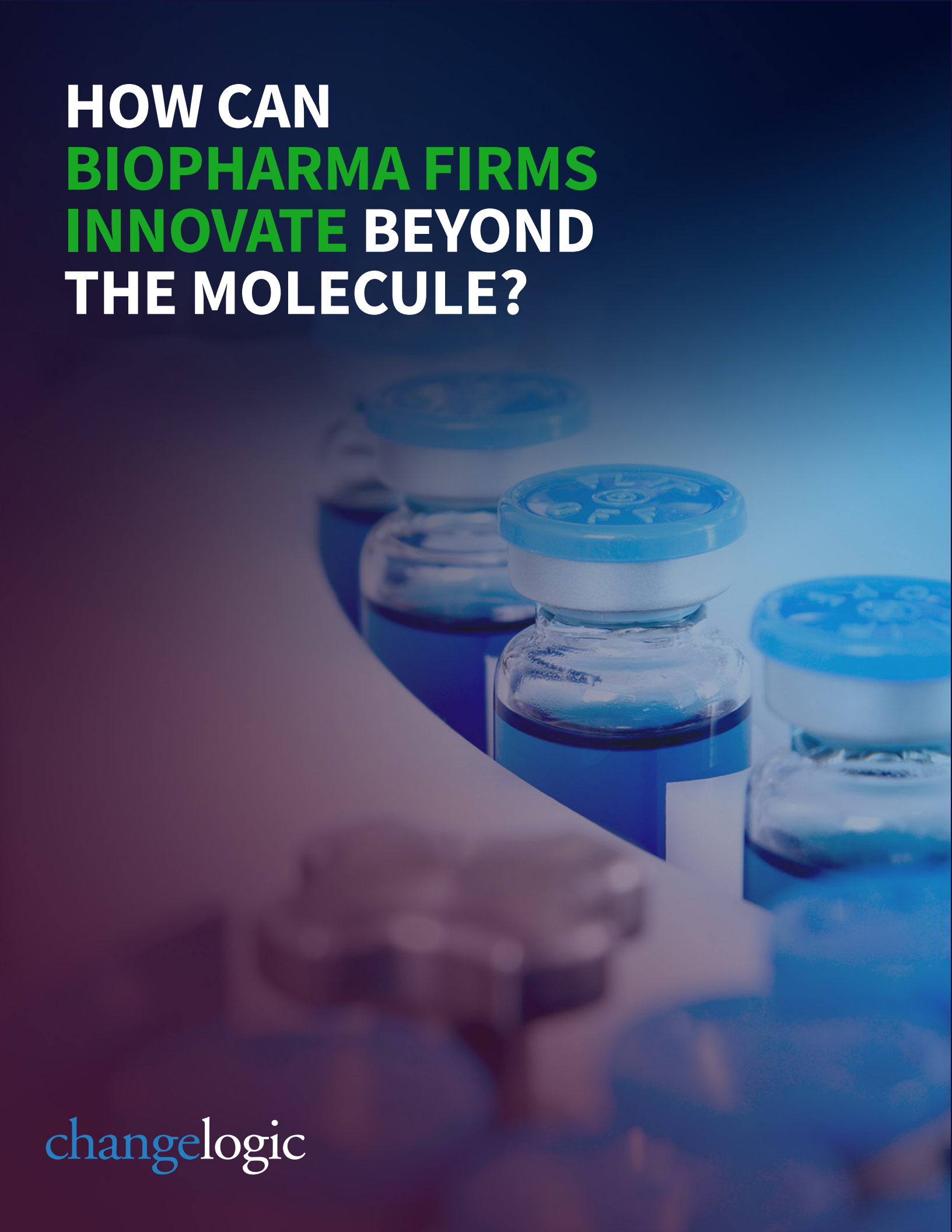
HOW CAN BIOPHARMA FIRMS INNOVATE BEYOND THE MOLECULE?



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Are Molecules Enough?

Pharma's business model isn't dead – yet. Innovative drug development has fueled immense growth in the biopharmaceutical industry, and that model isn't going away anytime soon. Yes, new therapy approvals are declining as R&D costs are increasing, but there is still plenty of value to be created and captured in developing new treatments.

Even so, the coming digital revolution in pharma is inevitable. Digital technologies are starting to disrupt all parts of the clinical lifecycle – from artificial intelligence identifying new molecules, to machine learning improving trial efficiency, to wearables and other sources of real-world evidence that are changing how pharmaceutical firms commercialize their therapies.

