UNLOCKING VALUE IN DIGITAL HEALTH:

CHALLENGES AND OPPORTUNITIES TO IMPLEMENTING HIGH-VALUE TECHNOLOGIES

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PETERSON CENTER ON HEALTHCARE

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NORC at the University of Chicago

INTRODUCTION

Digital health technologies (DHTs) have the potential to revolutionize healthcare delivery by advancing health outcomes, improving patient experience, promoting equity, and lowering costs. Recent studies have indicated that DHTs can serve as effective tools for remote disease management, facilitate access to timely care, and potentially increase affordability.[1,2,3]

However, unlike other sectors where the introduction of automation and technology tends to reduce costs, technological advancements in healthcare have often led to increasing costs and only marginal improvements in quality.[4]

The last decade has witnessed a major boom in digital health technology investment, despite limited evidence about the clinical and economic impact of new apps, digital therapeutics, remote patient monitoring, and other technologies. Without a clear regulatory pathway or independent assessor, healthcare stakeholders struggle to make decisions regarding coverage, price, and investments for these technologies.

As a nonprofit dedicated to making higher quality, more affordable healthcare a reality for all Americans, the Peterson Center on Healthcare ("the Center") aims to promote better digital health purchasing decisions – both encouraging broader uptake of

DHTs Are Transforming Healthcare Delivery

- Remote patient monitoring tools allow healthcare providers to monitor patients' health from afar (e.g., blood sugar for diabetics)
- Chronic care management platforms empower patients to make changes that improve their health (e.g., improved nutrition and weight loss)
- Virtual care programs improve access to care and convenience for patients (e.g., behavioral health services)

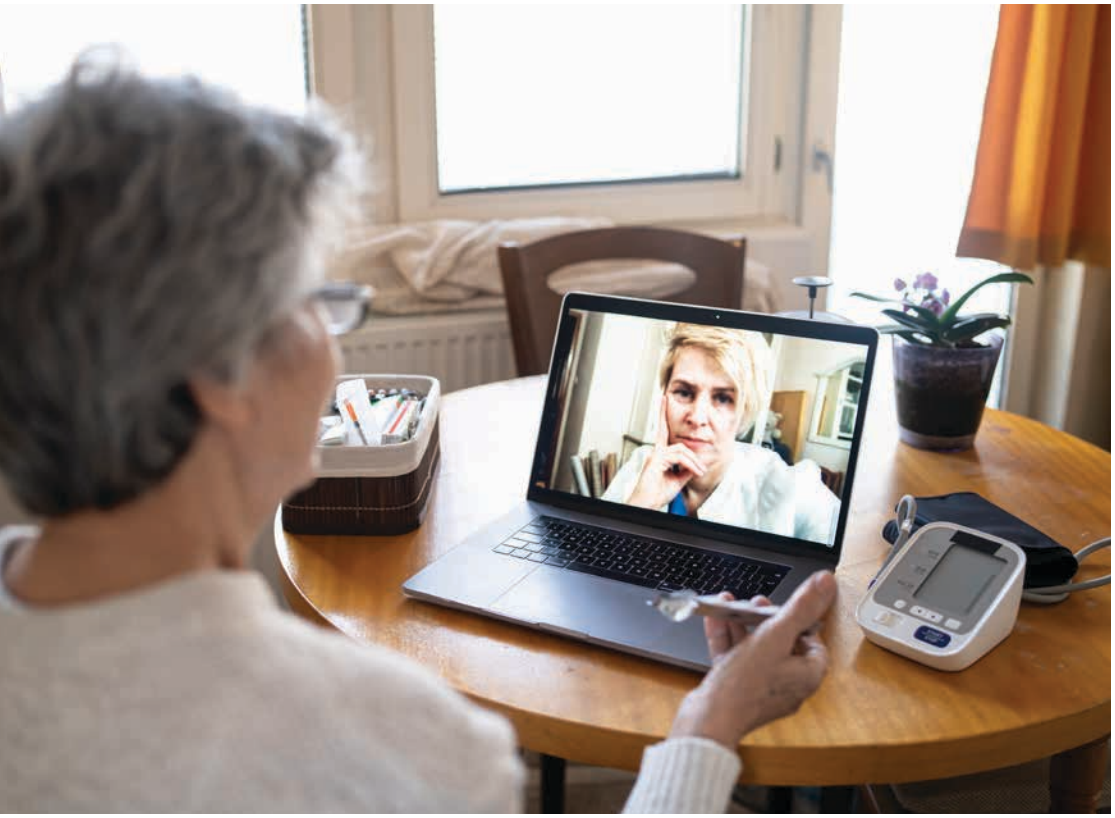
high-value technologies and discouraging adoption of low-value technologies. This means setting a higher bar for clinical effectiveness and value that DHTs must clear to achieve market adoption, as well as ensuring that evidence generation aligns with purchaser incentives.

