



# BrightInsight Overview

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BrightInsight

# Provider of the leading global regulated digital health platform for biopharma and medtech.

Spun out of Flex with venture backing from top healthcare and technology investors

100 years of combined experience in digital health within biopharma & medtech

HQ in Silicon Valley with corporate presence in NJ, UK, Switzerland and Copenhagen



Platform available in US & EU (regulated)  
Available 11 additional countries (privacy)

Customers include global biopharma and medtech

Awards and recognitions as the leading regulated IoT platform for life sciences



# Our Vision & Mission.

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## Vision

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To **transform patient outcomes globally** by bringing the power of digital technology to healthcare



## Mission

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To **accelerate regulated digital health innovation** for our biopharma and medtech customers through our scalable medical-grade platform

# Biopharma & medtech companies can reap rewards today by leveraging the power of digital.



## > Enhance clinical trials.

McKinsey estimates that big data can help generate \$100 billion in value across the US healthcare system by accelerating clinical trials and optimizing R&D activities.<sup>1</sup>



## > Improve adherence.

Improving adherence not only saves lives, it's a revenue windfall for pharma companies. Just a 10% adherence improvement could generate an extra \$124 billion in annual revenues.<sup>2</sup>



## > Putting real-world data to work.

There is escalating pressure surrounding pricing transparency and reimbursement for therapies costing upwards of \$100K. Real-world data can demonstrate improved outcomes and adherence.

1. <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-big-data-can-revolutionize-pharmaceutical-r-and-d>  
2. [https://www.capgemini.com/wp-content/uploads/2017/07/Estimated\\_Annual\\_Pharmaceutical\\_Revenue\\_Loss\\_Due\\_to\\_Medication\\_Non-Adherence.pdf](https://www.capgemini.com/wp-content/uploads/2017/07/Estimated_Annual_Pharmaceutical_Revenue_Loss_Due_to_Medication_Non-Adherence.pdf)



# Prior to BrightInsight, biopharma and medtech had no alternative but to build their own underlying platform.



## Expensive to build.

It can cost up to \$20M to build and \$10M/year to maintain a custom bespoke platform that barely meets requirements for one product and one country.



## Challenging to maintain & scale.

It can take up to 2+ years to build and 10+ engineers to build a custom, bespoke siloed platform that does not integrate into the broader digital health ecosystem.



## Complex regulatory, privacy & security compliance.

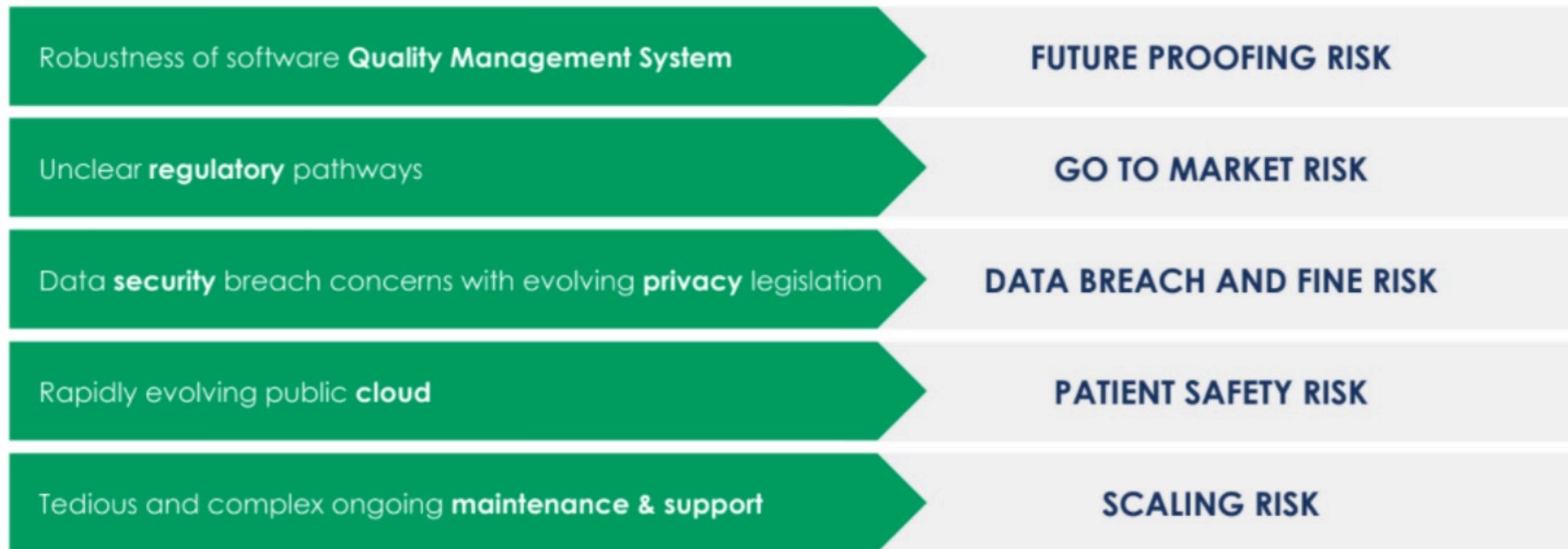
Building a robust Quality Management System is resource-intensive with the added complexity of evolving privacy, security and quality regulations