> **Digital innovation is booming in drug development. In clinical trials alone, the use of digital products was growing at a CAGR of 34% before Covid-19 drove a punctuated increase in adoption, and 2021 digital spend on clinical trials will exceed $33 billion.[i,ii]**

The drug development impact could be rapid and dramatic – one McKinsey report estimated that artificial intelligence could improve biopharma EBITDA by 30% within 5 years, and up to 75% within 10 years.[iii]

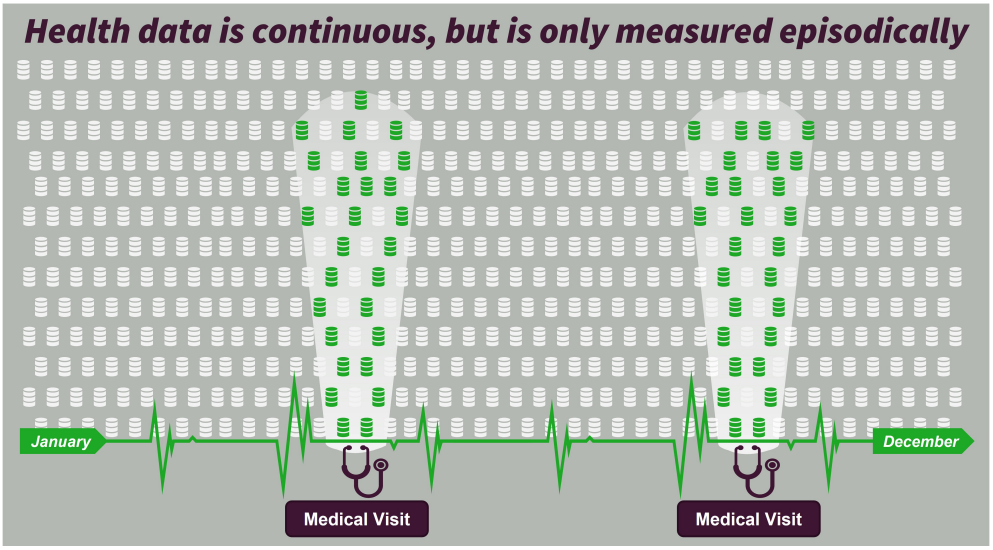
Though drug development innovation has received most of the attention and investment thus far, it is just the beginning of biopharma's digital revolution. Sensors, real world evidence, and advanced computing will enable biopharmaceutical firms to move beyond the molecule and reimagine their role in healthcare. This move is already happening – a Deloitte survey showed that 60% of pharma firms are using machine learning to analyze real world data, and 95% plan to use it in the future – but as promising as the technology and business models for moving beyond the molecule are, they remain largely unproven.[iv]

The Paradox of Moving Beyond the Molecule

Digital innovation beyond the molecule is coming, but it isn't here yet. Despite increasing investment activity, digital solutions won't drive revenue close to that of drugs for decades, if ever. Drugs will remain the cornerstone of pharmaceutical firms' value propositions for the foreseeable future, and those drugs will still have significant value once the future beyond the molecule is realized. **That leaves biopharmaceutical firms with a paradox: how does one build for a digital future beyond the molecule, while sustaining a commitment to drug development?** Many firms are approaching the digital revolution by investing heavily in digital innovation for drug development. These investments make perfect sense, but innovative drug development alone will not crack the problem of innovation beyond the molecule, where long term value is likely to be created.

Creating Value Beyond the Molecule: Real-World Evidence

Patient condition is constant, but healthcare systems measure patients at specific points in time. Digital solutions enable real-time monitoring, generating objective measurements that can be combined with other patient data to derive valuable insights. Medical insights can help patients and providers better manage disease, and outcome data can improve value-based pricing by providing objective measurements of the value a medicine creates for a given patient or disease indication.



The path to generating value with real world evidence seems straightforward: generate data, aggregate data from different sources, and interpret those data to generate clinically valid and relevant insights that can be utilized to improve patient health at significantly lower costs.

GENERATE DATA ▶ AGGREGATE DATA ▶ INTERPRET DATA ▶ UTILIZE INSIGHTS

In practice, this path can be incredibly complex and uncertain: thousands of companies are generating data, aggregating those data creates technical and legal challenges, and deriving insights that are valid and clinically meaningful is a difficult endeavor that can take years to mature and deliver value.

3 Reasons Why Pharma Should Act Now

1. INNOVATION BEYOND THE MOLECULE WILL TAKE YEARS TO MATURE

Using real world evidence to predict, prevent, and better treat disease is a simple idea. But, the process of generating, aggregating, and interpreting data to develop valid and relevant insights will require years of iterative experimentation and failure to reach maturity, and so will the process of developing business models to capture the value that those insights create.

2. COMPETITION IS INCREASING

Competition is increasing among incumbent biopharma firms and from new entrants. Even previously uncontested areas, like ultra-rare disease, are seeing increased investment targeting overlapping indications. Intense competition, combined with the shift towards value-based reimbursement, will make it increasingly difficult for firms to achieve commercial success and capture the full potential value of their R&D investments.