To better understand these complex dynamics, the Center undertook a landscape analysis of the digital health market, focusing on the specific challenges and drivers of DHT purchasing. The Center engaged Tapestry Networks to integrate research and synthesize insights from Tapestry-led discussions with executives from leading payers, self-insured employers, innovators, and other key stakeholder organizations to explore current decision-making processes and pain points around DHT development, evaluation, and adoption (*see Appendix for the full list of interview participants and affiliations*). The Center also partnered with NORC at the University of Chicago to integrate additional research and findings, offering a holistic picture of the digital health purchasing environment. Across conversations, respondents considered an array of questions, including:

- How are purchasing and coverage decisions for DHTs made?
- What kind of tools, processes, and external resources are used to identify, prioritize, and evaluate DHTs on the market?
- What challenges do stakeholders face in the DHT purchasing process, and how can these challenges be addressed?

Informed by interview findings and external sources, this report examines the current state of the DHT purchasing environment and offers key insights around opportunities to improve discernment and uptake of high-value DHTs.

> "A LARGE GULF EXISTS BETWEEN MARKETING CLAIMS AND WHAT [DHTS] ACTUALLY DO."
>
> – INTERVIEWED STAKEHOLDER

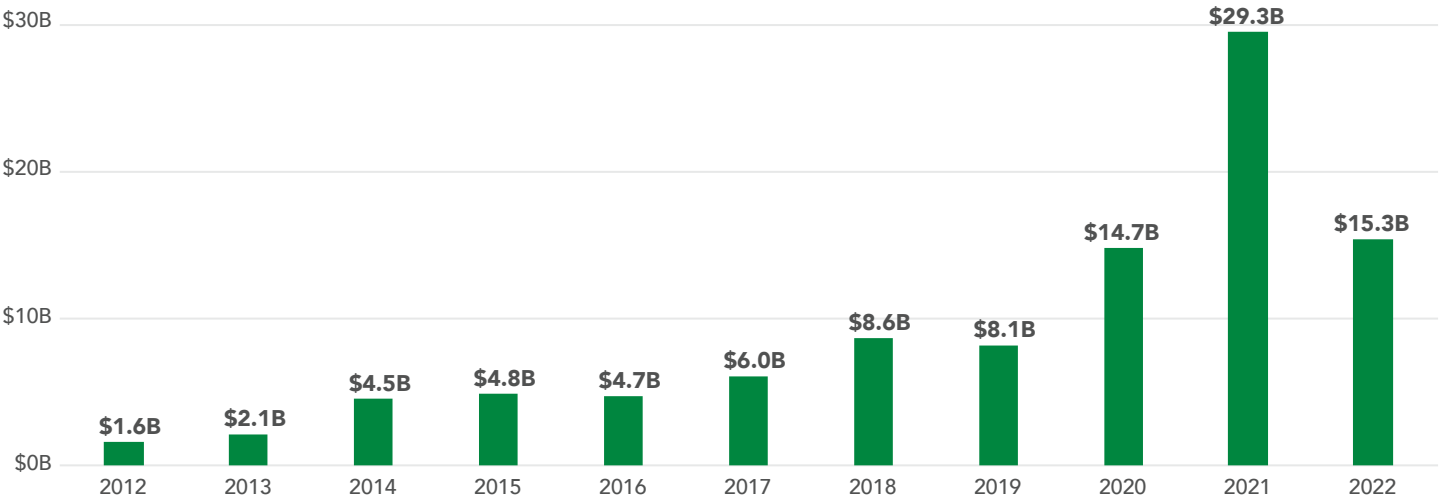


DIGITAL HEALTH TECHNOLOGY LANDSCAPE

Investment in DHTs has ballooned with limited evidence on clinical outcomes and economic value

