COALITION FOR INNOVATION

HealthTech Blueprint for the Future

Coalition for Innovation, supported by LG NOVA

Jami Diaz, Director Ecosystem Community & Startup Experience
William Barkis, Head of Grand Challenges & Ecosystem Development
Sokwoo Rhee., Executive Vice President, LG Electronics, Head, LG NOVA

Blueprint Chairs

Alex Fang, CleanTech Chair
Sarah Ennis, AI Chair
Alfred Poor, HealthTech Chair

Authors

John Barton, Victor L. Brown, H. Timothy Hsiao, John Hsu, Sylwana Kaźmierska, Ricardo Machado, Ann M. Marcus, Nicholas Matias, Qiana Martin, Alfred Poor, Refael Shamir, Mark Wesson

The views and opinions expressed in the chapters and case studies that follow are those of the authors and do not necessarily reflect the views or positions of any entities they represent.

Senior Editor, Alfred Poor

October 2025

Preamble

The Coalition for Innovation is an initiative hosted by LG NOVA that creates the opportunity for innovators, entrepreneurs, and business leaders across sectors to come together to collaborate on important topics in technology to drive impact. The end goal: together we can leverage our collective knowledge to advance important work that drives positive impact in our communities and the world. The simple vision is that we can be stronger together and increase our individual and collective impact on the world through collaboration.

This "Blueprint for the Future" document (henceforth: "Blueprint") defines a vision for the future through which technology innovation can improve the lives of people, their communities, and the planet. The goal is to lay out a vision and potentially provide the framework to start taking action in the areas of interest for the members of the Coalition. The chapters in this Blueprint are intended to be a "Big Tent" in which many diverse perspectives and interests and different approaches to impact can come together. Hence, the structure of the Blueprint is intended to be as inclusive as possible in which different chapters of the Blueprint focus on different topic areas, written by different authors with individual perspectives that may be less widely supported by the group.

Participation in the Coalition at large and authorship of the overall Blueprint document does not imply endorsement of the ideas of any specific chapter but rather acknowledges a contribution to the discussion and general engagement in the Coalition process that led to the publication of this Blueprint.

All contributors will be listed as "Authors" of the Blueprint in alphabetical order. The Co-Chairs for each Coalition will be listed as "Editors" also in alphabetical order. Authorship will include each individual author's name along with optional title and optional organization at the author's discretion.

Each chapter will list only the subset of participants that meaningfully contributed to that chapter. Authorship for chapters will be in rank order based on contribution: the first author(s) will have contributed the most, second author(s) second most, and so on. Equal contributions at each level will be listed as "Co-Authors"; if two or more authors contributed the most and contributed equally, they will be noted with an asterisk as "Co-First Authors". If two authors contributed second-most and equally, they will be listed as "Co-Second Authors" and so on.

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The Coalition is intended to be a community-driven activity and where possible governance will be by majority vote of each domain group. Specifically, each Coalition will decide which topics are included as chapters by majority vote of the group. The approach is intended to be inclusive so we will ask that topics be included unless they are considered by the majority to be significantly out of scope.

We intend for the document to reach a broad, international audience, including:

- People involved in the three technology domains: CleanTech, AI, and HealthTech
- Researchers from academic and private institutions
- Investors
- Students
- Policy creators at the corporate level and all levels of government

Chapter 11:
The Role of Evidence Standards

Author: Mark Wesson

Overview

Digital healthcare involves the use of information and communication technologies (ICTs) to improve health management, disease prevention, diagnosis, and treatment. With the rise of user-generated health data and advanced technology, this information is now complementing traditional electronic health records. The shift toward patient-centered, value-based care increases the relevance of such data in clinical decision-making and Real-World Evidence (RWE) generation in the Age of Big Data.

Development of breakthrough technologies requires rigor in many areas: the steady accumulation of information that describes the technology, its intended uses, and convincingly studied and understood data. In health-related innovations, these data are intended to support not only regulatory approval from agencies such as the U.S. Food and Drug Administration (FDA), but also to ensure that the product is safe and effective as a diagnostic, monitoring, or treatment technology and achieves its best fit in the marketplace.

Most of us are familiar with the idea of the Age of Big Data. Many of us are increasingly interested in monitoring our own health, doubtless spurred onward by the COVID-19 pandemic's tectonic interruption to health services delivery across the globe. With sensors, wearables, and other forms of software and devices capturing more and more real-time data, the FDA continues to develop definitions and rules that only began to apply in the last few years.

The FDA defines digital health broadly to include tools such as wearables, telemedicine, mobile apps, health IT, and personalized medicine. In recent years, companies have developed health technologies under new forms of regulation such as the FDA's "Software as a Medical Device". These regulations have added higher bars for demonstrating safety and efficacy, as well as the incorporation of learnings back into the technology's updates. Ultimately, digital health aims to enable seamless, intelligent communication between patients, healthcare providers, and devices, supporting a more predictive, preventive, and customized approach to care.

