outcome measures, expected magnitude of impact, and early indicators of impact for patients, providers, payers, and the community.

Investment Insights

Evidence generated at this stage should help the company identify key measures for relevant populations and users, guiding initial assessments of health value impact as implementation begins. A data and evaluation strategy based on HV-ROI assessment demonstrates that the company or its clients have a feasible pathway toward the data collection and evaluation ultimately needed for compelling evidence of health value. This initial analysis should demonstrate that a product or intervention has meaningful potential for health value and should identify indicators or measures to track for potential harm.

Stage 2 Early Indicators of Real HV-ROI Impact

Companies should develop early evidence on the leading HV key performance indicators (KPIs) drawing from internally performed descriptive analyses or case studies, with pre/post-comparisons as available. Data at this stage should be reasonably standardized. Randomization is not generally expected at this stage, though some early evidence may be generated by comparing early adoption sites to non-adopters where consistent data are available. Early indicators of performance should be those most likely to predict real HV-ROI impact and may include patient engagement and continuing participation, satisfaction measures, and short-term impacts on utilization or indicators of clinical response. Early evaluations may be qualitative, augmenting limited or inconsistent quantitative data.

Investment Insights

Evidence generated at this stage provides direct empirical insights into an investment's HV-ROI potential. These findings provide increasing confidence in the company's HV-ROI model, identify areas for modification and refinement to address early gaps in impact, and lead to business decisions to improve HV-ROI and financial returns. Early evidence supports a refined strategy for developing better evidence quality and also helps justify further investment in the company's capabilities or expansion to additional sites.

Stage 3

Statistically Significant Evidence that the Portfolio Company is Likely Achieving an HV-ROI Impact

At this stage, companies should be carrying out observational studies on larger populations with more consistent data collection, including both key outcome measures and early HV-ROI indicators. While still internally performed and not necessarily randomized, these evaluations should begin to show statistically significant and meaningful results for relevant outcomes. Prospective studies are preferred, but well-designed retrospective studies also add to HV evidence.

Data should include well-characterized population information, including demographic features (e.g.g, age, race, geography), socioeconomic features or indicators, early HV-ROI indicators, and key clinical and nonclinical outcome measures, including major safety concerns. Methods should specify inclusion/exclusion criteria, define a control group with appropriate steps to address potential biases and data limitations, and include key hypothesis tests. Both data collection and evaluation protocols should be well defined.

Many of these activities can be advanced through an intentional collaboration with client early adopters. While some clients may prefer to conduct evaluations on their own, initial feedback and interaction from users and engagement with an experienced evaluator will help refine the company's products and services and improve their effective use in particular contexts. At this stage, there may be some level of independent validation, such as external review or a publication in peer-reviewed journals. The resulting evidence should provide a foundation for a more formal evaluation conducted by an independent evaluator.

Investment Insights

Evidence at this stage will demonstrate the value of the company's products and services and informs strategies that support refined implementation and growth. These results build confidence and customer and market recognition that the company is achieving significant health value impact. In turn, this creates a clearer pathway for further significant investment, greater client interest in additional adoption and scaling, a clearer infrastructure and foundation for independent evaluation, and more confidence about the likely result.

Stage 4

Statistically Significant,Iindependent Evidence that the Portfolio Company is Achieving a Substantial and Compelling HV-ROI Impact

Evidence generated at this stage consists of independent analyses overseen by evidence development experts from an external evaluation organization. Reflecting existing assessment frameworks, we distinguish between evaluation methods that are observational with no or limited contemporaneous control groups (Stage 4a) and those that involve prospective randomization at the site or patient level, or more advanced observational methods involving richer complete data and methods that enable more contemporaneous and well-matched comparison groups (Stage 4b). Independent evaluation should help assure that data are fit-for-purpose, especially if collected as part of the routine delivery of health care, with adequate reliability and relevance to the populations of interest for the company including reliable data on key covariates and outcomes. Results at this level should lead to HV-ROI evidence that supports publication in relevant, peer-reviewed journals.