Over the past decade, interest and investment in DHTs has rapidly accelerated. Cumulative DHT investment in the United States peaked in 2021 with over $29 billion in funding, fueled by pandemic-induced stimulus measures, regulatory reforms, and heightened interest in digital health solutions.[5] Although 2022 signaled a transition to a less frenzied investment period, DHT funding trends over the last 10 years show sustained growth: from 2012 to 2022, venture funding for digital health in the United States increased nearly tenfold, from $1.6 billion to $15.3 billion.[6] Some predict that the global market size for these technologies will reach $1.5 trillion by 2030.[7]

U.S. DIGITAL HEALTH VENTURE FUNDING



Note: Includes U.S. deals >$2M; data through December 31, 2022
Source: "2022 year-end digital health funding: Lessons at the end of a funding cycle." Rock Health.

Despite high investment, many DHTs on the market today do not offer rigorous evidence supporting their claims of improving health outcomes or care quality. A 2022 study of 224 digital health companies found that many "have a low level of clinical robustness and do not make many claims as measured by regulatory filings, clinical trials, and public data shared online."[8] Interviewed stakeholders shared similar insights when attempting to parse out promotional messaging from performance, with one noting that *"a large gulf exists between marketing claims and what [DHTs] actually do."* Throughout the interview process, payers and self-insured employers expressed a common sentiment: there is misalignment between the evidence that digital health developers produce and the data that many purchasers need to make informed decisions.

> "WITH AN INDEPENDENT SOURCE OF INFORMATION, BENEFIT LEADERS WILL BE EMBOLDENED TO TRY NEW SOLUTIONS WITHOUT JUST RELYING ON DATA FROM [CONFLICTED] CONSULTANTS."
>
> – SELF-INSURED EMPLOYER

There is no independent authority evaluating the value of DHTs in the United States

Given the pace and volume of DHTs entering the market, some countries have recognized the need for a well-defined evaluative pathway to promote the uptake of high-value DHTs. In the United Kingdom, the National Institute for Health and Care Excellence (NICE) created an Office of Digital Health dedicated to identifying high-value DHTs, establishing universal evidence standards for digital health, and working to improve DHT approval pathways.[9] In 2022, NICE issued its first DHT assessment, recommending a prescription sleep app as an effective alternative to sleeping pills after evaluating evidence from 28 studies, including 12 randomized control trials.[10,] In Germany, the German Federal Institute of Drugs and Medical Devices utilizes an evaluation framework for DHTs, and in 2019, the passage of the Digital Healthcare Act entitled those covered by statutory health insurance to reimbursement for certain DHTs.[11,12] Belgium, Canada, Denmark, Sweden, and Singapore are also beginning to evaluate and integrate high-value DHTs into their healthcare systems.

In contrast, the United States lacks an independent assessor committed to analyzing the effectiveness and value of DHTs. The U.S. Food and Drug Administration (FDA) determines baseline safety and efficacy for a narrow segment of DHTs, predominantly software that meets the definition of a medical device and "poses a risk to a patient's safety if the software were to not function as intended."[13] Many DHTs, such as low-risk technologies intended for wellness use, do not meet this definition and thus remain largely unregulated.[14] Others are subject to the FDA's risk-based framework for medical devices, with Class I and II – the categories applicable to many DHTs – not required to demonstrate safety and efficacy through clinical trials.[15] Even when it applies, the FDA review process for DHTs is more flexible than the framework applied to pharmaceuticals, occurs too infrequently to keep up with the evolving nature of health technology, and focuses primarily on safety without examining critical aspects of digital health, such as value and equity.

Purchasers face significant challenges in making DHT coverage decisions

In the current environment, purchasers – encompassing payers, self-insured employers, hospital systems, and providers – face a number of obstacles that hinder their ability make informed decisions in the digital health space:

They are overwhelmed by the volume of DHTs on the market that lack credible, comparable data

The rapid rise in digital health investment and interest has led to a flurry of market activity. DHT companies regularly approach purchasers with a wealth of claims on improved patient outcomes, user retention, and other value metrics, the validity of which can be difficult to verify and compare to other alternatives. Interviewed purchasers noted that they are now "*solicited by so many vendors on a regular basis*" that it has become increasingly challenging to "*separate the wheat from the chaff.*" One self-insured employer said, "*We don't really have the time to ask the tough questions…when a [DHT company] says certain outcomes will improve by 40%, what we need to know is where did the math come from? How good is underlying evidence for that? It would be helpful for an organization to put an analysis of the data out in the public space.*"