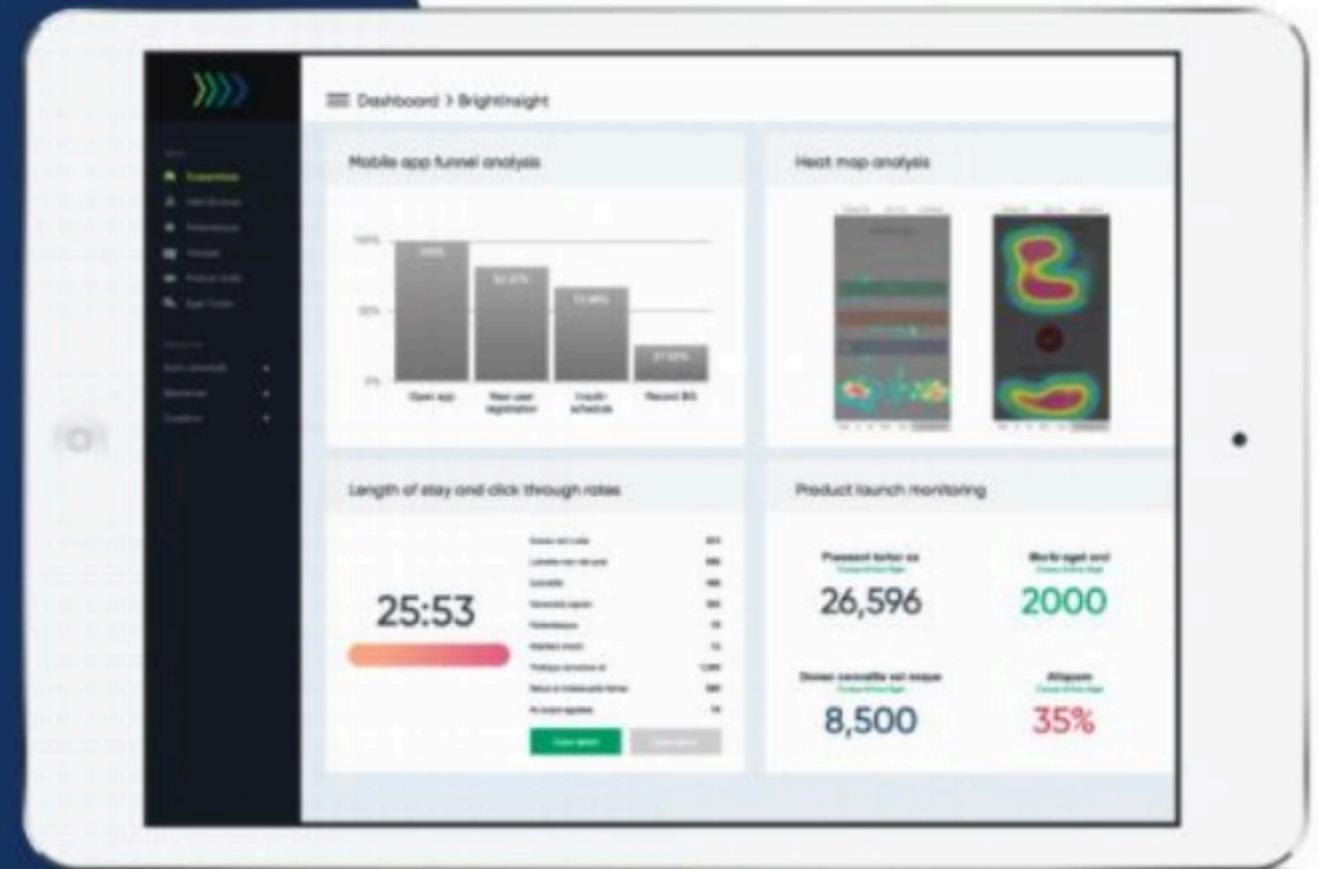
## Not a competitive advantage.

