BrightInsight

WHITE PAPER

Building a digital health platform that scales

How to Know When to Partner (and Why)

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Executive Summary

Biopharma and medtech executives are faced with a number of complex considerations when developing digital health platforms to differentiate therapies and brands.

Building a platform that can support your most important and high-visibility digital initiatives is no small task, and the stakes are high—especially as the digital health space gets more competitive by the day.

Internal tensions among stakeholders can run high, as some think the best path is to handle the entire build and launch internally, while others believe that bringing in an outside partner is the most efficient way to get a solution to market.

But here's the truth: It's rarely a clear-cut buy vs. build choice. It's more useful to think of it as build vs. build, with companies developing some digital capabilities in-house and partnering on others.

So, the real choice for biopharma and medtech companies is not buy vs. build, but rather determining *how* you want to build. Biopharma and medtech companies need to decide which teams or team members should spend their time and energy on a platform build, and then identify when and where an outside partner can add value.

For most companies, picking a platform partner that has industry expertise and a strong track record of bringing solutions to market makes the most sense. That partner can act as an extension of your team, freeing up your internal resources to focus on their core competencies.

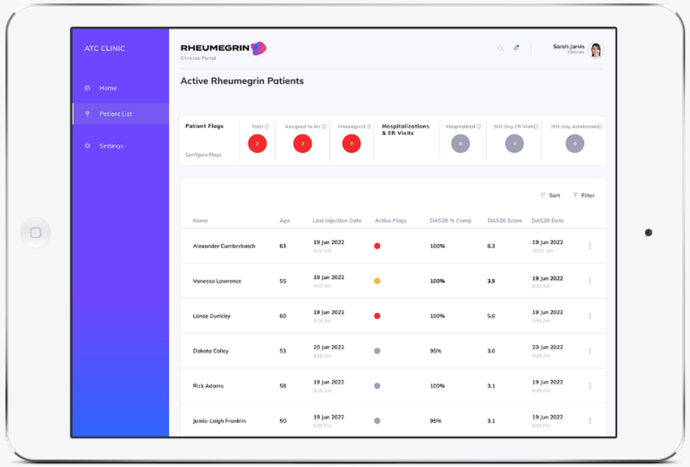
This white paper raises the key considerations for both build approaches and offers helpful criteria for deciding when it makes sense to bring in a partner to augment your in-house capabilities.

Choosing the Right Path to Build Your Digital Health Platform

Today's biopharma and medtech companies face two options when setting out to build a digital health platform. Option A is to build a custom underlying platform and digital health solution in-house, leveraging internal talent and resources, in addition to third-party resources on an as-needed basis.

Alternatively, in Option B, you can choose to bring in a platform partner who leverages their expertise to configure their pre-built platform for your digital solutions, while allowing you to scale for future product launches, freeing your team to focus on differentiating your product offerings.

In this white paper, we'll outline both options.



Whether you decide to take Option A or Option B depends on a few key considerations:

- **Expertise**: Does your internal team have the knowledge and experience required to successfully build regulated solutions, from platform architecture to development to regulatory approvals and launch?
- **Bandwidth**: Does your internal team have the time to take on a project of this size? What other project will need to be deprioritized in order for you to take on such an intensive build? Will you need to recruit and retain new software talent?
- **Focus:** Even if your team can handle a platform build, is it the best use of their time to focus on the underlying foundational platform, rather than the value-adding upper layer?
- **Timeline**: How quickly do you need or want to launch? Can your internal team meet the milestones without deprioritizing other company priorities?