Investment Insights

Stage 4 evidence provides confidence that the investment is achieving a significant positive impact on health value, supported by positive assessments of value by independent organizations. This enables confident adoption and scaling across diverse client environments and provides a clear basis for addressing potential concerns about the investment. The resulting impact on scale and sustainability leads to more significant and lasting financial returns.

Compelling HV-ROI

Continued growth and investment is guided by further evidence on value – validating and updating earlier findings, enabling broader adoption, and ultimately establishing a new standard of care.

We acknowledge that these evidence requirements may appear to be a substantial lift for investors and their portfolio companies, particularly for investments where assessing key health value impacts require large-scale, longer-term randomized studies. However, where large effect sizes and validated early indicators of clinical impact are present, such as sustained weight loss or blood pressure control, smaller and less time-consuming studies are likely to be feasible. Sound application of RWD and RWE methods can also significantly reduce evidence development costs.

Forward-Looking Investor and Company HV-ROI Evidence Strategy Toward Reducing the Cost and Increasing the Quality of HV-ROI Evidence

The evolving nature of innovative companies' business plans, and the improving real world evidence infrastructure and learning networks that can inform that evolution, are reasons why investors and company executives should develop a forward-looking strategy to grow their evidence potential–their capacity to generate needed evidence as the company evolves. The absence of a plan to generate evolving evidence about future financial returns at any stage of investment will likely lead to reluctance by investors and users in proceeding to the next stage. Similarly, greater uncertainty about HV-ROI will likely lead to less confidence and less adoption by users, resulting in potentially slower and less certain financial returns.

Providing a clear pathway to the next stage of evidence as a company proceeds, to generate the progressively better evidence in the HV-EQ framework, is therefore a fundamental element of investment planning. For example, as an early-stage company engages with potential early adopters, there are likely practical steps that can be taken in advance not just to collect appropriate early evidence, but to lay a foundation for collaborations or study designs to improve evidence quality as the products and services mature. This planning will help companies advance to Stage 3 or Stage 4 evidence faster.

Our framework suggests that investors and entrepreneurs should have a clear set of questions to address throughout the holding period of the investment, and that acquirers should consider as well:

- **Looking ahead:** What are the costs associated with generating needed evidence as the investment advances, including any costs associated with collecting or acquiring data, funding parties carrying out the analysis, etc.? What are the best forward-looking steps to minimize the total time and cost of needed upcoming evidence generation?
- **Evolving data strategy:** Are there access or sharing limitations with respect to acquiring and using critical "fit for purpose" data, and what is the most efficient and effective way to address privacy and proprietary concerns?
- **Evolving methods strategy:** How will the needed evaluations be conducted, including both in-house or collaborator capabilities, and what is the most efficient way to engage an independent evaluator and prepare for such an evaluation when appropriate? Are there available platforms, learning networks across potential clients, or other supporting resources?
- **Sharing health value evidence:** What is the best pathway for sharing and disseminating findings, e.g., including initial reports to inform clients and LPs, white papers, and publication and dissemination of peer-reviewed journals?

Even for companies with Stage 4a or 4b evidence, opportunities usually exist to expand use of the company's services to additional populations, and to continue to improve capabilities and efficiency in ways that could lead to higher value. As the company's capabilities mature and become more widely deployed in market, an ongoing RWE strategy can provide further HV-ROI evidence generation

to enhance the company's overall impact of solutions on the access to care, cost, quality, experience, and outcomes. Companies and investors can collaborate with their clients–and with the assessment experts and independent advisors used by their clients–to align on processes for practical evidence collection as part of their ongoing commercial relationship. Indeed, with RWE capabilities and methods continuing to improve, clients are likely to increasingly pursue these approaches on their own if the investors do not engage.

