BrightInsight

The leading global platform for biopharma and medtech regulated digital health solutions, including SaMD, apps, and connected devices.

https://brightinsight.com/

Overview

BrightInsight provides the leading global regulated digital health platform for biopharma and medtech companies, enabling them to build, launch, and scale regulated digital health solutions, such as companion apps, algorithms, connected combination products, and Software as a Medical Device (SaMD).

Built under a robust Quality Management System (QMS) and deployed as a managed service, the platform accelerates time to market by offering pre-built capabilities that cover 60-80% of core digital health requirements, allowing biopharma and medtech companies to launch solutions in as little as six months.

Key Features and Capabilities

The platform is medical-grade, device-agnostic, and built on a microservices-based architecture for automated scalability. It is designed to capture, transmit, and analyze data from CE-marked and FDA-regulated medical devices and software, ensuring compliance with global security, privacy, and regulatory requirements.

Core features include:

Data Management & Analytics: Real-time analytics dashboards providing actionable insights for clinical, operations, and patient engagement.
Interoperability: Extensive Electronic Health Record (EHR) integrations connecting over 1,700 healthcare organizations and 3,000+ applications, including major vendors like Epic and Cerner.
Patient & Provider Tools: Robust user onboarding, account management (including Single Sign-On, SSO), medication management, electronic patient-reported outcomes (ePRO), care plans, secure messaging, and physician alerts.

Device Connectivity: Device-agnostic approach with over 400 medical device integrations.
Regulatory Support: Can serve as the Legal Manufacturer of Record and maintains all necessary documentation for global regulatory compliance, including FDA Device Master File acceptance.

Target Users and Use Cases

The primary target market is **Enterprise Biopharma and Medtech** companies. Use cases include developing SaMD, connected combination products, drug companion apps, remote patient monitoring (RPM), and digital solutions for clinical trials.

Key Features

- Regulated Digital Health Platform (SaMD, Apps, Devices)
- Global Regulatory Compliance (FDA, CE-marked, MDSAP)
- Real-Time Analytics Dashboards (Clinical, Operations, Patient Engagement)
- EHR Interoperability (Epic, Cerner, etc.)
- Device-Agnostic Connectivity (400+ device integrations)
- Patient Management Tools (ePRO, medication management, care plans)
- Single Sign-On (SSO) and Account Management
- Accelerates Time to Market (Pre-built modules)

Pricing

Model: enterprise

Pricing is not publicly disclosed. It operates on a licensing model, typically structured as a long-term subscription or milestones-based agreement for enterprise biopharma and medtech customers. Contact the vendor for a tailored quote.

Target Company Size: enterprise

Integrations

Epic, Cerner, MEDITECH, AllScripts, athenahealth, AdvancedMD, Rhapsody (Interoperability Partner), 400+ Medical Devices

Compliance & Certifications

HIPAA, GDPR, ISO 13485:2016, ISO/IEC 27001, HITRUST CSF, MDSAP, HDS (Hébergeur de Données de Santé), IEC 62304, IEC 82304-1, FDA Device Master File Acceptance