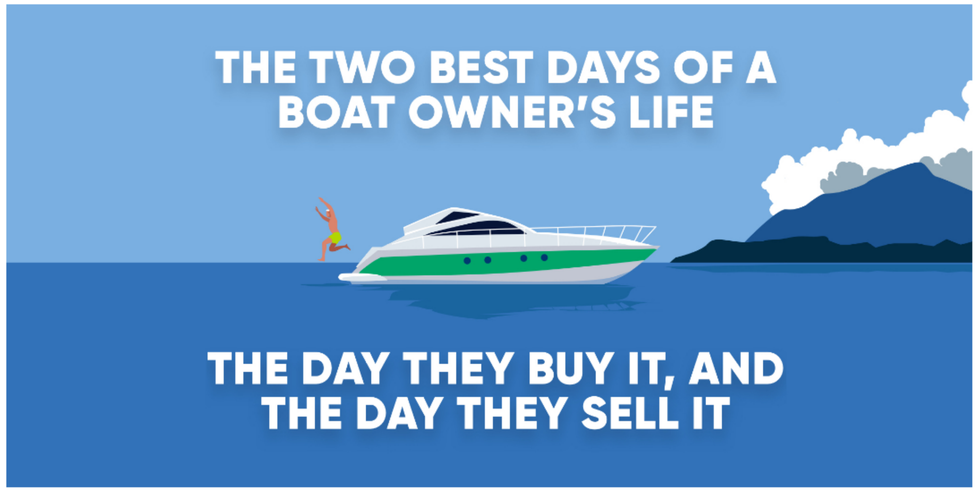
We'll explore the answers to these questions for both Option A and Option B below, although after understanding the significant investment and resources needed to build and maintain a custom platform in-house, readers will come to understand Option B as the only viable option.

OPTION A:

Managing Your Build in-House

There are many reasons why stakeholders may want to build their platform in-house. In this competitive space, senior leadership may have concerns about intellectual property as well as the reliability of external partners. Often, leaders have been burned in the past by vendors with poor communication, lack of effort or unexpected cost overruns.

It's also important to note that building in-house does not eliminate the need for external partners—you're still likely to use the services of task-specific vendors, like consultants, system integrators or cloud partners. But these vendors are not experts in the full depth and breadth of digital health solutions. Rather, they have niche expertise that can alleviate specific blind spots among team skills, so they're not likely to add much value to the final product, or help it scale.



Have you ever heard the phrase, "the two best days of a boat owner's life are the day they buy it, and the day they sell it"? The same adage can be applied to biopharma or medtech companies who build their own custom platform. After years of maintaining a platform that increasingly falls short of meeting the needs of internal stakeholders and trying to retain digital health engineers who are relentlessly recruited by tech startups, companies will wish they had partnered from the start.

Building your own custom solution in-house introduces five main challenges

1. **Expensive to build:** It can cost up to $20M to build and ~$10M/year to maintain a backend infrastructure, and that's for a bespoke platform that barely meets requirements for one product and one country.
2. **Complex regulatory compliance:** Building a robust Quality Management System is resource-intensive, especially when you consider the added complexity of evolving global regulations in the U.S., E.U. and beyond.

   You can learn more about the importance of an ISO 13485 certified Quality Management System in this blog >
3. **Increased privacy and security risk:** Maintaining a homegrown digital platform requires significant resources devoted to complying with nonuniform privacy laws and evolving security threats, yet it's crucial in order to avoid the financial penalties, bad publicity and harm to patients that can result from a breach.
4. **Challenging to maintain and scale:** It can take two years or more and 10+ engineers to build a bespoke siloed platform that does not integrate into a broader digital health ecosystem.
5. **Not a competitive advantage:** At the end of the day, it is not a competitive advantage for biopharma and medtech companies to build the underlying infrastructure. You should focus your team on the specific digital health IP that is core to your business and partner for everything else to drive speed to market.

System integrators

If you decide to build internally, another consideration that helps illustrate the high cost and major workload associated with choosing Option A is system integrators.

Major consultancies—or system integrators—can be very helpful in building out strategies or thinking through new digital health business models, but at their core they are not experts in developing regulated software.

From a scalability perspective, a custom platform will limit a company's ability to add additional products or brands onto the platform, integrate with third party medical devices or Health IT systems or expand into new regions. Having an open, managed service platform that isn't custom built for one product or company eliminates these scalability issues.

Building a platform from the ground up can delay time to market for a biopharma or medtech company as there are no pre-built functionalities or systems to leverage. It can take years to build a new platform, which also can lead to product delays or allow competition to leapfrog you.