The United States' FDA distinguishes between "Real-World Data" (RWD) and "Real-World Evidence" (RWE) as follows:

"**Real-world data** are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status."

"**Real-world evidence** is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD."

These forms of evidence can complement regulators' expectations of data describing the technology, its use, and how it performs. Real-World Evidence is the information that healthcare providers, administrators, insurers, and consumers can use to make everyday decisions while they deploy a new process or technology in what they do or want to know.

Many health technologies that collect data can themselves provide datasets that may be used or analyzed by other researchers and commercial partners. There are many reasons – beyond the opportunities in the data economy – to make the

generation, interpretation, and use of evidence a distinctive advantage in digital health innovation.

While the principle of evidence-based medicine is widely accepted, translating evidence into action is a human and organizational challenge. Lack of time, information overload, skepticism, misaligned incentives, and structural hurdles all contribute to the lag. Recognizing these barriers has led to a new focus on implementation science: the study of methods to promote the systematic uptake of research findings into routine practice. This field treats adoption as its own science, testing strategies (education, audit-and-feedback, workflow redesign, policy levers, etc.) to close the gap between "what we know" and "what we do." As one 2023 Journal of the American Medical Association article quipped, "It takes an average of 17 years for evidence to change practice; the burgeoning field of implementation science seeks to speed things up." Implementation research emphasizes that simply publishing evidence is not enough; one must also address the social and behavioral factors to achieve change in practice.

Most change in matters of health is slow, requires credible agents to facilitate, and may or may not contribute in a measurable and direct way to "better practice" by a provider or "better health outcomes" for the patient. However, the technologies we seek to make available for use by providers and patients need study for many reasons.

Challenges / Gaps: New Forms of Evidence

While randomized controlled trials (RCTs) have long been considered the gold standard in clinical research, the evolving landscape of healthcare innovation is prompting a broader and more flexible approach to generating evidence. Increasingly, real-world evidence (RWE) — derived from electronic health records, wearable devices, and patient-reported outcomes — is being recognized as a valuable complement to traditional trial data.

This shift is particularly relevant in the context of digital health technologies and therapeutics for rare or orphan diseases, where prospective observational studies and adaptive trial designs offer viable, efficient alternatives for generating timely insights. Moreover, the rise of medical devices and continuous learning systems driven by artificial intelligence (AI) demands an ongoing validation model, as these tools evolve and adapt post-deployment. Regulatory frameworks are beginning to accommodate this dynamism, acknowledging that evidence in the modern era must be both rigorous and responsive to technological advances. However, approaches and submission requirements vary considerably from one country to the next, and the recent explosion of data in the last 10 years or so has not yet produced a harmonized idea of what required or insightful evidence should be produced.

The advent of *in silico* studies (that are conducted entirely within computer simulations), powered by AI, has opened new frontiers in clinical research by enabling the simulation of molecular interactions and treatment effects on virtual patient models. These approaches allow researchers to rapidly explore multiple clinical scenarios with broad implications using fewer resources and greater flexibility than traditional methods.

Dosing guidelines could improve therapeutic outcomes compared to standard protocols, though the need to further refine and manage toxicity risks remains. Similarly, machine learning (ML) algorithms are now being used to personalize treatment strategies, such as predicting bleeding risk in patients with chronic kidney disease or organ rejection in transplant recipients. These innovations offer a more individualized and data-driven approach to care, potentially replacing expert opinion or case reports in some settings. However, to integrate these methods into routine practice, we must have robust implementation and validation frameworks to ensure their reliability, safety, and clinical utility.

Understanding One Form of Evidence Is Not Like the Other (i.e. Levels of Evidence, Scientific vs. Regulatory vs. Clinical vs. Consumer)

The trustworthiness and reliability of scientific evidence are foundational to safe, effective, and equitable healthcare. In clinical practice, high standards — often defined by formal "levels of evidence" — are essential for documenting, validating, and disseminating best practices. These standards ensure that innovations are not only effective in theory but also proven to work in the complexity of real-world care settings. In high-risk clinical environments, introducing a new intervention, form of patient or provider monitoring, quality measure, reimbursement change up or down, or innovation that replaces some form of labor performed by licensed human professionals requires a body of evidence that meets rigorous thresholds for reproducibility, safety, and impact. Sometimes, innovators may learn only prior to commercial launch that any or all of these features may apply to introducing what they have created into daily use by patients, providers, payers, families, and caregivers.