It is not a competitive advantage for biopharma and medtech companies to build the underlying infrastructure. You should focus your team on specific digital health IP that is core to your business and partner for everything else to drive speed to market.

But, building and maintaining a regulated digital health platform is resource intensive and increases risk.



BrightInsight is the leading regulated digital health platform for biopharma and medtech.



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



# Five factors make BrightInsight an obvious and easy choice.

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**Robust QMS that future  
proves your digital journey**

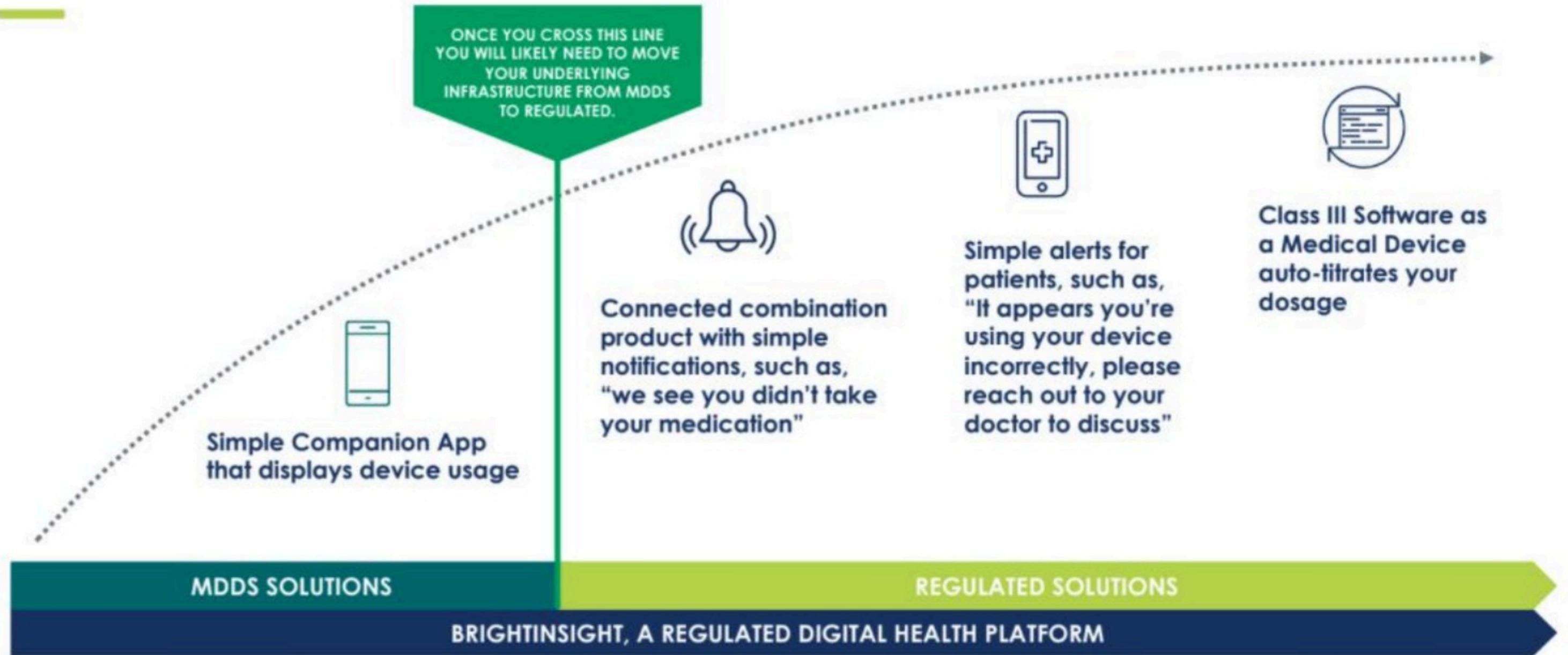
**Comprehensive  
functionality that speeds  
time to market**