There are also significant costs involved any time a biopharma or medtech company wants to make any of these types of updates, in addition to high upfront costs for the custom build. Our biopharma and medtech customers have validated that the total cost of building a custom platform can be ~$10 to $20 million, and the resources required to maintain a custom platform cost ~$10 million annually per product.

Beyond simply selecting a system integrator, a company then needs to identify, onboard and maintain ~25 technology vendors and ~20 software tools to support the development, security, privacy and analytics capabilities. In both of these scenarios, it's clear that building a custom platform is expensive, requires a lot of upfront work and ongoing maintenance, and often ends up not being able to scale to meet an organization's evolving needs.

After further exploration, Option A becomes simply untenable for most biopharma and medtech companies. Fortunately, Option B is a solid alternative..

OPTION B:

Collaborating with a True Platform Partner

Deciding to partner and purchase a digital health platform can feel uncomfortable at first, especially for biopharma and medtech companies that mostly develop proprietary products internally. But remember, organizations used to be uncomfortable about transitioning to the cloud, feeling it would be better to maintain their own data center. Now it's a competitive disadvantage to not be on the cloud.

By partnering with a digital expert and purchasing a compliant platform, biopharma and medtech companies will experience a number of advantages.

- Accelerated time to market by leveraging a purpose-built platform that's available today
- Reduced upfront costs and ongoing investment
- Ability to stick to your core competency of developing life-saving drugs and devices
- Reduced regulatory burden of ongoing file management of a regulated software solution
- Minimized privacy and security risk through secure and medical-grade processes and tools
- Differentiated products with machine learning and artificial intelligence capabilities

> **"We leverage off-the-shelf products from a cloud infrastructure perspective, so we can focus internally on developing differentiated data models and algorithms that drive business value. Our IT organization works directly with the businesses to think holistically about the insights we can generate from the data—outcomes can be one objective, but we also think about the new types of insights we can generate from real-world data in the future."**
>
> – Scott Sandschafer, former CIO, Novartis

> **"At Roche, most of our commercial products and clinical trials are multi-national, so our regulatory strategy needs to be contemplated across regions and across varying regulations. This will be the case for most leading biopharma companies. If you leverage a solution like BrightInsight that meets the most stringent requirements and maintains compliance as part of their managed service, you don't have to worry about your regulated digital solutions in the U.S. versus Europe versus U.K. and so on. You just know they're compliant."**
>
> – Paul Upham, Head of Smart Devices, Roche/Genentech

Future-Proofing Your Digital Health Roadmap with the BrightInsight™ Platform

The BrightInsight Platform has pre-built capabilities to meet most core digital health needs out of the box and can be configured to support specific use cases. The Platform includes robust user onboarding and account management tools, including integration with external identity systems via single sign-on (SSO), as well as healthcare functionality, like medication management, electronic patient-reported outcomes (ePRO), physician alerts and more.

Our device instrumentation capabilities can manage medical devices, in vitro diagnostics and other connected medical instruments. Patient management tools—including care plans and surveys, medication and appointment management, patient education, secure messaging and more—are designed to empower providers and patients alike.

The Platform can be adapted to meet specific needs with full-featured configuration management and administration tools. And analytics dashboards provide actionable insights to optimize digital health solutions.

The BrightInsight Platform is built using a microservices-based architecture to capture, transmit and analyze data from CE-marked and FDA-regulated medical devices, combination products, apps and Software as a Medical Device, in compliance with global security, privacy and regulatory requirements. With this Platform in place, you're well positioned for future digital health expansion: new products and features, scaling your user base and expanding into new markets.

