COALITION FOR INNOVATION

HealthTech Blueprint for the Future

Coalition for Innovation, supported by LG NOVA

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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

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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 2:
The Innovation Gap: From Concept to Market

Author: John Hsu, MD

The "innovation gap" refers to the challenges and barriers that prevent a concept from reaching the market as a viable product or service. Bridging this gap involves navigating multiple stages—ideation, development, testing, and commercialization—while overcoming obstacles such as funding, technical feasibility, manufacturability, market fit, customer demand, and scalability. As an example, it currently takes 10-15 years of research and development and billions of dollars to bring a new medication to market. Commercial success is also not guaranteed; FDA regulatory compliance, the complicated world of drug reimbursement by insurance companies, adoption by the medical community, and patients' willingness to take the drug can sink a new product.

From my vantage point as a founder of two pharma companies and one medical device company, here are the key factors that contribute to the innovation gap, as well as some strategies that address those factors.

Challenges / Gaps & Potential Risks

Several challenges contribute to bringing an innovation to market. It is a road well-traveled by many successful entrepreneurs but there are many exits along the way before reaching the final desired destination.

1. The first exit is very obvious. It is the lack of funding and other resources. Innovators with early-stage ideas often lack sufficient capital for research, prototyping, or market entry so the idea remains stuck in the idea stage. To emerge, the innovator may try to secure a funding investment but that can be difficult without a proven track record or tangible product. Family and friends may assist but that source of funding often is not enough to support a real effort. Sometimes innovators will pool resources to attract and pitch to venture capital firms. These founders often struggle, however, because they often do not have a product or their idea is too niche or unproven. Investors prioritize quick, safe returns over long duration investments that present multiple risks for failure. Often 70% of digital transformation initiatives fail due to inadequate funding or resource allocation. https://businessmap.io/blog/why-digital-transformation-fails
2. Second, if they get past the funding and resources stage, founders must face technical and development challenges. Turning an idea into a functional product requires overcoming technical limitations, such as engineering complexities and lack of expertise. A novel medical device may face years of delays due to FDA regulatory requirements or difficulties in achieving consistent performance during testing. Continued iterations and constant prototyping quickly consumes scarce funding and resources and often leads to failure.
3. The third is lack of monetization strategy or reimbursement scheme. The best idea can be turned into a product but if it does not make money, it will fail. For example, Pear Therapeutics raised millions of venture funding and reached a billion

dollars in valuation but could not get insurance companies to pay for the services it offered. It could not service its financial obligations and declared bankruptcy. https://www.forbes.com/sites/katiejennings/2023/04/07/pear-therapeutics-files-for-bankruptcy-as-ceo-blames-shortfalls-on-insurers/

4. The fourth challenge is missing a market fit and gaining customer adoption. Even if a company produces a technically sound product, commercial success is far from assured. If the product doesn't meet customer needs or if the market isn't ready, the product will not have customer channels and fail. Many entrepreneurs build a product but misjudge demand or fail to communicate value propositions. 60% of new products fail to gain traction due to poor market fit. https://eximiusvc.com/blogs/why-startups-fail-top-10-reasons-failure-rate/#:~:text=The%20leading%20cause%20of%20startup,the%20market%20actually%20needs%20it
5. The fifth is underestimating the regulatory and compliance barriers to market entry. Many industries including healthcare, finance, and energy face stringent regulations that can delay market entry for years or even derail a product completely. Biotech innovations often require years of clinical trials and FDA approval, increasing costs and time-to-market.
6. The sixth is lack of scalability and ability for commercialization. Most startup founders do not have experience with supply and logistics. They have no experience in moving their product from a prototype to mass production. Widespread adoption requires a robust supply chain, distribution networks, and operational capacity, all of which must be created, nurtured, and financed. When promises are made but products are not delivered, orders stop, and the company goes out of business soon after. 45% of startups fail to scale due to operational inefficiencies.
7. The seventh is failure to perceive market change and corporatization. Startup entrepreneurs often have a vision that turns into a dream to disrupt the status quo. They see a new, better, and more efficient method to do something that has been done the same way for years. When the business grows, their continued focus

Example

The opioid epidemic costs the U.S. 100,000 lives and $2.7 trillion in added healthcare costs every year. The founders of a new company identified a specific need by a certain population of patients and created a medical device to address that need. It was designed to improve remote monitoring of patient adherence to medication treatment.