They face competing incentives and complex interests

The spectrum of DHT purchasers encompasses a diverse set of entities from individual consumers to providers to self-insured employers and payers, each with distinct criteria and goals for DHT adoption. Among these purchasers, large payers wield enormous potential to transform industry dynamics given their size and generally aligned purchasing incentives. In total, a relatively small number of payers determine whether and how DHTs are covered and reimbursed, directly influencing market access and uptake. Medicaid and Medicare Advantage plans in particular appear to have a highly aligned interest in increasing patient access to effective technologies while simultaneously controlling spending.

> "WHEN A [DHT COMPANY] SAYS CERTAIN OUTCOMES WILL IMPROVE BY 40%, WHAT WE NEED TO KNOW IS WHERE DID THE MATH COME FROM? HOW GOOD IS UNDERLYING EVIDENCE FOR THAT?"
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Yet even these payers can be driven by an intricate – and sometimes conflicting – set of internal incentives and goals. For example, a Medicare Advantage plan might expend funds on digital tools that increase member enrollment and retention, even if such tools do not reduce overall spending or measurably improve health outcomes. At the same time, many payers are not only purchasers but also developers and investors themselves. Some invest in internal and external technologies through a venture or innovation arm with goals and decision-making processes than stand apart from the core business. For those developing DHTs in-house, conflicts of interest can arise when prioritizing the array of available digital health solutions to implement. These competing incentives further compound the complexities of decision-making around digital health and increase the volume of DHTs used across healthcare stakeholders.

Purchasers often lack centralized decision-making

Purchasing decisions often vary by DHT category and business unit, and a majority of purchasers lack systematic approaches to screening, evaluating, and selecting DHTs for implementation. Unlike the single-payer, government systems found in other countries, the DHT ecosystem in the United States contains a diversity of public and private purchasers, each with their own business agendas, definitions of value, and purchasing processes. For payers in particular, interviewees generally described three models of DHT purchasing:

- **Streamlined:** A single, standardized pathway for decision-making
- **Multicentric:** Decision-making at individual business unit level based on specific needs
- **Decentralized:** Decision-making largely driven by market forces

Although most aim for a more streamlined or centralized approach to DHTs, very few national and regional payers utilize this model. Some large national payers may adhere to a multicentric model in which purchasing is driven by the business needs of different branches of the company: *"We're really a company of 30 different companies, and lots of people get involved in decision-making–chief medical officers, business executives, actuaries, etc."* However, most fall into the final and most common decision-making model: decentralized. This approach is heavily driven by inbounds and employer DHT demand and is largely perceived as unsustainable for major purchasers.

> "WE'RE REALLY A COMPANY OF 30 DIFFERENT COMPANIES, AND LOTS OF PEOPLE GET INVOLVED IN DECISION-MAKING–CHIEF MEDICAL OFFICERS, BUSINESS EXECUTIVES, ACTUARIES, ETC."
>
> – PAYER

There is a market need for independent, timely, and transparent DHT assessments

Many purchasers currently pay for evaluative tools and service providers (e.g., Aon Cost Efficiency Measurement, Forrester, Gartner, Hayes, Organization for the Review of Care and Health Apps, Validation Institute) and are engaged in DHT consortiums such as AVIA Health and the Employer/Payer Health Innovation Roundtable. However, interviewed purchasers reiterated that available resources lack the transparent methodologies, neutral financing, and/or analytical rigor that they seek

in a credible assessment entity. As one respondent noted, *"There are all sorts of groups that try to do clinical evaluations, but the methodology is unclear and sometimes they're actually selling a product"* so it would be *"powerful to have a neutral party doing the research."*

Purchasers overwhelmingly affirmed the need for clinical assessments that provide the robust, timely data they need to make informed purchasing decisions. Such assessments would particularly benefit payers and self-insured employers that lack the resources to conduct in-house evaluations, but even large payers more equipped to conduct in-depth DHT analyses affirmed the value of external assessments, with one stating that it *"is aways helpful to have a disinterested third party opining about the market."*

Interviewed purchasers also highlighted non-clinical aspects of DHTs that could provide powerful insights if properly assessed. On the economic side, respondents noted the obstacles that they face when evaluating DHTs: the practical challenge of tracking economic outcomes over time, the difficulty of evaluating cost savings with fluctuating patient utilization, and the complexity of measuring the financial impact of a DHT that addresses a previously unmet need, among others. Many believe that DHTs have the potential to improve healthcare access and equity, two factors that have historically not been included in cost-related analyses. In contemplating the evaluative components missing from the current environment, one payer noted that a good assessment framework should account for *"user experience and privacy as well as equity and access outcomes"* in order to holistically determine value.