ALGORITHMS

SOFTWARE AS A MEDICAL DEVICE

APPS

CONNECTED COMBINATION PRODUCTS

DIGITAL THERAPEUTICS

DIAGNOSTICS

DATA INTEGRATION

Pre-built integrations with medical devices, Electronic Health Records (EHRs) and other health IT systems

DATA MANAGEMENT

Data aggregation & advanced data processing to enable diagnosis, prevention and treatment of clinical conditions

ANALYTICS

Dashboards to provide valuable insights about your digital heath products

BRIGHTINSIGHT PLATFORM

PRIVACY | SECURITY | REGULATORY | QUALITY MANAGEMENT SYSTEM

How the BrightInsight Platform Transforms Your Digital Health Journey

BrightInsight replaces the need for lengthy and complex 'build from scratch' implementations. Instead, we offer a proven platform and configurable solutions, built to meet the most stringent global security, privacy and regulatory requirements.

Accelerate time to market

Biopharma companies launch digital solutions in as little as six months with the BrightInsight Platform.

- Pre-built capabilities that meet 60% to 80% of requirements
- Electronic Health Record (EHR) integrations and identity data management solutions connecting more than 1 million data endpoints across more than 1,700 healthcare organizations and over 3,000 applications into 1,400+ U.S. provider networks
- Device-agnostic approach with 400+ medical device integrations across 50 manufacturers
- Available in 48 countries around the globe, with additional countries planned
- Microservices architecture with advanced security, scalability and configurability

Proven, trusted digital health platform

Top 20 biopharma companies trust BrightInsight to build and launch their commercial regulated digital health solutions.

- We are experts at building and maintaining biopharma and medtech regulated digital health products
- We have vast experience launching high-risk Class C Software as a Medical Device (SaMD), dosing algorithms, patient support and engagement apps, chronic disease management platforms, connected combination products, diagnostics and more
- Our tested technology is used by patients and providers at leading healthcare systems
- We have experience supporting regulated products across therapy areas including diabetes, respiratory, oncology, ophthalmology, obesity, hematology, immunology, neurology and more
- We completed seven SaMD launches in 2021 alone

Regulatory compliant digital health infrastructure

We handle global regulatory compliance, so you don't have to.

- We support CE-marked and FDA-regulated Class I, II and III medical devices, combination products and Software as a Medical Device (SaMD)
- Our cutting-edge Quality Management System is ISO 13485:2016 and MDSAP (Medical Device Single Audit Program) certified
- BrightInsight Platform Master File has been accepted by the FDA
- Design History File and documentation follows IEC 62304 requirements
- EC Certification allows us to run SaMD modules on the BrightInsight Platform
- The BrightInsight QMS complies with the requirements of the EU MDR
- Compliant with IEC 82304 which establishes best practices for software-only medical device development and software-only product development
- Medical Device Single Audit Program (MDSAP) Certified

> **"After conducting a rigorous evaluation, we selected BrightInsight because it has the only regulated solution with a robust Quality Management System and comprehensive privacy and security certifications. BrightInsight's Platform allows us to focus on therapeutic innovation, rather than the underlying digital technology."**
>
> - Brian Johnson, Director, Digital Health, CSL Behring

BrightInsight: A Partner You Can Trust

BrightInsight provides the leading global platform for biopharma and medtech regulated digital health solutions. We are the launch partner companies trust to accelerate time to market for regulated digital health products including apps, algorithms, medical devices, connected combination products, companion diagnostics and Software as a Medical Device.

We can also serve as the Legal Manufacturer of Record for your digital health products. When building your digital health solutions on the BrightInsight® Platform, you are future-proofing compliance while ensuring scalability across geographies.

Our vision is to transform patient outcomes globally by bringing the power of digital technology to healthcare, and we work every day to achieve this by accelerating regulated digital health innovation for our customers through our scalable medical-grade platform.

Conclusion

There are a number of variables biopharma and medtech companies need to consider when building a digital health platform. At the end of the day, it's important to invest in a solution that can support your evolving needs quickly—such as adding new products or entering new markets—in a regulated environment that meets the requirements of regulatory bodies globally.

Additionally, purchasing an open, managed service platform will delight healthcare providers and patients. Investing in the BrightInsight Platform means that clinicians and patients won't have to deal with another siloed solution, app or system that won't integrate with their other devices and systems.

When building a digital health solution, partner with our best-in-class team and leverage our regulated BrightInsight Platform to maximize your speed to market, minimize your risk and future-proof your platform.