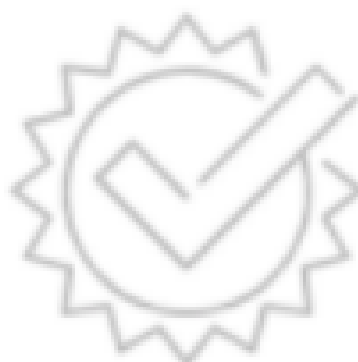# BrightInsight Overview

June 2020

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

AstraZeneca   CSL Behring

novo nordisk   Roche

Google Partner of the Year Healthcare & Life Sciences in 2018 and 2019

Medtech Breakthrough Best IoT Platform, Healthcare

Top-20 Most Promising Biotech Solution Providers

Global Digital Health 100

BrightInsight

2

Our Vision & Mission.

Vision

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

Mission

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

BrightInsight

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.[1]

> ## 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.[2]

> ## 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

BrightInsight

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.

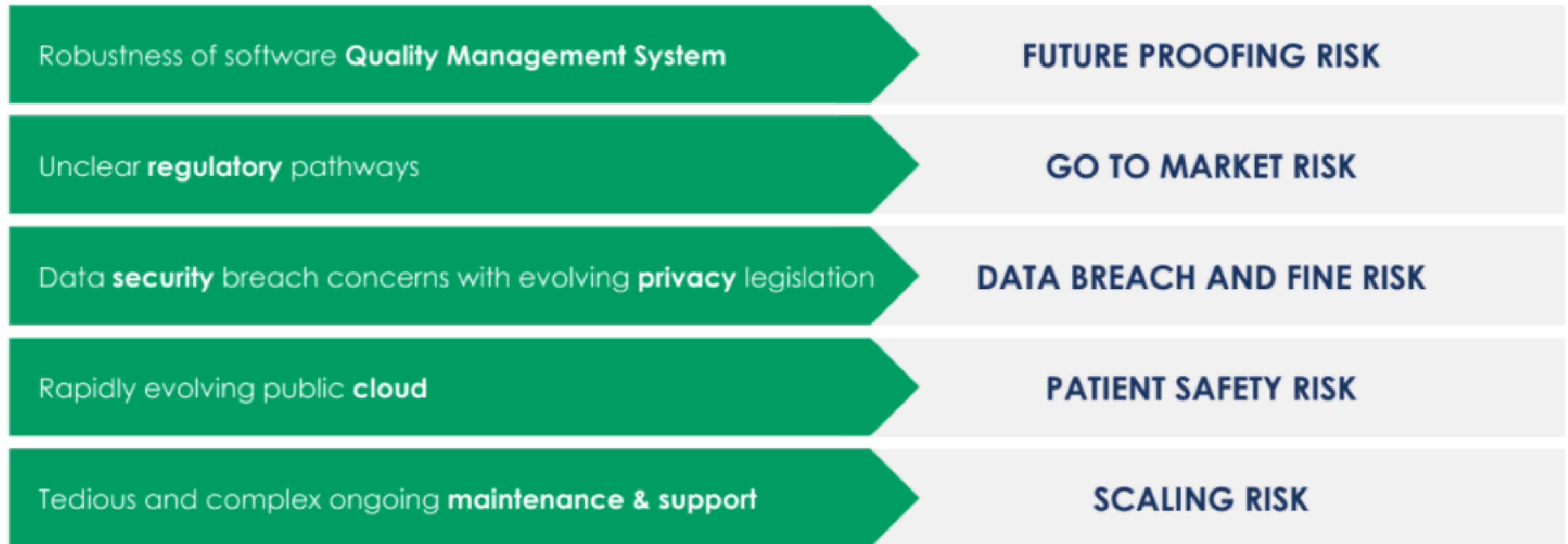## Complex regulatory, privacy & security compliance.