For all these reasons, we expect that companies with a clearly defined HV-ROI **rapid learning path** will be more likely to achieve scale and sustainable financial returns. A commitment to generating evidence on HV-ROI, potentially supported through participation in public-private learning platforms, "sandboxes," and partnerships with technology assessment organizations, applied research organizations, and philanthropic supporters can enable faster development of better evidence on HV-ROI.

Applying the CIC EQ Framework

To demonstrate and promote the generation of evidence to drive health value impact, 2025 CIC members, with support from their portfolio companies and clients, provided case examples of how they are currently applying the framework principles in their own investments. The examples provided in this section represent a broad range of companies and interventions, both in terms of clinical focus and investment stage, highlighting best practices and insights learned through the process. As described above, the evidence quality stages assigned to these examples are not intended to rank companies as more or less worthy of further investment or scaling, but rather to denote stages of evidence development that correspond to where an investment is in its holding period, informing a pathway to more robust evidence collection and generation. A summary of the full CIC HV-EQ case examples is provided in **Table 2**.

Table 2 | Summary of Relevant Frameworks

Portfolio Company	Impacts on Outcomes and Costs	HV-EQ Stage
Amae Health Amae Health is a psychiatry-led outpatient care provider for people living with severe mental illness, including schizophrenia, schizoaffective disorder, and bipolar disorder.	**Clinical Outcomes:** 3.4% 30-day ER readmissions, compared to 23% in the external standard of care data; 70% of patients complete metabolic lab screenings, compared to 23% in the standard of care; 86% of patients routinely take their medication, compared to 53% for the standard of care; 100% of patients complete a follow-up visit within 7 days of discharge, compared to 31% for the standard of care; and 84% of patients stay beyond their first 2 visits, compared to 30% for the standard of care. **Health Care Costs:** Only 9% of patients who started in care at Amae in 2025 were re-hospitalized, relative to 33% for the standard of care, translating to ~$22,367 per patient per year in estimated savings (relative to the standard of care).	2
Cylinder Cylinder Health provides virtual, data-driven gastrointestinal care that improves clinical outcomes, drives health equity, and generates measurable cost savings for employers and payers.	**Clinical Outcomes:** 91% of patients report improved GI symptoms; 83% of users reported better symptom management1; and severe symptom prevalence decreased from 80% to 48% post intervention. **Health Care Costs:** 65%+ decrease in ED costs; $2,000 PMPY medical and pharmacy savings; and downstream savings from reduced hospitalizations, procedures, and medication use, driven by higher adherence and improved symptom control among high-acuity GI members.	3
NOCD NOCD provides clinically validated, digital OCD, body-focused repetitive behavior (BFRB), hoarding disorder, and tic disorder treatment using exposure and response prevention therapy that improves outcomes, increases adherence, and lowers behavioral health costs across populations.	**Clinical Outcomes:** 38–44% reduction in OCD symptom severity within 12–16 weeks of treatment; 60+% achieve clinically significant symptom improvement; 33% reduction in BFRB severity within 14-16 weeks of treatment; and reductions in anxiety and depression symptom scores over the course of care. **Health Care Costs:** Estimated payer reduction in OCD-related spending of 20-25% annually; savings to payers of more than $3k per patient per year.	3