Cognizant of the difficulties in dealing with insurance reimbursement, the founders monetized their product by avoiding reliance on insurance reimbursement. Instead, they went to multiple customer channels that could reimburse for the device from opioid litigation settlement funds, revenue share programs with customers, and the government. In assessing market trends and customer needs, the company founders were able to identify multiple other customer channels providing multiple revenue streams.

A prototype medical device was produced and tested in the market and iterations were based on consumer feedback. Engaging an FDA consultant early allowed for quick FDA registration. The founders prepared to scale to meet the high potential demand for the device by partnering early with an industry leader in supply chain and logistics. The company is now well on its way to market launch with a potential of commercial success.

on innovation often leads them to engage corporate executives to operate the business who have preconceived ideas of how a business should operate based on their own previous experiences. Executives are risk-averse while entrepreneurs embrace risk. Within companies, resistance to change or risk-averse cultures can stifle innovation. Bureaucracy and siloed teams further widen the gap. Kodak failed to capitalize on digital photography due to internal resistance to disrupting their film business that was safe and financially sound, which ultimately led to the company's demise.

https://www.forbes.com/sites/chunkamui/2012/01/18/how-kodak-failed/

Mitigations

To make the road smoother, strategies can bridge the Innovation Gap. Early-stage companies can secure funding from alternative sources. They can leverage angel investors, crowdfunding, or government grants for initial capital by developing a compelling pitch with clear milestones that can attract capital.

To save money and build a better product, innovators should be agile in the development and prototyping of their products to test and refine concepts, reducing technical risks. To test market fit, they can use minimum viable products (MVPs) as a tool to gather valuable real-world feedback and customer validation. Robust market research tools include surveys, focus groups, beta testing, and analysis of competing products and market trends. In today's AI driven craze, AI-driven tools can quickly narrow the innovation gap by accelerating prototyping and aid with market analysis. AI tools can also mitigate the monetization risks by providing analysis of outcomes data, demonstrating high customer demand, and demonstrating positive healthcare economics which often leads to insurance reimbursement. To reduce the regulatory risk, it is best to proactively engage early with regulators and partner with legal or compliance experts to streamline the approval process. To reduce commercialization growing pains, establishing reliable supply chains and manufacturing partnerships early can often avoid complications later.

Next Steps

The innovation gap is a multifaceted challenge requiring strategic planning, resource allocation, and adaptability. By securing funding, iterating rapidly, validating market fit, navigating regulations, scaling efficiently, and fostering a supportive culture, innovators can increase their chances of success. Founders can also use tools such as AI-generated real-time market insights to bridge the gap.

The obstacles to launching and sustaining a successful healthtech product or service are real and significant, but with preparation and planning, founders can greatly increase their chances.

Author (In order of contribution)

John Hsu MD, Founder, CEO of iPill inc, CEO Quivivepharma
Dr. John Hsu practiced 32 years in anesthesia, chronic pain, and addiction medicine. He holds 8 granted patents in medical devices and drug development and was awarded a $1.9 NIDA/NIH grant. Dr. Hsu founded: iPill inc. a biometric secure pill dispenser to improve remote medication adherence; Quivivepharma a drug development company for an opioid-respiratory stimulant combination pill to make opioids safe and abuse deterrent; Fentavive a drug development company for a Narcan-respiratory stimulant combination injectable to address Narcan dosing ambiguity and is in the early stages of working with the DOD/DARPA; NAOMI systems, a practice management software company.

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

View the Next Chapter