BrightInsight

The leading global platform for biopharma regulated digital health solutions.

Digital health is a significant opportunity for biopharma

SITUATION

Across therapeutic categories, clinical competition continues to increase, driving the need to innovate beyond the pill through digital

CHALLENGE

Developing digital health products is completely different than traditional drug or combination product development, making it challenging for biopharma to successfully build and launch differentiated digital offerings

OPPORTUNITY

Digital health has the opportunity to transform the entire patient journey – from diagnosis, to patient selection, to adherence, to disease management, to dose management

RECOMMENDATION

Focus on core therapy innovation and take a partner-first approach to developing, launching and maintaining digital health products

BrightInsight can support your high-value regulated digital health use cases

From accelerating clinical development to digital health commercial products that differentiate your therapies – digital is playing a pivotal role in biopharma across therapeutic areas.

BRIGHTINSIGHT USE CASES

PATIENT DIAGNOSIS

Leverage powerful algorithms to diagnose patients more quickly and accurately when early intervention matters

PATIENT SELECTION

Give providers the tools they need to quickly and accurately match individual patients with the right therapies

DOSE MANAGEMENT

Ensure optimal drug dosing and titration while increasing adherence, through early detection of missed doses or over-dosing to enable early provider intervention

PATIENT ADHERENCE

Unlock better patient adherence with innovative digital drug companion apps and Software as a Medical Device

DISEASE MANAGEMENT

Improve patient outcomes while driving care delivery efficiency for patients with chronic conditions

Each one of these use cases requires a trusted and compliant cloud infrastructure.

Key Challenges Exist to Build and Maintain Regulated Digital Health Offerings

REGULATED SOFTWARE DEVELOPMENT CHALLENGES

- In-house software builds can take years, and developing regulated software in an agile manner is a unique skill that biopharma co's do not have experience in

Read more on this »

REGULATORY COMPLEXITY

- Creating a robust Quality Management System is resource-intensive, with added complexity as regulations are increasing and vary by region.

Read more on this »

PRIVACY & SECURITY RISK

- With cyber-security threats on the rise and evolving and increasing privacy requirements, regulated digital health products must be built from the ground up with privacy and security robustness.

Read more on this »

MAINTENANCE & SCALABILITY

- Maintaining a digital health software product is incredibly complex – from geographic expansion to integrating into the broader healthcare ecosystem.

Listen to our webinar with Roche on this »

Source: https://healthitsecurity.com/news/over-41.4m-patient-records-breached-in-2019-as-hacking-jumped-49

Building an in-house digital infrastructure to support your regulated digital health products is a competitive disadvantage for biopharma companies. To drive speed to market and enable your teams to focus on clinical innovation and specific digital health IP that is core to your business, we recommend taking a partner-first approach for your digital health platform.

Hear from top biopharma CIOs about this »

BrightInsight takes the hard work out of building, scaling, and maintaining your regulated digital health offerings

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

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

When building your digital health solutions on the BrightInsight® Platform, you are future-proofing compliance while ensuring scalability across geographies.

We accelerate your time to market while lowering costs.

- Pre-built functionality that covers 60-80% of initial requirements to accelerate time to market by 6 – 24 months
- Electronic Health Record (EHR) integrations into 500+ U.S. provider networks
- Integrations with 400+ medical devices across 50 manufacturers
- Available in 48 countries around the globe with additional countries planned
- Device-agnostic solution to easily support any type of product and use case
- Microservices architecture providing advanced security, scalability, and customization options

✓ Took AstraZeneca from project kick off to commercialization in less than a year for its AMAZE Disease Management Platform

✓ Launched Roche's Software as a Medical Device (SaMD) Dosing Calculator for hemophilia A in less than 6 months

A proven platform and team to bring you peace of mind.

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

- Experts at building and maintaining biopharma regulated digital health products, with multiple commercial launches in the last year alone
- 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, and more
- Tested technology used by patients and providers at leading healthcare systems
- Experience supporting regulated products across therapy areas including diabetes, respiratory, oncology, ophthalmology, obesity, hematology, immunology, neurology, and more
- Streamlined implementation and training for your team
- Platform performance monitoring
- Level II and III support for the BrightInsight Platform

"The BrightInsight team proactively identifies and takes transparent action to potential risks. In one instance, BrightInsight implemented a critical operating system patch within 48 hours to mitigate CSL Behring's risk and eliminate downtime for our patients."

Brian Johnson, Senior Director, Customer Engagement Management at CSL Behring

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

To be prepared for the future, you need a regulatory strategy for your digital health products now. Most medical Device Data Systems (MDDS) do not offer a sustainable regulatory infrastructure to support digital health solutions as they mature to regulated offerings. BrightInsight is more than just MDDS and supports up to Class III medical devices.

- Quality Management System is ISO 13485:2016 certified
- Global regulatory monitoring to ensure compliance across regions
- 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
- One-of-a-kind cloud change control process with Google Cloud
- Medical Device Single Audit Program (MDSAP) Certified
- French HDS ("Hébergeur de Données de Santé")

Read our white paper on how to future-proof your regulatory strategy »

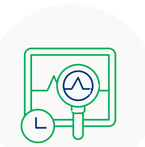
> "If you leverage a solution like BrightInsight that meets the most stringent requirements and maintains compliance… you don't have to worry about your regulated digital solutions in the U.S. versus Europe versus U.K. and so on. You just know they're compliant."
>
> Paul Upham, Head of Smart Devices at Roche/Genentech

Our unwavering commitment to security and privacy minimizes your risk.

- Novel and turnkey privacy infrastructure to safely store PII data in a compliant way globally
- Global privacy and security monitoring to ensure our compliance across regions
- HITRUST CSF® v9.3 Certified
- Monitored security and prevention
- HIPAA and GDPR compliant
- ISO/IEC 27001:2013 Certified

See our full list of certifications here »

We provide analytics dashboards to optimize your digital health products.



We provide the analytics you need to optimize your digital health products.

- Out-of-the-box dashboards with actionable insights into user behavior, Digital health program 'stickiness' reporting, App funnel metrics
- Custom report creation leveraging a range of healthcare and other data sources to support evidence generation and market access negotiation

A trusted partner and proven platform you can count on

Based in Silicon Valley with teams all over the globe, BrightInsight is backed by leading healthcare and technology VCs. Our leadership team brings over 100 years of combined digital health experience in the biopharma and medtech industries.

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 compliant platform.

We are the launch partner and underlying platform for the world's leading biopharma companies. Our clients trust BrightInsight to accelerate time to market for their regulated digital health products including apps, algorithms, medical devices, connected combination products, companion diagnostics, and Software as a Medical Device.

AstraZeneca

" We selected BrightInsight because its pre-built, compliant platform accelerates our time to market while allowing us to focus on digital health innovation and leveraging our clinical know-how to improve patient outcomes instead of the underlying infrastructure."

Karan Arora, Chief Commercial Digital Officer and Global Vice President, AstraZeneca.

LEARN MORE

CSL Behring

" After conducting a rigorous evaluation, we selected BrightInsight because it has the only regulated solution with a robust Quality Management System and a comprehensive list of 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

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novo nordisk®

" Medical-grade digital health platforms like BrightInsight are key to helping us improve the conversation between people with diabetes and their caregivers."

Anders Dyhr Toft, Corporate Vice President, Commercial Innovation, Novo Nordisk

LEARN MORE

Roche

" 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

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Want to learn more?

Visit our Digital Health Knowledge Center to access our latest white papers, webinars, and more. »

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