Table 2 | Summary of Relevant Frameworks

Portfolio Company	Impacts on Outcomes and Costs	HV-EQ Stage
SimpliFed SimpliFed is a maternal health-tech company providing virtual peri- and post-natal lactation and baby feeding support alongside remote patient monitoring for high-risk conditions such as hypertension and gestational diabetes.	**Clinical Outcomes:** At 4–6 months postpartum, PHQ-9 scores improved more among telelactation appointment users, indicating a meaningful trend toward reduced postpartum depression. GAD-7 results showed a similar directional trend. **Health Care Costs:** By supporting breastfeeding initiation and duration, telelactation may decrease costly maternal and infant health complications (e.g., infections, postpartum depressive episodes).	3
Sober Sidekick Sober Sidekick is a digital health engagement company for people with substance use disorder. The company powers peer-based engagement in a community-driven behavioral change model.	**Clinical Outcomes:** One peer-to-peer interaction cuts relapse rates by 48.2%; 61% sobriety at 6 months (compared to clinical alternative: 54% low adherence, 84% high adherence); and 55% sobriety at 12 months (compared to clinical alternative: 49% low adherence, 78% high adherence). **Health Care Costs:** Reduced relapse creates an estimated $7,959 savings per actively engaged member to the health system.	3
Strive Health Strive Health delivers value-based kidney care aimed at improving outcomes for patients across the chronic kidney disease (CKD) spectrum, from stage 3 to end-stage kidney disease (ESKD).	**Clinical Outcomes:** 67% increase in rate of optimal dialysis starts compared to unenrolled patients in Strive markets, and 31% increase in nephrology visits, compared to initial baseline. **Health Care Costs:** 20% reduction in Total Cost of Care (nationally).	3
Thrive Mobile Thrive Mobile is an engagement platform delivered on a fully integrated mobile carrier and cellphone, Thrive Mobile stays with users 24/7/365 – enabling continuous engagement and making it easier to access essential services directly from their device.	**Clinical Outcomes:** Thrive members had lower utilization of high acuity services compared to members never enrolled in Thrive, with 34% lower ED utilization, 85% lower IP utilization, and 15% lower substance use claims. **Health Care Costs:** 27% reduction in Total Cost of Care for Thrive members Pre vs Post joining. 20% lower Total Cost of Care for Thrive members vs Non-Thrive members.	3
FlyteHealth FlyteHealth combines intelligent care navigation with virtual clinical support to address the full complexity of cardiometabolic disease, including prediabetes, hypertension, hyperlipidemia, obesity, and related conditions.	**Clinical Outcomes:** Patients had 16.6% 12-month weight loss, 7.2% reduction in elevated HbA1c levels, and 9.4% reduction in blood glucose levels. **Health Care Costs:** Avoidable pharmacy costs reduced by up to $1.2 million annually, representing 1%–3% of total medication costs. Additional potential downstream savings from reduced hospitalizations and obesity-related interventions.	4a
Foodsmart Foodsmart is a comprehensive food-care platform designed to manage chronic conditions and help patients change their food environment to promote sustained behavior change and improve core biometrics.	**Clinical Outcomes:** Foodsmart's Foodcare program showed a 0.6 point average reduction in HbA1c compared to standard care for Medicaid members with diabetes during the interventions; increased odds of being food-secure by ~230% and nutrition-secure by ~370%. **Health Care Costs:** Foodsmart's Program saved >$20-58 PMPM over one year for the health plan's customers for total spend, and >$150-$353 PMPM savings for diabetes pharmaceutical spend.	4b
Omada Omada is a digital care solution focused on chronic care conditions with personalized programs to adapt to every member.	**Clinical Outcomes:** Members had 5.5% average weight reduction after 12 months, 58% achieved normal A1C levels through the prevention program within 12 months. Patients in the diabetes program had a 2% average reduction in A1C levels at 12 months. **Health Care Costs:** $3-4K average annual savings per member for prevention, diabetes, and hypertension programs. $1-2K average annual savings per member for musculoskeletal programs.	4b
Twin Health Twin Health sets a new standard of metabolic care using AI Digital Twin to restore health, eliminate high-cost medications, and reduce total cost of care.	**Clinical Outcomes:** Impact of the AI Digital Twin against usual care for patients with type 2 diabetes and a BMI ≥27 kg/m found: Higher glycemic control than the usual care cohort; higher sustained target glucose levels for at least 90 days; greater weight reduction; significant average A1c reduction; and significantly reduced use of high-cost medications. **Health Care Costs:** Estimated $5,413 in avoided medical costs per person. Estimated total avoided pharmacy spend of $4,720 per person.	4b

Collaborations to Strengthen Health Value Evidence

Generating high-quality evidence is challenging, as individual companies and their clients often have limited resources and capacity to apply the CIC framework in specific contexts. However, the cost and time required to develop evidence are declining, and investors can accelerate these opportunities. With experience, visibility, and impact across multiple companies and clients, investor are uniquely positioned to lead efforts to make HV evidence generation easier and more routine. Investors can develop and share best practices to assess health value, and support collaborations that disseminate the findings, and make these best practices easier to implement. By creating easier and more routine evidence generation and providing a clearer path for investing in HV-ROI evidence development, these steps can lead to an evolution in understanding and expectations around what constitutes meaningful health value evidence.