In short, purchasers are facing a slew of new DHTs with a notable gap between their marketing claims and available data, internal competing interests, and an often reactive decision-making process shaped by market forces. The Center believes this purchasing environment can and should be different. An opportunity exists to set a higher standard for DHTs to enhance sector efficiency, productivity, and affordability, and now is the time to seize it.

> "THINK OF ALL THESE TECHNOLOGIES—THERE'S A LOT OF MISSING EVIDENCE, NO LONG-TERM STUDIES, AND A LOT OF POORLY CONSTRUCTED COHORT STUDIES. WE NEED EVIDENCE AND A FOCUSED ENTITY TRYING TO KEEP UP AND EVALUATE WHAT IS MISSING, ESPECIALLY FOR [DHTS] WITH AN IMPORTANT SOCIAL MISSION."
>
> — PAYER

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PETERSON CENTER ON HEALTHCARE

ABOUT THE PETERSON CENTER ON HEALTHCARE

The Peterson Center on Healthcare is a non-profit organization dedicated to making higher quality, more affordable healthcare a reality for all Americans. The organization is working to transform U.S. healthcare into a high-performance system by finding innovative solutions that improve quality and lower costs and accelerating their adoption on a national scale. Established by the Peter G. Peterson Foundation, the Center collaborates with stakeholders across the healthcare system and engages in grant-making, partnerships, and research. For more information about the Peterson Center on Healthcare, visit petersonhealthcare.org.

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Tapestry Networks brings leaders together to share and shape solutions to today's most pressing challenges in in corporate governance, financial services, and healthcare. We are an independent, credible, and trusted convenor of senior executives, board members, policy makers, regulators and other key market stakeholders, connecting them with information, insights, and each other. Together, we share perspectives and experiences, and catalyze and create new approaches to work through today's most critical issues and look ahead to prepare for and influence tomorrow's biggest challenges. For more information, please visit tapestrynetworks.com.

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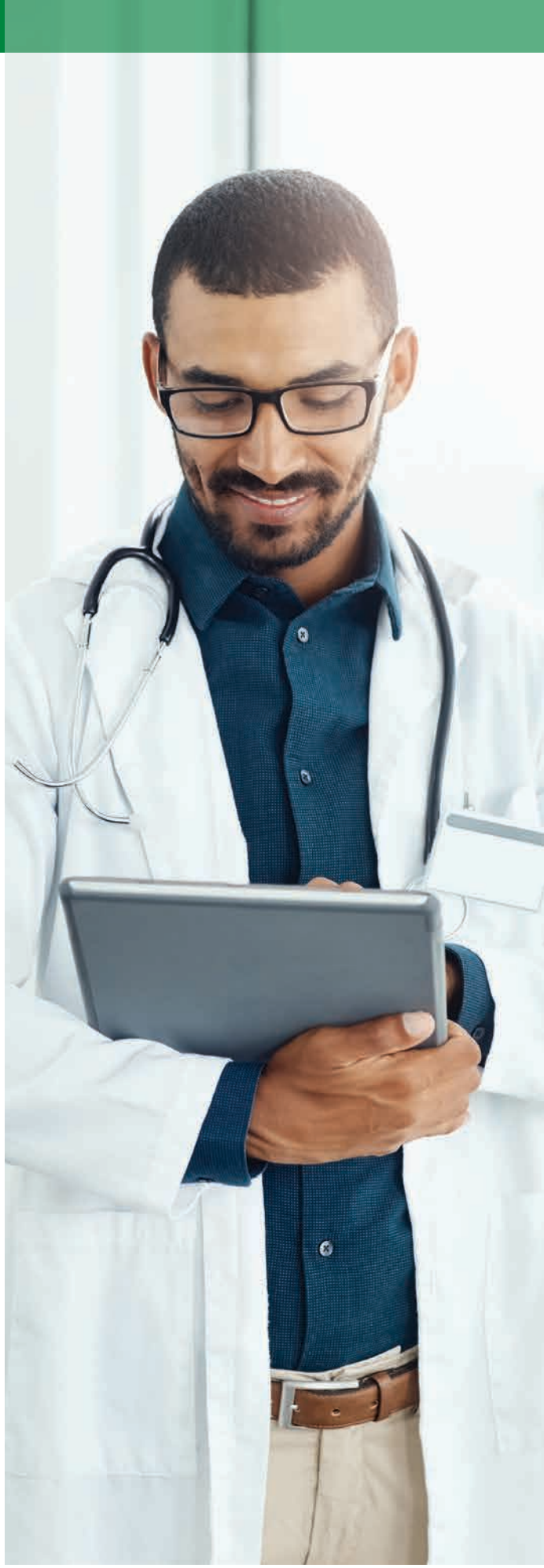
ABOUT NORC