When a technology or therapeutic is truly cutting-edge, the burden of scientific responsibility becomes even greater. The introduction of novel tools must be approached with caution, transparency, and methodological rigor. Yet the path from innovation to clinical adoption is rarely linear. Innovators must navigate unclear regulatory and institutional contexts, market incentives that may not align with patient outcomes, and inherent human resistance to change. Often, this journey involves painstaking efforts to replicate and validate early findings before the broader medical community is willing to revise entrenched clinical norms.

Today, this landscape is being reshaped by rapid digital transformation in healthcare. The rise of AI, Big Data, and other emerging technologies is disrupting long-standing paradigms of how clinical evidence is generated, assessed, and adopted. Traditional models such as the evidence-based medicine (EBM) pyramid, which have guided research hierarchies for decades, are being re-evaluated in light of new methodologies. New models including real-world evidence, adaptive trials, and AI-powered decision tools challenge the assumptions of a static, one-size-fits-all approach.

A New Vision: Technology Tools and Opportunities to Apply Them

Bellini et al. (2023) suggest a thoughtful revision to the hierarchy of evidence that considers the addition of a number of factors to this pyramid that are increasingly important in an age of Value-Based Care. These considerations, termed a third dimension of the pyramid, reflect the effort and complexity required to advance to higher levels of scientific validation and the key legal, ethical, educational, and cost-effectiveness challenges that must be addressed to integrate the innovation into practice. The fourth dimension is also introduced: the volume of each step, symbolizing the real-world clinical impact associated with each level of evidence. This creates a more comprehensive, multidimensional model of evidence generation in the age of advanced technologies.

Digital health innovations must go beyond novelty; they should enable care anywhere, lower costs, improve quality, and leverage both real-time and longitudinal data. As information consumers in healthcare, we have long underutilized the vast data at our fingertips, hindered by fragmented systems and privacy silos. The shift from intermittent to continuous, multi-source data — from wearables to biobanks — demands new frameworks beyond traditional evidence-based medicine. AI-powered tools, including in silico research and adaptive decision support, offer unprecedented speed and precision, often outperforming static methods.

Ultimately, what matters most is not just methodological rigor, but real-world impact as measured through clinical relevance, usability, and tangible improvements in health outcomes.

Companies with Clear Evidence-to-Practice Strategy

Here are thumbnail descriptions of nine companies that are leading the way to apply RWE to healthcare issues.

Aetion (United States / Spain)

Aetion provides one of the leading software platforms for regulatory-grade RWE analytics. Its flagship Aetion Evidence Platform (AEP) enables rapid analysis of real-world clinical data to uncover causal relationships and comparative effectiveness. Pharma companies use AEP to answer questions for FDA submissions, optimize trial designs, and monitor post-market safety. Uniquely, Aetion has collaborated directly with the FDA. For example, the FDA has used RWE to study COVID-19 treatments and to address oncology care disparities. This focus on rigorous, "decision-grade" evidence and active work with regulators distinguishes Aetion in the digital health ecosystem.

Clarify Health (United States)

Clarify Health brings "Moneyball" analytics to healthcare by churning through billions of health records from over 300 million patient journeys. Its Atlas platform applies big-data and AI methods to longitudinal patient data (including medical, social, and behavioral factors) to predict outcomes and identify care improvements. For example, Clarify can model multi-year patient trajectories and assess the impact of social determinants of health on outcomes. Health systems and payers use Clarify's real-world insights to reduce costs and optimize quality, making Clarify stand out for its breadth of data and focus on predictive analytics in RWE.

Evidation Health (United States)

Evidation bridges everyday digital life and clinical research. Through its Achievement app (now MyEvidation), Evidation has recruited a network of over 5 million individuals who consent to share data from wearables, smartphones, and surveys in return for points and insights. Evidation's platform passively collects real-world health metrics – steps, heart rate, sleep, etc. – and actively engages users in research studies (e.g. prompting surveys or digital health interventions). The company specializes in analyzing these patient-generated data to validate digital health solutions and measure outcomes in the real world. By directly connecting participants with research (including collaborations with pharma, big tech, and government), Evidation creates "real-world evidence in everyday life," demonstrating how behaviors and digital markers translate into health outcomes. Evidation Health adds rigor to a source of data historically considered less structured and reliable as information generated by providers in a patient's record. Improved rigor, market receptivity, and reliable evidence standards have enabled their success.

Huma (United Kingdom)

Huma is a global digital health company enabling remote patient monitoring and decentralized clinical trials. Its platform can collect continuous real-world data from patients at home – symptoms, vital signs (via connected wearables), patient-reported outcomes – and aggregate these for research or care management. Huma's technology has been used in partnerships with national health systems (e.g. NHS's COVID-19 remote monitoring programs) and pharma companies. Notably, Huma emphasizes compliance with regulatory-grade evidence needs; it helps medtech and pharma partners generate RWE for device approvals and post-market studies by running virtual studies on its platform. The platform's ability to securely handle sensitive patient data in a distributed way (while meeting quality standards for Software as a Medical Device) sets it apart. Huma's work on federated data collection and analysis shows how real-world patient data can support new indications or regulatory submissions, essentially acting as a digital Chief Research Officer for the era of RWE.