Collaborations to advance HV Evidence, building on this framework, can support both the supply of evidence–by making it easier to collect standardized, fit-for-purpose data and evaluate it using well-validated methods–and the demand for evidence, by increasing awareness and expectations among its consumers in the LP, customer, and policy communities. Private capital investors can help bridge the supply and demand gap by bringing public attention, capital, commercial partnerships, and the ability to accelerate evidence collection and learning. In turn, these steps will improve the alignment between financial and health value returns.

Beyond sharing case studies and examples of HV evaluations, CIC members are sharing best practices for advancing collaborative platforms for evidence generation. For example, CIC member company Echo Health Ventures formed the Echo Innovation Alliance, which brings together four potential early adopters of Echo Health backed services and products–Cambia Health Solutions, Blue Cross NC, USAble Corporation, and BlueCross BlueShield of Tennessee–to generate and share meaningful evidence of health value impact for the populations they serve.

CIC members are also seeking to strengthen the ability of independent assessment organizations, such as the Peterson Health Technology Institute (PHTI) and the Digital Medicine Society (DiMe), to strengthen and clarify evidence standards in particular areas of private investment.

Investors, with their experience across multiple companies in key areas of health care innovation, are well positioned to collaborate on strategies to enhance evidence on health value and to share insights from independent assessment organizations across their portfolios. Investor engagement in the advancement of learning hubs or collaborations that include evaluation experts, health care organizations, employers, and government purchasers can help improve the efficiency of evidence collection and generation. These collaborations can amplify the impact of independent assessment organizations and reduce the uncertainty and cost associated with generating the evidence needed to support scaling.

Looking beyond privately led collaborations and hubs, philanthropic and public-private partnerships offer an additional avenue for accelerating and normalizing evidence generation on health value. This is particularly important in areas of investment that are directly relevant to high-priority health policy reforms.

For example, advancing digital- and AI-enabled care is a high CMS policy priority, as reflected in CMS' Health Technology Ecosystem and the CMS Innovation Center's Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model launching in 2026. The ACCESS model is designed to provide payments linked to improvements or reaching targets on validated outcome measures such as impacts on beneficiary body mass index, diabetes, and cardiometabolic risk factors, and on functional status for common musculoskeletal and behavioral health conditions. ACCESS is paired with a proposed FDA regulatory pathway to use such data generated on a particular digital/AI company to help provide the evidence needed for labeled claim of impacts on health risk and disease outcomes, and potentially costs. CMS is also developing an evaluation strategy of the pilot's impact on Medicare beneficiary outcomes and spending, to determine if the model itself should be expanded and made permanent, modified, or discontinued. The Health Care Payment Learning and Action Network, a CMS-supported collaboration to accelerate progress on payment and care reform, has highlighted public-private opportunities for advancing evidence-based prevention that align with our recommendations for investors.

The ACCESS model and other CMS innovation priorities present opportunities for public-private collaboration to develop better evidence on these products more quickly, going beyond a broad evaluation of whether the whole program improved outcomes and lowered Medicare spending. Investors, their companies, and their client health care organizations have access to more timely and extensive data on patient characteristics and clinical impacts compared to an evaluator with access to CMS data. These data, along with sound assessment methods, can help CMS identify promising early impacts as well as opportunities to improve the program and its impact on beneficiaries and their clinicians. The investment community, in particular, can leverage well-designed HV-ROI evaluations to augment evidence on questions that will be part of the CMS evaluation. This can accelerate insights to refine payment and coverage policies for digital technologies and other programs intended to improve beneficiary outcomes and reduce total costs of care.