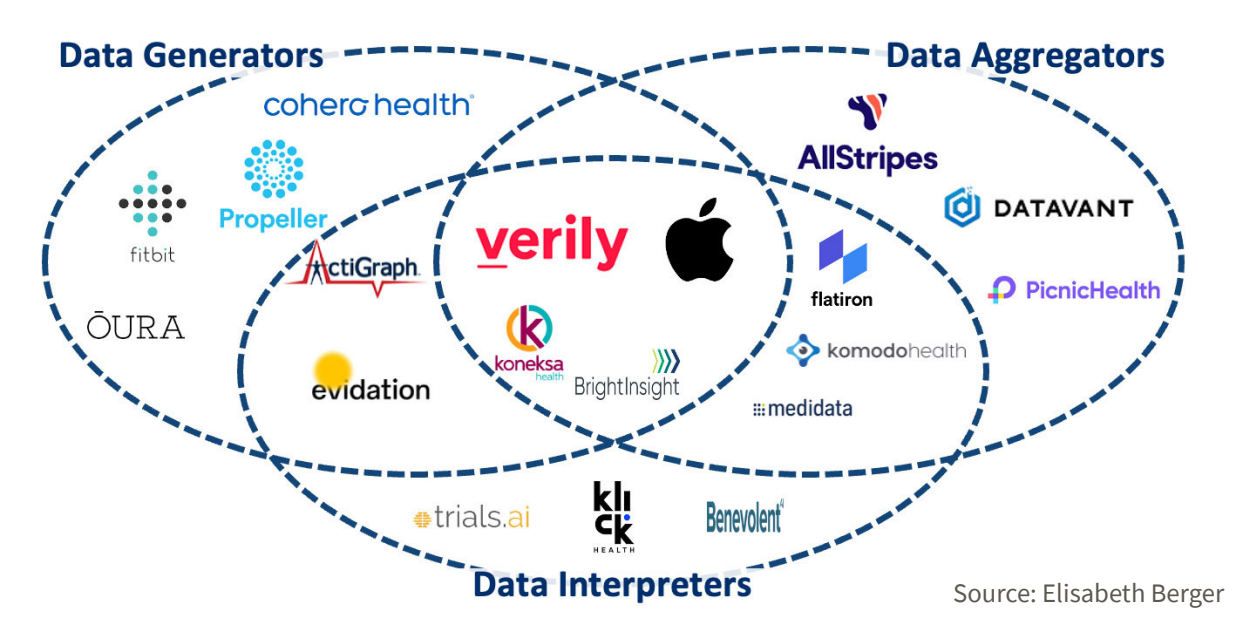
3. HEALTHCARE IS CONSUMERIZING, AND APPLE AND GOOGLE ARE COMING FOR PHARMA'S CUSTOMER

Patients are taking increasing control over their healthcare, and Apple and Google are building on existing consumer relationships to develop platforms that will predict, prevent, and recommend the best approaches to treat disease. In the near-term, this may help pharma firms by driving patients towards earlier treatment. In the long-run, big tech could disrupt pharma's traditional commercial model, limiting pharma firms' ability to differentiate in the market and capture full value for the drugs they develop.

Apple & Google in Healthcare

What does biopharma's go-to-market strategy look like in a world in which Apple and Google own pharma's patient relationships and are the patient's entry point into the healthcare system?

Apple and Google are two behemoths in an ecosystem of hundreds of companies that are working to generate real world evidence, aggregate patient data, and build platforms to generate insights that can eventually be used to predict, prevent, and recommend the best approaches to treat disease. Apple and Google already own consumer relationships, have a foothold in biopharma, and are building a future in which data-driven insights transform how disease is treated. If Apple or Google succeed, they could disrupt biopharma's commercial model, relegating pharma firms to the role of drug supplier and limiting their ability to capture value for the drugs they develop.[v,vi]



Source: Elisabeth Berger

Verily, Google's life sciences company, has more than a dozen projects – from wearable patches to Covid-19 testing – generating data from which Verily hopes to derive valuable insights about how to deliver better healthcare at lower costs.[vii] Verily is already partnering with a half dozen major biopharmaceutical firms to improve access to clinical trials with data. It's not hard to see how Verily could use their trove of data and insights, along with their technological prowess and consumer relationships, to move from clinical research to data-driven clinical care in the near future.

Apple is taking a healthcare-first approach with its 1B+ devices that give it immediate access to hundreds of millions of consumers and a trove of health data. Apple is leveraging its strong technology ecosystem to build and deliver more and more healthcare innovations. Apple is already giving direct health advice to consumers with alerts about atrial fibrillation, and its investments in personal health records could enable expansion into disease prevention and treatment. Like Verily, Apple is also partnering with major biopharmaceutical firms to power clinical research and has a foothold from which it could expand further into pharma's traditional value chain.

Source: Elisabeth Berger, Change Logic Research

5 Ways Pharma Can Move Beyond the Molecule

We know the disruption is coming, but moving beyond the molecule is uncharted territory for most biopharmaceutical firms. Research shows that most firms who succumb to disruption do so not because they failed to see it coming, but because they were unable to act.[viii] The demanding nature of drug development, and the immense value it creates, puts pharma firms at risk of being unable to act in the face of disruption. The following approaches developed based on research at Harvard and Stanford, and Change Logic's work with clients in life sciences, can help biopharma firms lead disruption beyond the molecule instead of being threatened by it.

