

# Helping life sciences bring digital health solutions to patients faster with a pre-built healthcare platform

Compliant cloud platforms can help life sciences companies bring digital health solutions to market faster to enable increased patient adherence and engagement.

We are currently living in the age of personalized healthcare, where treatments can be tailored to the individual to maximize therapeutic benefit. As medicine becomes more personalized, it becomes increasingly complex to determine the correct dosing. This is the case for the treatment for Hemophilia A, a rare disorder that affects only 400,000 people worldwide. [Roche](#), the largest biotech company in the world, decided to leverage the power of digital technology to provide a simple and convenient solution for physicians who treat patients with Hemophilia A.

Because it lacks sufficient proteins, the blood of a person with Hemophilia A doesn't clot normally. Efficzumab, sold under the brand name [Hemlibra](#)<sup>®</sup>, brings the right proteins together to restore natural coagulation. Activating the blood clotting process isn't as simple as swallowing a pill, however. Hemlibra requires a subcutaneous injection that doctors must tailor to each individual using complex weight-based calculations.

## About Roche

A pioneer in healthcare, [Roche](#) creates innovative medicines and diagnostic tests that improve the lives of millions of patients globally. With their combined strength in pharmaceuticals and diagnostics, they strive to deliver personalized healthcare through better-targeted therapies.

## About BrightInsight

[BrightInsight](#) provides software and services that take the hard work out of building, scaling and maintaining digital health offerings. As Google Cloud's "2018 and 2019 Healthcare and Life Sciences Partner of the Year," BrightInsight helps biopharma and medtech companies accelerate regulated digital health innovation through their industry-leading Internet of Things (IoT) platform.



To maximize Hemlibra’s therapeutic benefits, Roche decided to develop a digital dosage calculator to aid prescribing physicians. But given the novelty of digital health solutions, navigating the regulatory landscape would be a challenge. Would the solution be regulated as a medical device? If so, should the relevant registration strategy be 510(k), CE marking, de novo, or something else? The platform for this kind of solution must meet requirements for a multitude of global standards, regulations, and certifications with monikers like IEC 62304, ISO 13485, ISO 27001, GDPR, HIPAA, and HITRUST.

**Why build something that’s already built for us?**

For Roche, the path forward was clear. “Our ability to provide a sustainable competitive advantage with our products won’t be based on developing our own cloud-based solutions—that’s not our expertise,” says Paul Upham, Head of Smart Devices at Roche / Genentech. Rather than engineer their own infrastructure, applications, and data stores, they partnered with BrightInsight.

“Prior to BrightInsight, biopharma and medtech had no other alternative but to build their own underlying platform,” explains Paul Schultz, Senior Director of Commercial Development at BrightInsight. “They found this a significantly expensive thing to do. Building that custom-bespoke solution barely meets the requirements for one solution in one country and doesn’t scale—not to mention [it takes] an army of engineers and several years to build that infrastructure.”

Hosted on Google Cloud, the BrightInsight Platform supports up to Class III medical devices and combination products. Schultz likens it to plumbing that large cap biopharma and medtech customers can build digital health solutions on top of. “We then take on the accountability of the data from a privacy, security, and regulatory perspective,” he says.



Paul Upham,  
Head of Smart  
Devices, Roche /  
Genentech

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Paul Schultz,  
Senior Director  
of Commercial  
Development,  
BrightInsight

“You can think of BrightInsight as the compliant platform through which our large cap biopharma and medtech customers can build their digital health solutions.”

### Reducing the regulatory burden for innovators

Companies like Roche are only too happy to transfer the onus of managing highly-regulated medical device data and personal health information to BrightInsight, which submits design documentation and obtains the necessary certifications for their platform so their customers don't have to. They also maintain a Device Master File (MAF) with the FDA for marketing approval in the US—something that can help life sciences companies get treatments hosted on the BrightInsight Platform to market much, much faster.

Leaving BrightInsight to manage regulatory approvals for its platform, Roche focused on designing the Hemlibra Dose Calculator for physicians treating patients afflicted with Hemophilia A. Because the architecture of the BrightInsight Platform is modular, Roche was able to customize their solution very rapidly for a complex use case that combines patient data with data from other sources. Developing and launching the solution as a CE-marked Software as a Medical Device (SaMD) took only five months.

As an added benefit, Roche only needs to participate in regulatory conversations if they make product changes or encounter issues they have to report. BrightInsight's fully managed service, which tracks privacy and regulatory changes on their behalf, handles the rest.



### Now streaming: digital health data to shape future discoveries

With the proliferation of Internet of Things (IoT) for healthcare, biopharma and medtech companies have a tantalizing opportunity to capture and analyze streamed data that can shape new development and demonstrate the efficacy and value of the treatments they put so much into. “Where we can generate new competitive advantages is in how we analyze and use the new data being generated by all of these digital health solutions,” says Upham.

Schultz agrees, and adds that “being able to capitalize on the insights from that data in a compliant way that adheres to global regulatory privacy and security is a very overwhelming and challenging task.” The BrightInsight Platform can ingest data from multiple devices and digital health solutions, integrate it with data from downstream health IT systems such as electronic health records or disease management programs, and analyze everything using machine learning and artificial intelligence algorithms. Insights gained will inform drug discovery and help create tools that improve the experience for patients and the efficacy of their treatments.

For companies like Roche, continued success depends on disruptive opportunities like connected combination products, Software as a Medical Device, and digital therapeutics. “We definitely learned so much from our work with the BrightInsight team,” says Upham. “I’ve been surprised by the significant interest and engagement from Roche’s country affiliates who are recognizing the value these digital health solutions can bring to each of their markets. It has really set the stage well for future projects.”



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