Building a robust Quality Management System is resource-intensive with the added complexity of evolving privacy, security and quality regulations
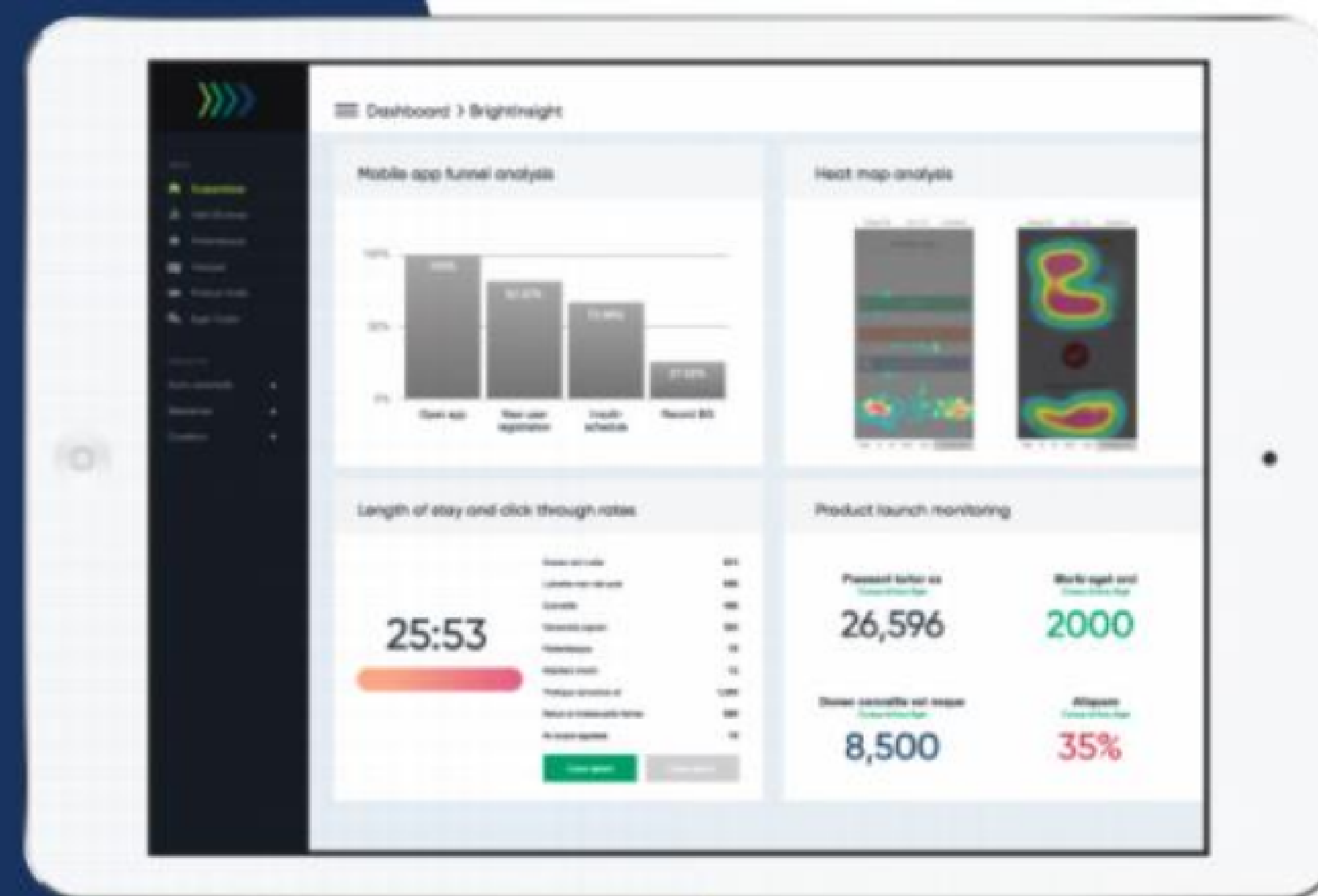
Not a competitive advantage.

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.

BrightInsight

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

Robustness of software **Quality Management System**	**FUTURE PROOFING RISK**
Unclear **regulatory** pathways	**GO TO MARKET RISK**
Data **security** breach concerns with evolving **privacy** legislation	**DATA BREACH AND FINE RISK**
Rapidly evolving public **cloud**	**PATIENT SAFETY RISK**
Tedious and complex ongoing **maintenance & support**	**SCALING RISK**

BrightInsight

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

BrightInsight

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

Connectivity

BrightInsight offers connectivity and management for regulated apps, algorithms, devices or combination products.

Data management

BrightInsight can aggregate data from multiple sources and can integrate with EHRs and other IT systems

Analytics & insights

Clinical, operation and patient engagement dashboards provide valuable insights in real-time.

Privacy Security Regulatory Quality Management System is ISO 13485:2016 Certified

BrightInsight

Five factors make BrightInsight an obvious and easy choice.

