



**BrightInsight, Inc.**  
A trusted healthcare  
technology leader.

BrightInsight, a Flex Company, provides the leading global regulated digital health platform for biopharma and medtech. Our medical-grade Internet of Things (IoT) platform is built under a Quality Management System to support and optimize regulated drugs, devices and software through integrated data and actionable insights to enable customers to drive increased patient adherence and engagement.

Our mission is to make digital health innovation easy for our customers through our end-to-end digital health capabilities and scalable, medical-grade platform. Together, our leadership team brings over 85 years of combined digital health experience in the biopharma and medtech industries.

Our parent company, Flex, helps their customers transform ideas into intelligent products for a connected world. With approximately 200,000 employees in thirty countries, Flex provides innovative design, engineering, manufacturing, supply chain insights, and logistics services to a global customer base across every major industry, including healthcare.

For over 30 years Flex has worked with leading healthcare companies deploying over 100 regulated hardware and software medical products worldwide. Flex Health Solutions is audited an average of 15 times per month, or roughly every other day by its healthcare customers.

## BrightInsight™ Platform

### A managed service IoT platform to minimize customer risk

The BrightInsight™ Platform uses software and services 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 security, privacy and regulatory requirements.

Deployed as a managed service, the platform accelerates the time to market for biopharma and medtech companies, reduces the cost of implementation and maintenance versus a custom solution, and scales across products and global markets.

Built from the ground up to address the needs of biopharma and medtech companies, the BrightInsight Platform securely manages highly regulated medical device data and personal health information.



#### Compliance and Audits

Our products regularly undergo independent verification of **quality**, **security** and **privacy** controls and achieving and maintaining certifications to meet our customer's requirements.



#### Quality

BrightInsight, Inc. is ISO13485:2016 certified, demonstrating that we operate a cutting-edge quality management system for software development services. With experience launching digital health products for biopharma and medtech companies, the BrightInsight team is adept at navigating complex and evolving regulatory environments on a global scale. In the US, the BrightInsight Platform Device Master File has been accepted by the FDA, reducing the regulatory burden for our customers by directing any FDA questions related to the BrightInsight digital health platform to the BrightInsight team, not our customers.

As a result, our regulatory managed service helps relieve the regulatory headaches that digital therapeutics carry with them related to the software system.

In addition to scheduled audits and inspections by certification providers or regulatory bodies, we regularly respond to audits by our biopharma and medtech customers in these key areas:

- ▶ Management Responsibility, such as training and resource allocation
- ▶ Feedback and Complaint Management, such as support escalation and corrective action
- ▶ Design Controls, such as management of risk or software verification and validation testing



## Security

The BrightInsight Platform is built from the ground up to securely manage and protect highly regulated medical device data and personal health information. The Platform applies the Security-by-Design principle and Defense-in-Depth best practices and built the entire BrightInsight software stack with security in mind for the whole software development lifecycle. Furthermore, the Platform security framework leverages established global security standards and frameworks (such as ISO27001, NIST 800, HITRUST CSF) including over 350 technical and operational security controls to safeguard customer data.

Our managed service for data privacy includes privacy policies and procedures, implementation of automated processes to decouple sensitive personal information from other health data, operational procedures for protecting Personal Health Information (PHI) and monthly employee trainings to safeguard customer's information. BrightInsight is compliant with HIPAA Privacy Rules, is implementing GDPR-compliance, and is pursuing HITRUST certification.

We regularly respond to audits by our pharmaceutical and medtech customers in these key areas:

- ▶ Security Certifications, such as HITRUST
- ▶ HIPAA Compliance
- ▶ Cloud Security Strategy
- ▶ Incident Response
- ▶ Risk Assessment and Impact Analysis

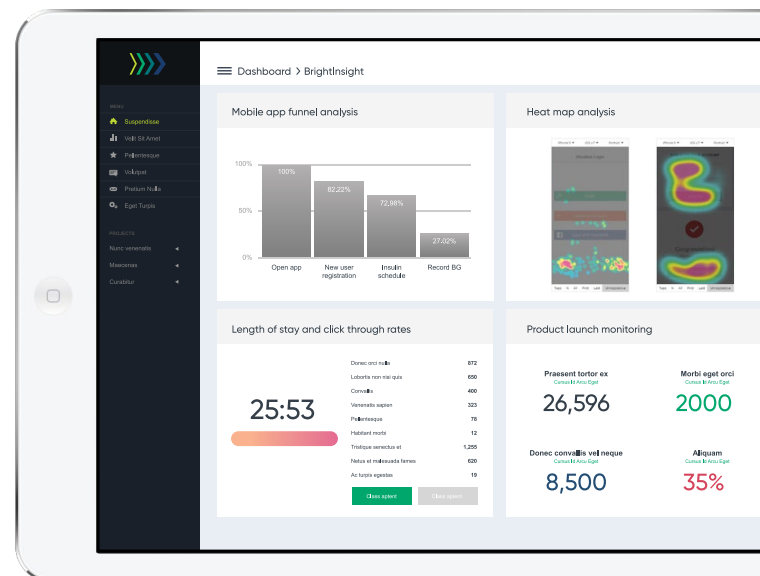


## Privacy

Our **managed service for data privacy includes** privacy policies and procedures, implementation of automated processes to decouple sensitive personal information from other health data, operational procedures for protecting Personal Health Information (PHI), and monthly employee trainings to safeguard customer's information. The **BrightInsight Platform is HIPAA-compliant to the HIPAA Privacy Rules and is pursuing GDPR-compliance.**

We regularly respond to audits by our biopharma and medtech customers in these key areas:

- ▶ Privacy Certifications, such as EU/US Privacy Shield
- ▶ HIPAA and GDPR Compliance
- ▶ Individual Rights, such as Right to be Forgotten
- ▶ Breach Notification Management
- ▶ Risk and Data Protection Impact Assessments



To learn more about BrightInsight  
and our managed service platform  
contact us at [contact@brightinsight.com](mailto:contact@brightinsight.com)  
or visit [BrightInsight.com](http://BrightInsight.com).