NORC at the University of Chicago conducts research and analysis that decision-makers trust. As a nonpartisan research organization and a pioneer in measuring and understanding the world, we have studied almost every aspect of the human experience and every major news event for more than eight decades. Today, we partner with government, corporate, and nonprofit clients around the world to provide the objectivity and expertise necessary to inform the critical decisions facing society. For more information, please visit norc.org.



APPENDIX: PARTICIPANTS

Thirty-three participants were recruited from 27 organizations to be interviewed for this landscape analysis. They were interviewed via videoconference for approximately 45–60 minutes by Tapestry Networks during the latter half of 2022.

- **Aledade:** Erin Smith, National VP, Business Development
- **Arnold Ventures:** Katherine Szarama, Director, Drug Pricing; formerly Lead Analyst Coverage and Analysis Group, Center for Clinical Standards and Quality, CMS
- **AT&T:** Luke Prettol, Lead Benefits Strategy Consultant
- **Blue Cross Blue Shield Association:** Naomi Aronson, Executive Director Clinical Evaluation, Innovation, and Policy; Vikrant Vats, Director, Clinical Services
- **Blue Cross Blue Shield North Carolina:** Natosha Anderson, Head of Population Health and Commercial Care Management
- **Blue Cross Blue Shield Massachusetts:** Karl Laskowski, VP of Clinical Programs and Strategy; Carolyn Noble, VP, Corporate Strategy (Strategy, Consulting, Innovation & Analytics)
- **Blue Cross California:** John Yao, Chief Medical Officer
- **Breakwater Strategy:** Steven Weber, Partner
- **Carelon:** Jim Perry, VP, Digital Care Products and Solutions
- **Centene:** Bryan Sivak, Former SVP, Tech, Innovation, and Modernization
- **CVS Health:** Kjel Johnson, VP Specialty Strategy and Client Solutions; Daphne Psacharopoulos, Former VP, Digital Strategy & Product Management
- **Elevance Health:** John Whitney, VP Medical Policy
- **Geisinger:** Emily Fry, VP, Innovation Operations; Phil Krebs, Director, Medical Policy and Clinical Guidelines, Rebecca Stametz, VP, Digital Transformation
- **Horizon Blue Cross Blue Shield of New Jersey:** Joe O'Hara, Former Director, Accountable Care Organization Solutions
- **Humana:** Mona Siddiqui, SVP, Enterprise Clinical Strategy and Quality and Home Clinical Operations
- **Jasper Health:** Len Lichtenfeld, CMO
- **National Institute for Health and Care Excellence:** Carole Longson, Former Executive Director
- **NyquistData:** Michelle Wu, Co-founder and CEO
- **Onduo by Verily:** Julia Feldman, Managing Counsel
- **Optum:** Jennifer Malin, CMO, Health Solutions
- **Prime Therapeutics:** Pat Gleason, AVP, Health Outcomes
- **Purchaser Business Group on Health:** Emma Hoo, Director, Value-Based Purchasing; Gerri Burruel, Managing Director, Purchaser Innovation and Engagement
- **Rubicon Partners:** David Johnson, Clinical Operating Partner
- **Teladoc:** Zayna Khayat, VP Client Success and Growth
- **UnitedHealth Group:** Lewis Sandy, EVP, Clinical Advancement
- **University of Maryland Medical System:** Warren D'Souza, Chief Innovation Officer
- **University of Pennsylvania:** Ravi Parikh, Associate Professor, Medical Ethics and Health Policy

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