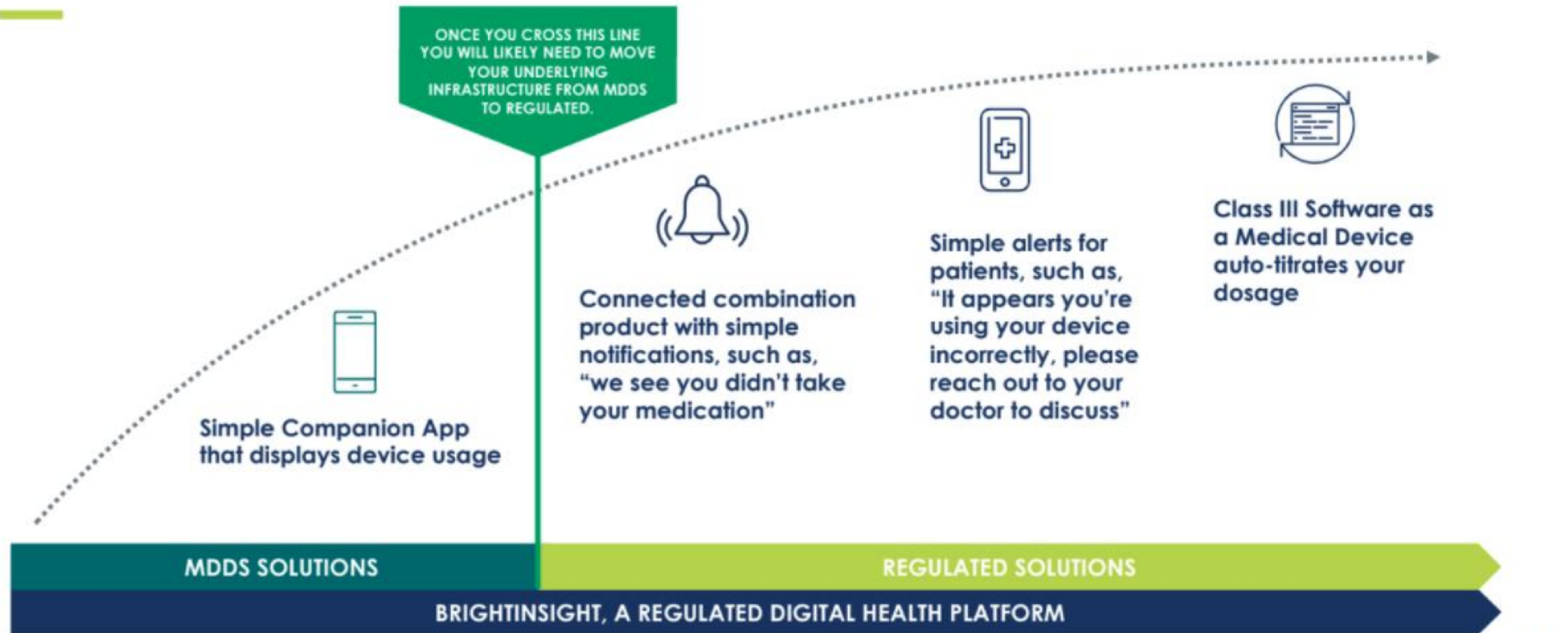**Robust QMS that future proofs your digital journey**

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

BrightInsight

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

ONCE YOU CROSS THIS LINE YOU WILL LIKELY NEED TO MOVE YOUR UNDERLYING INFRASTRUCTURE FROM MDDS TO REGULATED.

Simple Companion App that displays device usage

Connected combination product with simple notifications, such as, "we see you didn't take your medication"

Simple alerts for patients, such as, "It appears you're using your device incorrectly, please reach out to your doctor to discuss"

Class III Software as a Medical Device auto-titrates your dosage

MDDS SOLUTIONS

REGULATED SOLUTIONS

BRIGHTINSIGHT, A REGULATED DIGITAL HEALTH PLATFORM

BrightInsight

Our pre-built functionality accelerates time to market.

APIs

Customer dashboards

Starter software assets

Modular and scalable platform architecture

Electronic Health Record (EHR) integration

BrightInsight

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

BrightInsight

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

BrightInsight

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

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

BrightInsight

Digital health partnership to improve diabetes care.

"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

Data capture from connected insulin pens

Data integration from third-party blood glucose meters

Insights to improve adherence

BrightInsight

BrightInsight launched a CE-marked Dosing Calculator for Roche.

