



## The 5 Key Steps to Accelerate Biopharma Digital Health Innovation



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One of the impacts of the COVID-19 pandemic has been a substantial increase in digital investments by healthcare organizations, which have not traditionally been known as cutting edge when it comes to technology.

Now, a digital health strategy has become a “must have” for biopharma organizations that want to remain competitive, to thrive, and to best engage patients and providers. When done right, a digital health strategy can boost efficiency and profitability, and quickly differentiate companies and their therapies in a highly competitive and often crowded market.

A successful digital health strategy requires the cooperative effort of all parties, including Commercial and R&D, who have not historically worked closely on digital efforts.

“Part of the problem is that firewalls between Commercial and R&D have been built over time out of a risk-avoidance posture to avoid regulatory challenges,” says Dan Goldsmith, CEO at Tendo Systems, former CEO, Instructure, and former Chief Strategy Officer, Veeva. “Those firewalls grow roots, and organizations don’t necessarily revisit the ‘why’ behind them. With digital, the barriers that have been established should be revisited.”

“One benefit of establishing close collaboration across R&D and Commercial is building a loop between products being developed and those being used in the real world. “If you align the two, the digital innovations developed by R&D can translate as a huge benefit in the Commercial world,” shares Kal Patel, M.D., CEO & Co-Founder, BrightInsight.

BrightInsight sat down with top executives from many of the world’s leading biopharma and healthcare companies including Takeda, AbbVie, Roche/Genentech, Allergan, Amgen, McKinsey & Company Inc., AstraZeneca and others, to discuss how biopharma Commercial and R&D teams can accelerate digital innovation by working together.

## **The Critical Partnership between Commercial and R&D**

Experts agree there are five key steps to developing strong alignment between Commercial and R&D execs to ensure an organization's success with digital innovation.

### **STEP ONE: Have a strong business case for pursuing digital and define success up front**

The all-important first step is to define what a successful effort looks like so that everyone shares the same vision.

"Get access solutions teams and reimbursement experts involved early to think through, not only the digital ecosystem, but also what the business model that sits behind this should look like," Paul Upham, Head of Smart Devices at Roche/Genentech advised. "Is it going to be a traditional biopharma model, and all these digital tools are given away, or do the digital tools become an enabler of value-based contracts?"

Most importantly, the strategy should be patient-focused and driven by a clear business objective.

"One method for defining success with digital innovation is to figure out the best commercial model first, and then work backwards to determine metrics and mileposts," says Karan Arora, Chief Commercial Digital Officer and Global Vice President, AstraZeneca.

### **STEP TWO: Take an Enterprise-wide Approach**

For digital innovation to take hold, buy-in from the C-Suite is essential, and Commercial and R&D teams must come together in ways they may not be used to. They should take an enterprise approach when it comes to developing digital health products and selecting the supporting platforms and technologies.

"You need to have champions that have influence inside the organization - the people who can influence the culture, the attitude, the ability to get things done," stresses Brent Saunders, Chairman and Co-Founder, Vesper Healthcare Acquisitions Corp, Former Chairman and CEO at Allergan. "There is always natural resistance inside an organization for anything new or different. If I'm the CEO, I'm going to pick somebody who is respected inside the company and someone who's got a track record of getting things done. I don't care what department they come from. That's the person I'm going to ask to really get momentum behind a digital initiative."

Even if some digital projects and associated budgets reside in R&D and some in Commercial, aligning on a common infrastructure that can scale in a compliant way across regions and projects is critical. But you won't have these sorts of discussions unless Commercial and R&D are partnering.

### **STEP THREE: Understand the Impact of Regulatory Requirements**

Once an organization has decided on its strategy and gotten all parties committed to the vision, it must ensure it understands the regulatory complexity surrounding digital health. From the very start – in the development stages – you must build your digital health products on a regulated infrastructure.

Ensuring that your digital health products and their supporting platforms are compliant means a more seamless path to market and commercial launch. If you don't pay attention to this up front, you can experience huge delays.

"Tight collaboration with not only R&D and Commercial, but also medical affairs, government affairs, regulatory, quality and privacy is important, especially as the digital tools become more sophisticated and move up the regulatory maturity curve," notes Upham.

Dosing algorithms, patient engagement apps, connected combination products, and Software as a Medical Device are all examples of regulated digital health products that have a tremendous opportunity to improve patient outcomes and drive efficiencies. We're beyond thinking about digital just as a channel for marketing and are seeing game-changing digital health products being built...which, of course, are regulated.

#### **STEP FOUR: Take a Strategic Approach with IT and Third-party Vendors**

Few biopharma organizations are likely prepared to undertake a digital transformation effort without outside help. The reason is simple: Adopting a digital-first strategy involves rethinking how the organization does things – including practices, processes and even culture. Taking a strategic approach with IT and third-party vendors can significantly accelerate your time to market.

"The pendulum has swung back and forth over the years as to whether life sciences companies want to also build deep software development capabilities. Again and again time has shown that if your company's core DNA is science and therapies, you shouldn't try to be a software company. While biopharma IT groups can support customized technology needs in specific areas, it's not a scalable and sustainable approach," says Goldsmith.

Building, buying and managing systems to support digital health products is a new game for many IT organizations. A big challenge is that many biopharma organizations are finally starting to develop systems and technologies that are not built solely for internal use, but where patients or prescribers are actually using a company's digital health products. IT organizations have not historically had this external-facing mindset.

But that external-facing mandate mindset is critical to getting into the digital innovation space.

This is where partnerships become especially important.

“We've seen many biopharma companies fail at trying to home-grow the best infrastructure, ensure it will scale and be compliant around the extensive and changing requirements for regulatory, privacy, security and so forth. You want to find the best partner for that and focus your internal resources on developing differentiating IP around your digital products,” Patel explains.

#### **STEP FIVE: Measure Success and Celebrate Victories as You Go**

While it is important to get C-suite support before starting any digital innovation effort, it is also important to keep top executives apprised of the organization's progress along the way. Celebrating early and small victories is a great way to maintain their support.

“Celebrate the successes. You can convert more champions when people can experience the benefits of digital and data, and remember that different stakeholders are going to be receptive at different times. How and when you approach the laggards versus the early adopters of digital varies. I recommend starting with the early adopters to build more digital champions internally,” stresses Dimitriy Kolodin, Vice President of Innovation at AbbVie .

As the organization marks each victory in its digital health journey, it can expand its efforts.

Success does not necessarily need to be dramatic improvements in outcomes. Focus on demonstrating success and progress in advancing your biopharma organization's digital capabilities.

You can download BrightInsight's full white paper on this topic for more insights [here](#).

About BrightInsight:

BrightInsight provides the leading global platform for biopharma and medtech regulated digital health solutions. When speed matters, we help companies accelerate time to market for regulated digital health offerings across therapeutic areas, including apps, algorithms, medical devices, connected combination products, diagnostics, and Software as a Medical Device (SaMD). BrightInsight replaces the need for lengthy and complex 'build from scratch' implementations by offering configurable software modules and a proven platform built under a Quality Management System to support global security, privacy, and regulatory requirements. When building digital health products on the BrightInsight Platform, compliance is future-proofed as intended use changes scale across geographies.

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