Propeller Health (United States - now a ResMed company)

Propeller Health, a subsidiary of ResMed, produces FDA-cleared digital inhaler sensors and a platform for asthma and COPD management. Its sensors attach to patients' inhalers and passively track medication usage and environmental conditions. Real-world studies have shown Propeller's system can improve adherence and outcomes. For example, users experienced fewer asthma exacerbations and

better disease control by receiving personalized insights and alerts. Propeller's platform has been the subject of over 150 peer-reviewed studies and articles, demonstrating improved quality of life and clinical outcomes while lowering healthcare costs. Distinguishing features include integration with provider care (Propeller can share data to electronic health records – EHRs – for remote monitoring) and population-level analytics for public health. Propeller exemplifies how a medical device coupled with a digital app can yield RWE that not only validates the product's effectiveness but also actively guides patient care in everyday settings.

Tempus (United States)

Tempus is a precision medicine company applying AI to a massive real-world dataset of oncology patients. It has amassed over 70 petabytes (millions of gigabytes) of clinical and imaging data – matched with genomic sequencing results – by partnering with hundreds of medical centers. The Tempus Lens platform mines this trove of real-world data (RWD) to help clinicians personalize cancer treatment and to aid pharma in trial design and patient matching. Notably, Tempus's clinico-genomic approach – connecting EMRs, DNA/RNA profiles, and outcomes – distinguishes it from other services. The company collaborates with regulators and industry alliances to advance RWE use in approvals.

TriNetX (United States)

TriNetX operates a global health research network that connects hundreds of healthcare organizations and millions of de-identified patient records. Through its web-based platform, researchers can query aggregated EHR data in real time to perform cohort discovery, protocol feasibility, and outcomes analysis. The network's longitudinal clinical data and analytics tools allow creation of real-world evidence (e.g. synthetic control arms or epidemiological studies) from routine care data. A key differentiator is TriNetX's federated model – hospitals share data within a secure network – that enables collaboration between pharma and providers to accelerate trials and answer real-world clinical questions.

Verana Health (United States)

Verana operates a specialty data ecosystem by partnering with medical associations (ophthalmology, neurology, urology, etc.) to collect real-world clinical registry data. Through its AI-guided platform, Verana curates these EHR data pools to generate RWE for drug development, trial optimization, and even market insights (e.g. tracking treatment usage trends). This startup began with an eye-care app but pivoted to digital health. It has drawn major investments – including a $150 million round led by J&J's venture arm – underscoring its unique position in leveraging physician-sourced data networks for RWE.

Owkin (France/United States)

Owkin is an AI startup applying federated learning and real-world data to accelerate drug discovery and precision medicine. Instead of centralizing data, Owkin sends machine learning models to collaborate across many hospitals' datasets, which allows AI training on thousands of patient samples without pooling the data in one place. This privacy-preserving approach unlocks insights from diverse real-world sources (pathology images, genomics, clinical outcomes) that were previously siloed. Owkin's platform has been used to uncover novel disease biomarkers and optimize clinical trial designs (e.g. identifying high-risk cancer subgroups for targeted therapies). Major pharma companies have partnered with Owkin to leverage its AI on their data; Sanofi even invested $180 M. What distinguishes Owkin is this federated model and its focus on translational RWE: gleaning biological and clinical insights from real-world patient data while respecting data privacy. By improving trial design and drug targeting through RWE-driven AI, Owkin aims to reduce development time and increase success rates in the pharmaceutical pipeline.

Conclusion

As this transformation toward broader use of RWE accelerates, healthcare stakeholders must strike a delicate balance between embracing innovation and preserving the scientific rigor that underpins patient safety and trust. Only by evolving our standards of evidence — without compromising their integrity — can we ensure that new technologies genuinely

improve outcomes and are responsibly integrated into clinical practice.

Author (In order of contribution)

Mark Wesson, MPH, FACHE, **Venture Partner, Global Health Impact Fund**
Mark Wesson, MPH, FACHE, is a San Francisco Bay Area-based healthcare strategist and venture partner. With over 20 years of experience spanning clinical operations, digital health, and early-stage investment, he works with international founders, systems, and capital partners to accelerate the adoption of evidence-based, tech-enabled care. Mark is Managing Director at VitaX Ventures and a Venture Partner with Global Health Impact Fund. Mark brings deep expertise in healthcare innovation, implementation science, and strategic partnerships to his advisory roles worldwide.

For more information about the Coalition for Innovation,
including how you can get involved, please visit coalitionforinnovation.com.

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