1 ALIGN STAKEHOLDERS WITH A CLEAR AMBITION

Digital innovation beyond the molecule requires innovators to break down some of the traditional boundaries that exist across different parts of the clinical lifecycle. A clear ambition for the impact you aim to achieve, backed by strong senior sponsorship, can help your organization overcome the challenge of executing this kind of change. As firms like Nvidia and SpaceX have shown in other industries, a bold ambition for the impact a firm wants to achieve in the future helps all parts of the organization understand their role in creating that impact. A shared ambition for the patient and business impact you want to achieve creates room for the cross-functional collaboration required to innovate beyond the molecule.

A bold ambition is the first step to enabling the cross-functional collaboration needed to move beyond the molecule. Making that collaboration sustainable means understanding the value key stakeholders hope to achieve beyond the molecule, and the risks and tradeoffs they'll face on the journey to realizing that value. For R&D, this may mean considering an additional trial protocol or digital endpoint that may not have been on the initial roadmap. For commercial, this might mean dedicating time and attention to a project that may not directly contribute to this year's numbers, but could have long-term impact. Engaging stakeholders early and gaining their buy-in to the ambition helps business unit leaders develop plans for how their functions will support these kinds of tradeoffs in the move beyond the molecule.

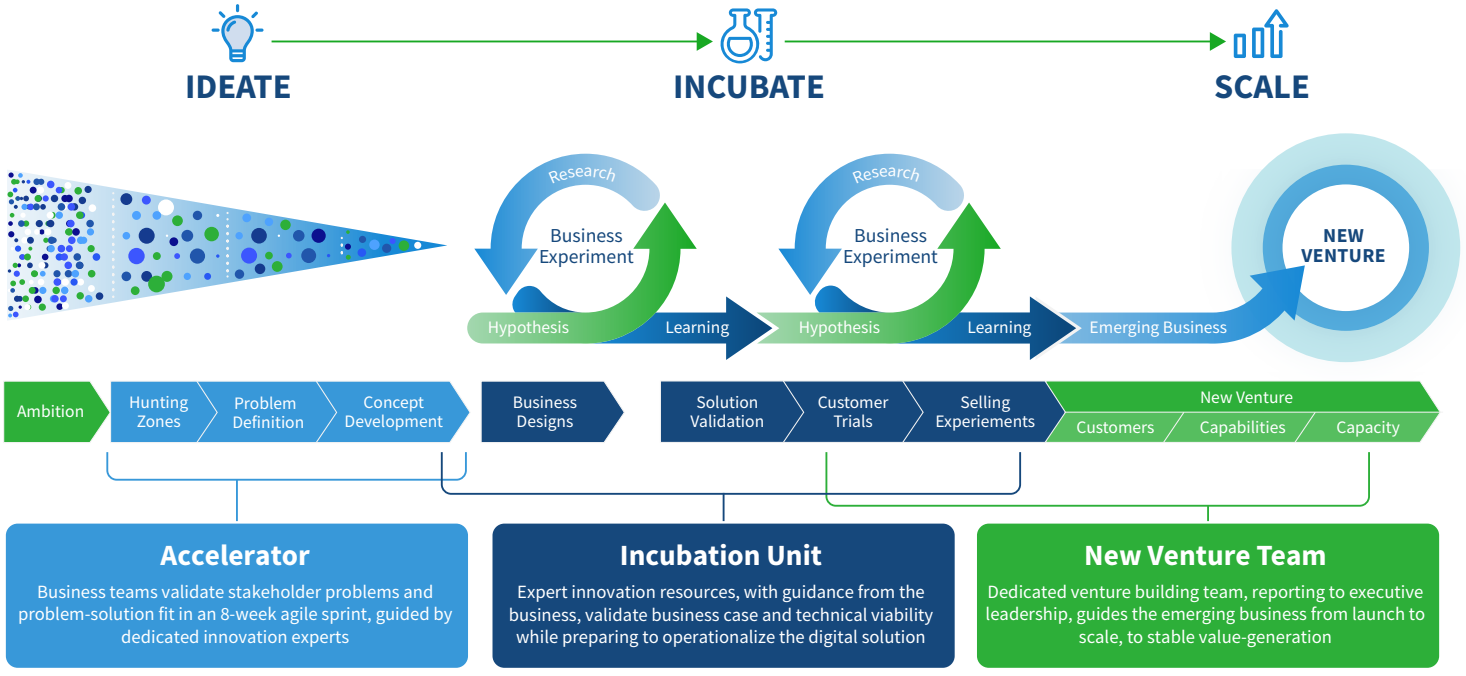
2 INNOVATE WITH AUTONOMOUS UNITS

Innovation beyond the molecule is different from innovation in drug development. Projects that go beyond the molecule have high market and technical uncertainty so the path to success will likely include many learning opportunities (i.e. failures). As these innovations progress from ideas, to experiments, to fledgling businesses, they are at risk of being suffocated by the pressing demands of the core drug development-driven business.