Such collaborative efforts building on the HV-EQ framework and similar tools might include:

- CMS support for events and other activities to identify critical evidence gaps and share reliable early evidence on product HV-ROI related to CMS priorities, which will in turn encourage and help investors and companies to produce such evidence.
- CMS support for rapid learning collaboratives, like the Center for Medicare and Medicaid Innovation's (CMMI) Rapid Cycle Innovation Program, where interested health care providers, systems, and plans working with investors could facilitate sharing data and methods to show impact of products on outcomes and total costs of care in a broad range of populations and settings.
- Insights from HV-EQ initiatives involving Medicare Advantage plans, employers, and states to help CMS improve incentives for companies in ACCESS and enhance effective health technology adoption system-wide by incorporating evidence from these other programs.

We note that health care organizations (particularly ACOs), Medicare Advantage plans, and other potential collaborators have important longitudinal clinical and financial data not available to CMS on large populations of Medicare beneficiaries. These organizations are increasingly leveraging advanced analytics to conduct A/B testing or other rapid learning approaches to assess the impact of interventions like digital and AI-enabled tools. They also share CMS's interest in finding and refining technologies that improve beneficiary access and outcomes while lowering costs.

Investors have a proprietary interest in ensuring that their own products succeed within CMS pilots and beyond. They also have a collective interest in securing long-term, reliable support from CMS, as well as states and employers–support that depends on growing confidence that these investments are addressing health value challenges without adverse unintended consequences. At this critical time for private investment in health care, we encourage investors and other stakeholders to consider and extend the CIC's HV-ROI framework as a pathway for achieving both financial and health value returns. Real impact will require continued private and public efforts to make publication of prospective approaches and meaningful evidence more routine and transparent. The evidence quality framework put forth in this framework aims to create a clear path for generating and utilizing robust evidence to advance health value impact alongside financial returns.

LOOKING AHEAD: NEXT STEPS FOR INVESTORS

CIC members are actively pursuing these strategies to support evidence generation and scale impactful solutions. Our review of these case examples of developing HV-ROI evidence, and the broader evolving evidence landscape, shows that while meaningful gaps remain, private capital investors have substantial opportunities to directly and routinely support their portfolio companies' efforts to measure health value. Doing so reduces long-term risk, strengthens company performance and increases their likelihood of achieving meaningful impact on health care and health.

Concrete steps investors can take include:

- Define and regularly revisit a core question set to guide a company's health value model throughout the entire holding period
- Build a forward-looking evidence strategy that advances as the company evolves
- Support and disseminate health value assessment best practices based on portfolio companies' experiences and prioritize funding for organizations that follow these practices

Private capital investors have substantial opportunities to directly and routinely support their portfolio companies' efforts to measure health value. Doing so reduces long-term risk, strengthens company performance and increases their likelihood of achieving meaningful impact on health care and health.

- Increase both the supply of and demand for stronger health value evidence by structuring commercial partnerships that accelerate evidence generation and by leveraging these partnerships to increase market demand for companies with strong health value evidence
- Collaborate with assessment organizations to clarify health value evidence pathways in the company's value impact area, reducing risk and increasing efficiency
- Participate in collaborative platforms for evidence generation, including those supported by philanthropic capital aligned with health value creation as well as public-private partnerships that normalize, reward, and scale evidence generation

Building on these strategies, the CIC aims to work with a range of collaborators to advance best practice models for demonstrating health value in private capital investment, and to strengthen and publicize measurement approaches to assess their own contributions to the development of health value. CIC members believe that the work of generating health value is a shared responsibility of high-performing portfolio companies and health value focused investors. The CIC's work is intended to increase the industry's acumen on both fronts, at a critical time for investment that delivers on the promise of greater access, affordability, and better health from health care innovation.

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