**Robust privacy and security  
compliance you can trust**

**Managed service model  
reduces your risk**

**Unrivalled pedigree  
and partnerships**

# Our robust QMS can support the highest level of risk for intended use of data.



# Our pre-built functionality accelerates time to market.



**APIs**



**Customer  
dashboards**



**Starter  
software assets**



**Modular and  
scalable platform  
architecture**



**Electronic Health  
Record (EHR)  
integration**

With our unwavering commitment to security and privacy, you can minimize your risk.

**CERTIFICATIONS**



**ISO 13485:2016  
Certified Quality  
Management System**



**Software development  
lifecycle process  
conforms to ISO/IEC  
62304**



**HDS (Hébergeur de  
Données de Santé)  
French certification for  
data privacy & security**



**HITRUST CSF® v9.1  
Certification**



**GDPR compliant**



**HIPAA compliant**



**HITRUST Certification of  
the NIST Cybersecurity  
Framework**



**ISO/IEC 27001:2013  
certified**



**Certified under both the  
EU-U.S. & Swiss-U.S. Privacy  
Shield frameworks**

# Our managed service model means less stress and ensures global regulatory compliance.



## Global regulatory compliance

- ISO 13485:2016
- ISO/IEC 62304
- Master File with the FDA
- EC Certification allowing us to run SaMD modules on the BrightInsight Platform



## Cloud change control

- One-of-a-kind change control process with Google Cloud to ensure ongoing compliance



## Global privacy & security monitoring

- Data localization, policy and procedure maintenance



## Platform Performance

- Platform performance monitoring
- Level II and III support for the BrightInsight Platform

# Our strategic partnership with Google Cloud is highly differentiated.



## Compliant cloud change control

Our partnership with Google Cloud allows BrightInsight to offer a highly differentiated solution in the market with the first and only compliant cloud change control



## Defense-in-depth security by design

The only public cloud provider that offers defense in depth security for data at rest and in transit by default



## Industry leading focus on life sciences

Given the highly regulated nature of the industry, Google Cloud has developed industry specific tools that are integrated into BrightInsight such as the Healthcare API

# BrightInsight can support a myriad of use cases across therapeutic areas.

## Example Use Cases

Dose Management Algorithms



Connected Insulin Pens



Connected Eye Droppers



Connected Thermometers



Dose Calculators



Connected Inhalers



Implantable Neuromodulation Pain Relieving Device



Connected Alarms