To succeed, digital innovation projects need autonomy to move at pace, unfettered by traditional organizational constraints. Autonomy allows teams to apply different skillsets, metrics, risk tolerance, innovation methods, and ecosystem partnership approaches to meet the needs of an uncertain, exploratory venture.

However, these teams can also go faster than a startup by leveraging the expertise, resources, and assets of the core business. This can both give them an advantage over the hundreds of startups in the space and make it easier to reintegrate and scale the innovation when ready.

We call this balance of autonomy with access an ambidextrous approach to innovation. There is no one-size-fits-all answer to how biopharma firms should approach ambidextrous innovation, but the best choice may depend on the scale of your ambition and the maturity of your innovations beyond the molecule. Models from other industries, like accelerators, incubation units, and new venture teams, can help pharmaceutical firms succeed beyond the molecule.



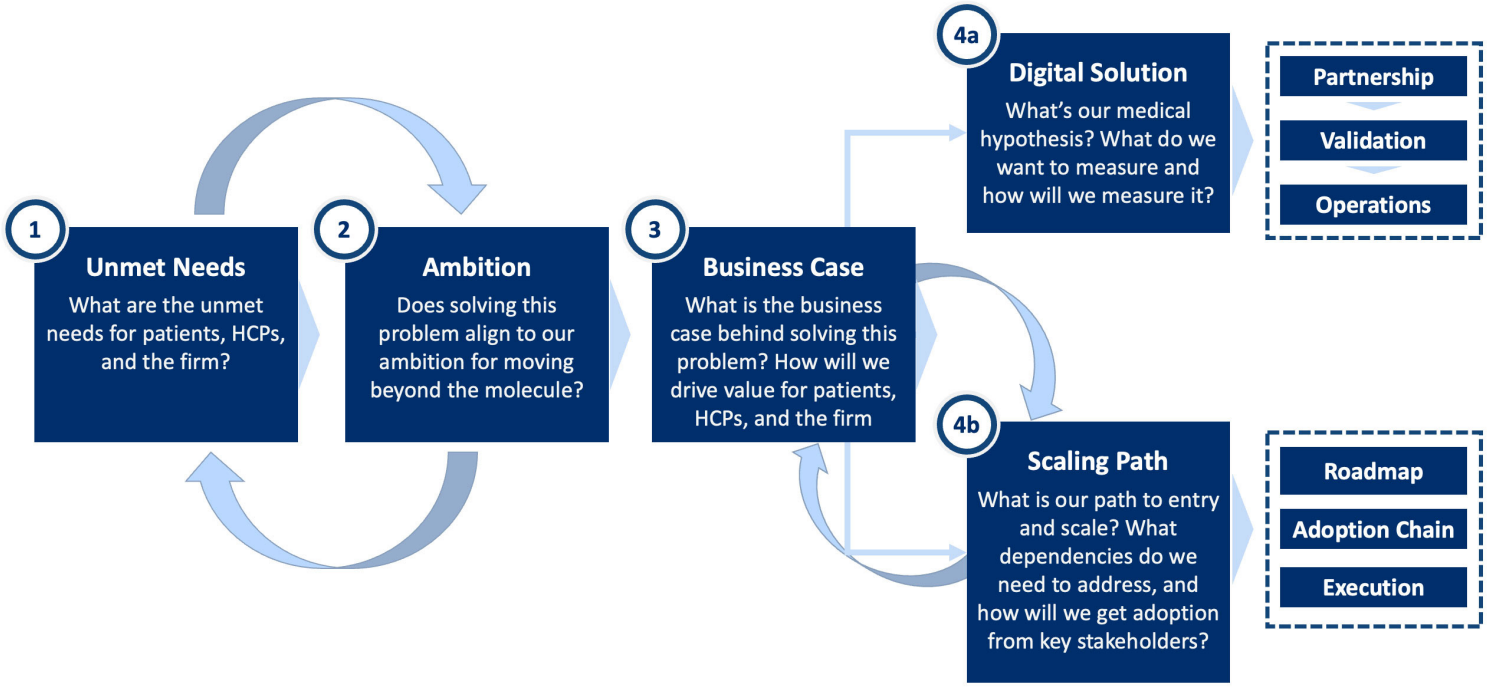
3 START WITH STAKEHOLDER NEEDS, NOT TECHNOLOGY SOLUTIONS

Efforts to move beyond the molecule often start with someone saying, “We found this cool technology, let’s do a pilot.” Enthusiasm for innovative ideas is fantastic, but technology-first approaches often miss a key question: what problem are we solving? This creates risk of wasting valuable time and resources on a pilot that was unlikely to scale because, while the solution may have been great, it didn't address a high-value problem for patients and the firm.

Instead of starting with technology, biopharmaceutical firms should start by identifying critical unmet needs for their key stakeholders – usually patients, providers, and/or payors. Asking three key questions can help innovation teams identify the right solutions:

1. Is this a significant problem our stakeholders want solved?
2. Does solving this problem help us achieve our ambitions beyond the molecule?
3. Is there a strong business case for solving this problem?

