## TECHNOLOGY SHOWCASE: FLEX DIGITAL HEALTH PLATFORM

# flex®

### CONVERTING DATA INTO INSIGHTS

Today's technologies are driving a proliferation of connected smart medical devices that are transmitting a wealth of data. This is driving significant disruption to the delivery of healthcare and introducing the need to harness new data sources, turn data into insights, and use these insights to drive patient, provider and care-giver behaviour change. For pharma, this translates into more direct patient engagement and, therefore, improved drug adherence.

> "Generating raw data isn't enough. Pharma and med tech companies must apply the analytics to derive valuable insights from multiple sources of data, applying data science and machine learning to derive more accurate insights, and they must do so at scale."

Over the last few years, leading healthcare companies have been enabling real-time data transfer via smart devices, effectively creating a closed-loop ecosystem that solves the problem of data-gathering in remote settings. However, generating raw data isn't enough. To create value at scale, healthcare companies must leverage analytics in conjunction with these newly created sources of data to identify valuable insights for their patient populations. This evolution requires a differentiated deployment approach in conjunction with integrated digital health solutions.

The speed of development timelines, economics involved and likelihood of success for pharma and med-tech companies are better when leveraging a technology partner that offers a solution that is scaled to support multiple customers, as opposed to a closed system. More importantly, this solution needs to meet and exceed the regulatory, privacy and security requirements that pharma and med tech companies need to adhere to in the US and across the globe.

### THE FLEX DIGITAL HEALTH PLATFORM

The *Sketch-to-Scale™* solutions provider, Flex, leverages investments and its expertise developing connected devices to empower and enable its medical partners in this new connected world. Flex recognises the substantial investment device and pharma companies are being faced with in terms of development and ongoing management costs to support a regulated software-stack, but also an opportunity to harness data from multiple sources to improve patient insight and thereby the patient experience.

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"The Flex Digital Health group is building the world's first medical regulated, HIPAA-compliant, open architecture platform of connected medical devices, tied to a complementary, cloud-based software stack for commercialisation and scale."
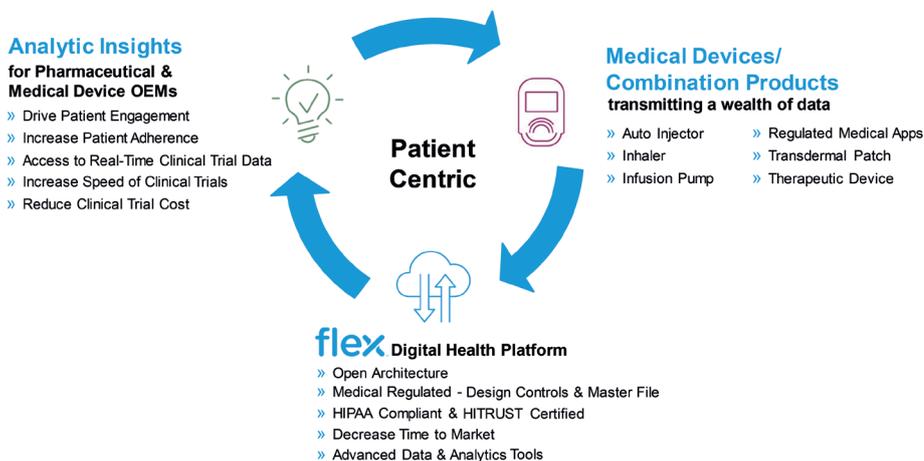


**Analytic Insights**
for Pharmaceutical & Medical Device OEMs
» Drive Patient Engagement
» Increase Patient Adherence
» Access to Real-Time Clinical Trial Data
» Increase Speed of Clinical Trials
» Reduce Clinical Trial Cost

**Patient Centric**

**Medical Devices/ Combination Products**
transmitting a wealth of data
» Auto Injector   » Regulated Medical Apps
» Inhaler   » Transdermal Patch
» Infusion Pump   » Therapeutic Device

**flex** Digital Health Platform
» Open Architecture
» Medical Regulated - Design Controls & Master File
» HIPAA Compliant & HITRUST Certified
» Decrease Time to Market
» Advanced Data & Analytics Tools

Figure 1: Flex is building a seamless, scalable platform to enable regulated connected medical device adoption.

"Med-tech and pharma companies do not want regulated IT to become a costly barrier to market, nor do they want this type of development and maintenance investment to distract from core innovation and R&D," says Dr Kal Patel, Senior Vice-President of Digital Health at Flex.

Flex estimates the upfront development cost for device manufacturers and pharma companies to implement a connected solution themselves to be in the US$3-$6 million (£2.4-4.7 million) range for a single product. "This cost doesn't even begin to address ongoing maintenance costs, including monitoring, security and updates," says Dr Patel. "Furthermore, how can an individual OEM or pharma company invest enough to ensure their platform is staying at the forefront of privacy, security requirements and product functionality capabilities?"

"The benefits of such a solution are inherent as medications and devices scale to commercialisation, but it also provides the optimal environment for collecting data during clinical trials."

The Flex Digital Health group is building the world's first medical regulated, US Health Insurance Portability and Accountability Act (HIPAA)-compliant, open architecture platform of connected medical devices, tied to a complementary, cloud-based software stack for commercialisation and scale. "We have always remained neutral in the marketplace, partnering with device OEMs and pharma to design and manufacture their products. Through our latest Digital Health solutions, we are complementing our *Sketch-to-Scale™* capabilities, offering a new engagement model to support device OEMs, pharma, patients, providers and payers," Patel explains.

Flex's Digital Health Platform provides core functionalities required by medical device and pharma companies interested in providing medical regulated software solutions to their end users. The Flex Digital Health Platform delivers an open-standard where multiple partners can introduce devices and apps, while providing the necessary core functionalities developed under the required design controls, such as clear integration points and change control. The Flex offering dramatically reduces the cost and effort for medical device and pharma companies to develop and maintain their own, regulatory-compliant platform. The Flex Digital Health Platform supports clinical use cases (class I, II, III,

and combination product) regulated by the US FDA and other global agencies, and manages data privacy compliance requirements for different regions.

As part of the managed platform solution, Flex provides platform monitoring, maintenance, updates, and security threat prevention. The functionalities of the solution include identity management, role management, access control management, user engagement and usability analysis, data ingestion and management, and reporting. As the platform matures, it will be capable of integrating data generated from multiple devices to provide a combined view of the patient for advanced analytics and comprehensive insight generation.

The benefits of such a solution are evident as medications and devices scale to commercialisation, but it also provides the optimal environment for collecting data during clinical trials. "Leveraging a PaaS (Platform-as-a-Service) offers medical device and pharma the opportunity to collect real-time data during clinical trials to determine the right features necessary for commercialisation and scale, without the cost burden," says Patel.

### ABOUT THE COMPANY

Flex is the *Sketch-to-Scale™* solutions provider that designs and builds *Intelligent Products for a Connected World™*. With approximately 200,000 professionals across 30 countries, Flex provides innovative design, engineering, manufacturing, real-time supply chain insight and logistics services to companies of all sizes in various industries and end-markets. Flex partners with a broad spectrum of healthcare OEMs to provide complete innovation, design, build, service and data solutions that make its customers more competitive in the areas of medical devices, drug delivery, diagnostics and medical equipment.

*The article, "Beyond Connectivity: Enable & Flex Announce the Enable Smart Device" (see this issue, Page 22), describes Flex's collaboration to integrate Enable Injections' wearable injector with the Flex Digital Health Platform.*