CE-marked Dosing Calculator (Software as a Medical Device)

Health Care Professionals input patient biometrics to determine the correct loading and maintenance dosage that should be administered based on approved dosing recommendations

Global digital health partnership to improve chronic disease management.

AstraZeneca

"We quickly dismissed the concept of building our own custom platform so we could focus instead on developing transformational digital health solutions...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

Data capture from apps, algorithms, Software as a Medical Device and connected devices

Data aggregated and integrated into EHRs to enable a population-level, aggregated view for care teams or providers

Insights to improve adherence

BrightInsight

Global partnership to improve improve treatment experience for patients with rare diseases.

CSL Behring

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

Data capture from digital health devices, apps, algorithms and Software as a Medical Device (SaMD)

Data aggregation across CSL Behring therapies on one common infrastructure

Insights to enhance treatment experience for patients with rare and serious diseases

BrightInsight

10 questions biopharma execs should ask their team before considering building their own platform.

1. How are we going to manage the **endless regulatory updates** and submissions required to maintain compliance?

2. How can the platform **scale as we launch our product(s) in new markets**? Is it easy to stand up new platform instances in different countries?

3. How will we **maintain security and privacy compliance** in every region we move into, when laws vary country by country and are constantly evolving?

4. Can the platform **integrate with the Electronic Health Records** used by the prescribing health care professional?

5. Is the **platform integrated into clinician's prescribing workflow** within their EHR?

6. Does the platform have **decision support dashboards** with relevant insights for clinicians, patients, payers, and our clinical and commercial teams?

7. What is the **analytics strategy** and technology for the platform so we can make sense of the data?

8. Will hospital and physician group CIOs be able to **integrate multiple therapies** from multiple diagnostic and therapy solutions?

9. Will the platform **operating costs** scale down with volume?

10. Do we have the **internal technical team** with the skills to support a global platform infrastructure?

BrightInsight

Our world-class leadership team has 100+ years of combined digital health experience.

Kal Patel, MD
CEO & Co-Founder

Ferry Tamtoro
CTO & Co-Founder

Ben Lee
Data Architecture
& Analytics & Co-Founder

Dave Matthews
Chief Commercial
Officer

Swati Reichmuth
Operations

Mark Tarby
Regulatory & Quality
Management System

Jamie Burgess
Marketing

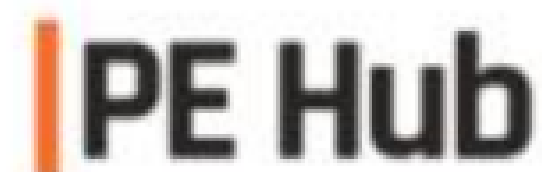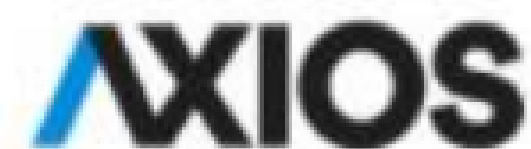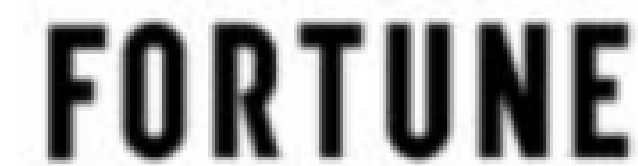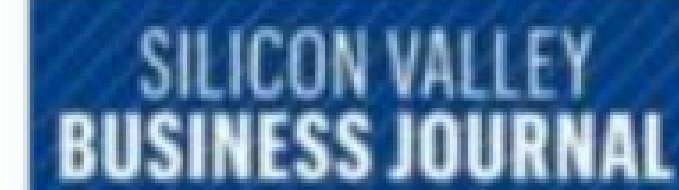**Bob Michitarian**
Chief Legal Officer

Marcelo Duhalde
Lead - Digital Health
Europe

Mia Naik
CPA, Finance

BrightInsight

Global coverage recognizing BrightInsight as the leading regulated digital health platform.

BrightInsight was selected as Google Cloud' Technology Partner of the Year for Healthcare for the past two years.

2018

GLOBAL

Partner of the Year

Google Cloud

Google Cloud

TECHNOLOGY

Partner of the Year

Industry: Healthcare

2019

BrightInsight

Capitalization History

Total of $65M raised

Latest Series B financing of $40M
June 2020

THANK YOU

JAMIE BURGESS (VP, MARKETING) // JAMIE BURGESS@

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