The process of aligning stakeholder problems, the firm’s ambition, a strong business case, and a viable digital solution is iterative. But, getting to “yes” on the three questions above before narrowing in on a technology solution increases the odds that your innovation will scale if the solution works, and that you'll generate valuable learning even if it doesn't.



4 RUN BUSINESS EXPERIMENTS TO INVEST AT THE SPEED OF LEARNING

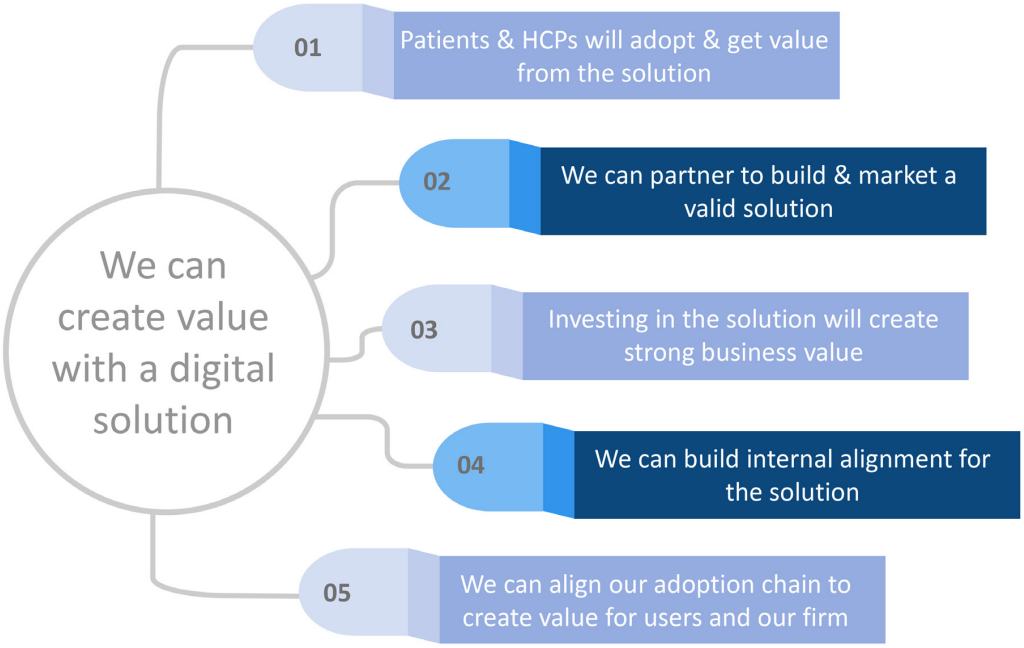
Even when teams take the time to identify the right problem to solve, there can still be a tendency to jump right into building the solution. While drug development risk can be quantified with reasonable accuracy, the world of biopharma solutions beyond the molecule is full of unknown unknowns, and these unknowns are risky. While it's impossible to identify all sources of risk, we find innovators beyond the molecule are most successful when they identify as many assumptions as possible.

Some of the common critical assumptions we encounter while helping clients build beyond the molecule solutions are below, but these assumptions will vary widely depending on a given solution's use case, target population, disease indication, technology, and more. Teams can identify the risks relevant to their specific solution by:

1. Identifying as many assumptions as possible by continuously asking "what must be true in order for this solution to work?"
2. Prioritizing critical unknowns by identifying the assumptions that would cause the solution to fail if proven false, and for which the team is least certain.

Identifying, testing, learning, and iterating the critical assumptions behind a solution's desirability, feasibility, and viability allows innovators to build evidence that the project is on the right track. Investing at the speed of learning minimizes the chances of over-investment in a project that won't succeed, and enables quicker pivots to different stakeholder problems, solutions, or business cases based on what the team learns through experimentation.

Common Critical Assumptions for Beyond the Molecule Solutions

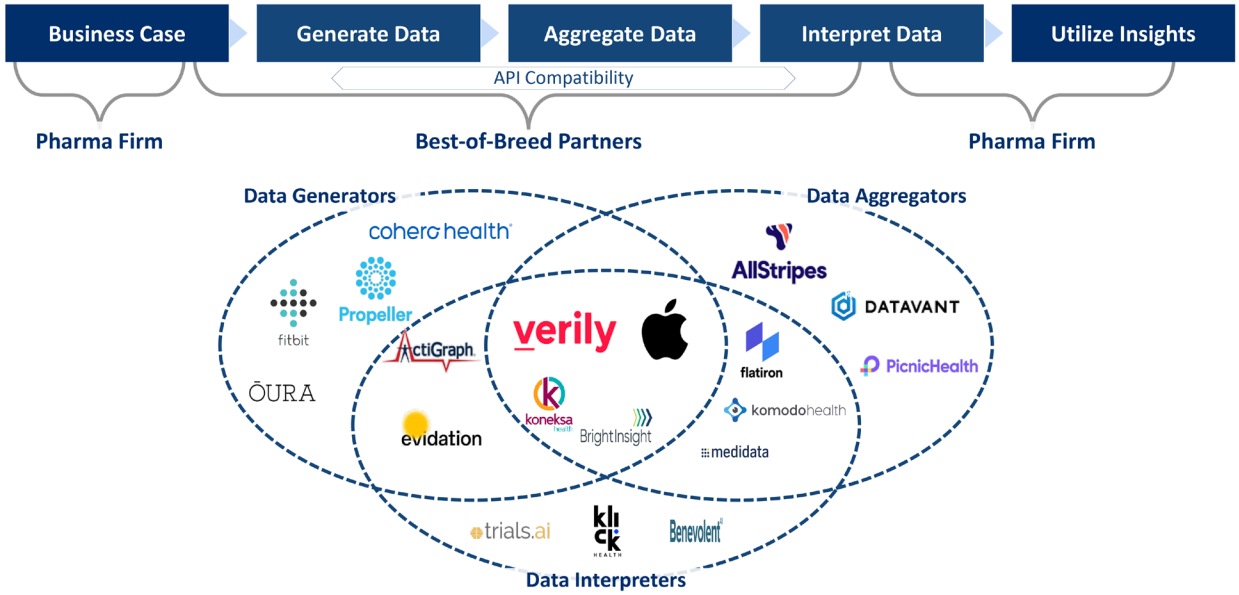


5 EMBRACE THE ECOSYSTEM

Biopharma firms are expert in developing molecules into drugs and therapies that treat disease. Biopharma firms, by and large, are not expert in developing digital solutions. To succeed beyond the molecule, pharma firms should leverage their strengths in understanding and treating disease to determine how an ecosystem of partners can help them close the gap on digital innovation capability.

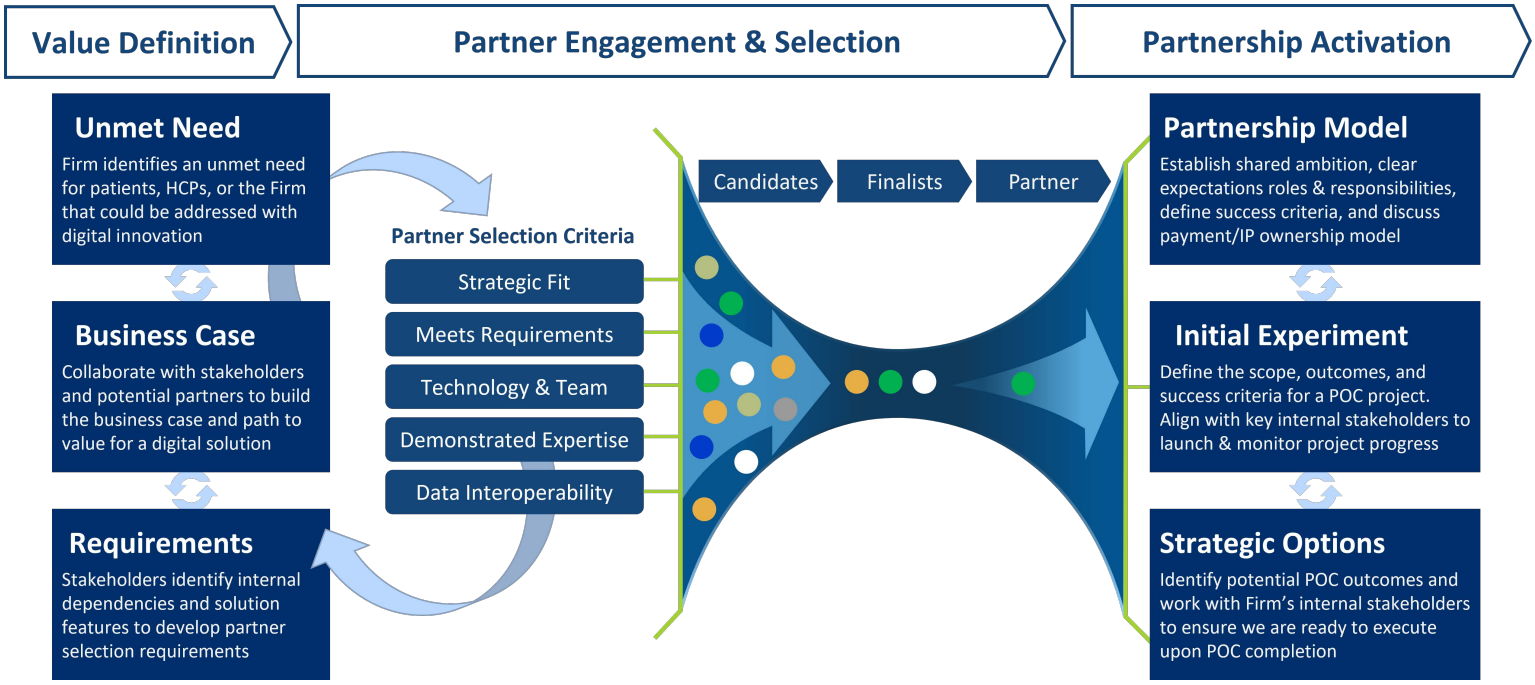
There is a rapidly growing ecosystem of technology innovators working to improve human health, with tens of billions of dollars in investment flowing to digital health companies each year.[ix] To lead their markets beyond the molecule, pharma firms should leverage that ecosystem to generate, aggregate, and interpret data – so long as the pharma firm bookends the process by defining the business case at the start and utilizing the insights to create value at the end.

The Path to Digital Value Creation Requires Ecosystem Partners



We recommend approaching new partnerships the same way you'd approach a new business venture – by iteratively experimenting and building your way to long-term value. Starting with a business case and proof of concept, while also aligning on the success criteria for moving forward, allows partnerships to grow from transactions into mutually beneficial collaborations. This approach allows for quick selection of qualified partners to validate technology and co-create solutions, while also establishing shared goals and incentives that allow the partnership to mature alongside the innovation.

An Iterative Approach to Ecosystem Partnerships Beyond the Molecule



Getting Started with Digital Innovation Beyond the Molecule

The digital revolution in biopharmaceuticals is already here. Artificial intelligence, machine learning, and other innovative uses of data and technology are disrupting drug development and having a significant impact on portfolio performance. Digital innovation beyond the molecule isn't far behind and has the potential to disrupt pharma's traditional business model, changing how firms market and capture value for the treatments they develop. Innovations beyond the molecule may become the key to maximizing the value of molecules in the drug development pipeline, so it's imperative that pharma firms act now to build for the digital future.

Based on Change Logic's experience helping firms lead disruption across dozens of industries, including biotechnology, healthcare, and pharmaceuticals, we believe the five strategies discussed here can help biopharmaceutical firms successfully innovate beyond the molecule. We look forward to hearing your point of view and experiences with digital innovation beyond the molecule. Reach out to our Healthcare and Life Sciences practice leaders below to start a conversation.

ABOUT THE AUTHOR

AARON LEOPOLD

Aaron works with senior teams and corporate innovators to develop and scale new businesses. As Change Logic's Global Healthcare Practice Lead, Aaron helps clients apply proven innovation methods from other industries to address the challenges of scaling innovation within the complex healthcare and life sciences ecosystem.

Aaron primarily serves clients in healthcare technology, life sciences, and insurance, and he has a background in healthcare innovation, strategy, and startups. Before joining Change Logic, he developed and executed a corporate turnaround as the strategy director for Source Medical, a privately-held healthcare software company. Prior to that, he worked with leading hospitals to implement complex enterprise software systems at Epic, and developed government affairs and charitable partnership strategies at Dell's Global Healthcare & Life Sciences unit. Aaron also co-founded a genomic oncology startup, where he led strategy and finance.

Aaron is a graduate of Vanderbilt University with a degree in Music Performance and Political Science, and is pursuing his Executive MBA at Wharton. While at Vanderbilt, he consulted to the Costa Rican government as part of a charitable partnership to aid in the development of their fledgling national music education system.

CHANGE LOGIC
IN HEALTHCARE & LIFE SCIENCES

The pandemic highlighted the critical needs of global healthcare systems. Technology has turbocharged drug discovery, setting a new bar for pharmaceutical firms. Telemedicine has demonstrated its value for increasing patient access and quality of care. Sensors and wearable devices are showing the potential of remote monitoring to increase convenience and reduce costs for patients and providers.

Even so, healthcare and life sciences ecosystems have historically been resistant to change. Derailed by complex systems and processes, many innovations fail to deliver anticipated benefits. Even with clear evidence that digital innovation can increase access, reduce costs, and improve patient quality of life, the challenge of aligning stakeholders from across the industry slows the rate of adoption.

Practice Leaders

Christine Griffin

Aaron Leopold

i Mara, Chen, et. al. "Quantifying the use of connected digital products in clinical research." NPJ Digital Medicine. April 2020.

ii MindCommerce, "IOT in Healthcare"

iii McKinsey, "How pharma can accelerate business impact from advanced analytics." January 2018.

iv Deloitte, "The rise of artifical intelligence across biopharma." October 2018.

v CB Insights, Apple's AI Strategy in Healthcare, September 2020

vi CB Insights, How Big Tech is Tackling the $780B Pharmaceuticals Industry, November 2019

vii www.verily.com/solutions

viii Tushman & O'Reilly, Lead and Disrupt

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DISRUPTION IS AN INSIDE JOB

Change Logic serves as a strategic innovation advisor to firms seeking to realize their potential for growth. We have honed methods for helping clients with complex problems, grounded in decades of research by our founders, Professor Michael Tushman from Harvard Business School and Professor Charles O'Reilly from Stanford University. Our approach is to unlock our clients' potential not only with what we know through our research, but also with the way we work. We are challenging and provocative, and passionate in our commitment to our clients' success.

- Strategic Ambition
- Growth Strategy
- Organizational Renewal
- Ambidextrous Organization

Change Logic works with senior executives in established firms to renew their organization and align them for growth.

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