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WHITEPAPER

Five steps to escalate value in digital medicine

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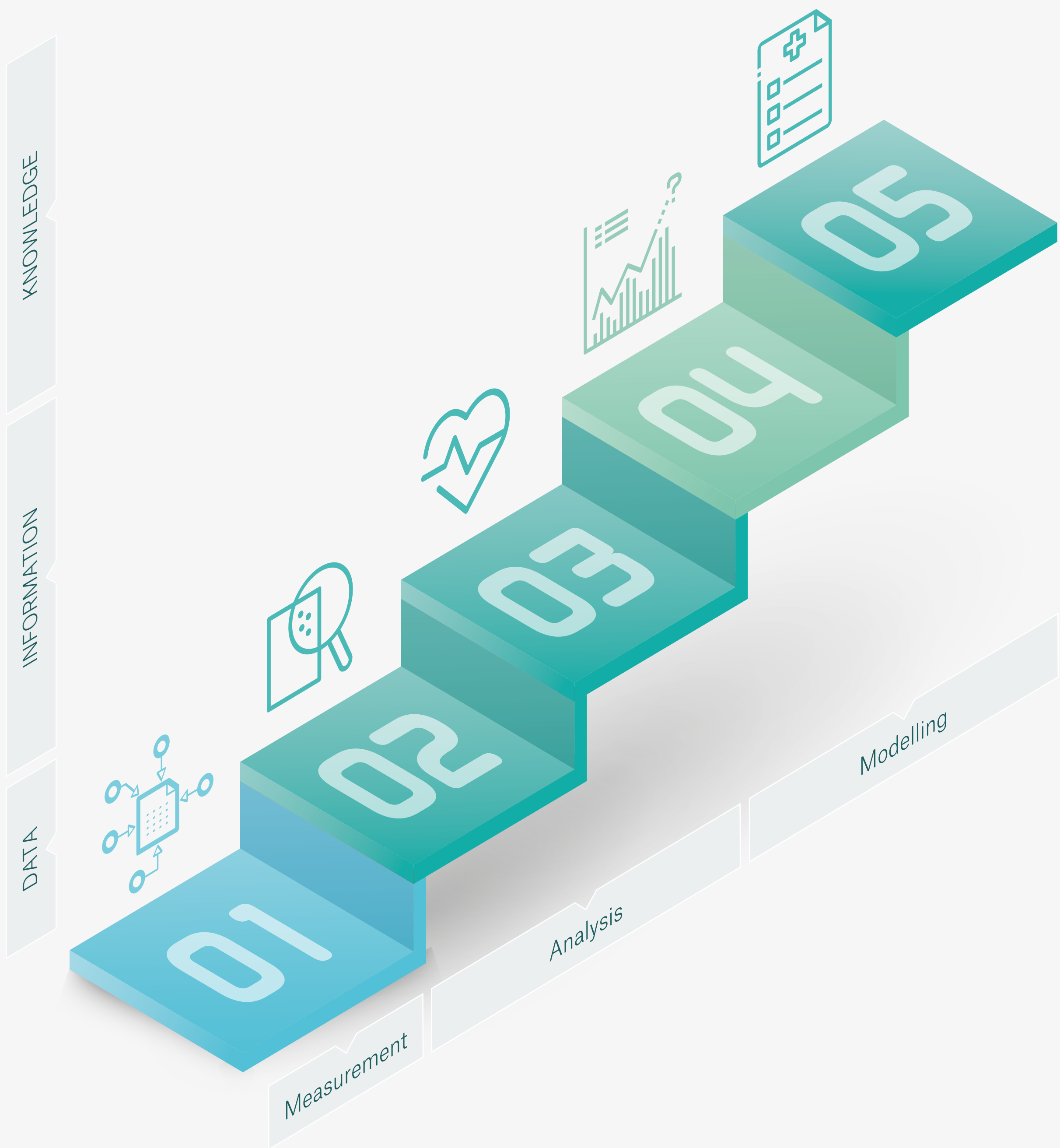

For digital medicine to realise its potential, the way value is created for patients, payers, and providers must be reinvented, and healthcare systems' efficacy needs to increase. Health data will fuel these changes. But it's not easy to harness, then leverage meaningful and actionable information from vast, multidimensional, and multimodal datasets. So, what's the best way to develop effective and efficient products in the age of digital medicine? This whitepaper outlines a five-step value creation framework with practical examples to guide the digital medtech product development process.

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Enabling digital medicine with data

Digital medicine spans connected diagnostics and pharmaceutical combination products, including biomarker sensing devices and digital therapeutics. It is characterised by evidence-based solutions, driven by software and algorithms, to measure and intervene to improve human health. The discipline is a key enabler of the major trends shaping the future of healthcare, such as decentralisation and patient empowerment.

At its best, digital medicine represents a catalyst for the transition from ‘sick care’ where people are treated after exhibiting symptoms, to true ‘health care’ where intervention begins much earlier. The focus is on preventing illness and preserving health by facilitating earlier action. In turn, this reduces the extent, cost and duration of treatment as well as delivering better health outcomes. At a personal level, it aids real-time clinical decision-making to improve patient health and experience. At a population level, it makes disease surveillance easier and enables tighter management of health economics.

Patient data is at the heart of these new possibilities, and it’s important to acknowledge both the power and the extreme complexity of this raw material. Data concerning patient health is often multimodal. It might be sourced from electronic health records, medical imaging, genetic repositories, or wearable devices. It is also rich and multidimensional, with many features and parameters. What’s more, because this personal data is considered highly sensitive, and is subject to very stringent data protection requirements, it must be robustly encrypted and may not be stored, distributed, or processed for any purpose other than that for which it was collected. This can present challenges in combining health datasets and developing insights from them.

Various factors must be considered when handling this data, from safety and security to the nuances of specific healthcare applications and disciplines. In this paper, we outline a systematic and streamlined value creation framework for innovation in digital medicine, powered by health data (Figure 1).

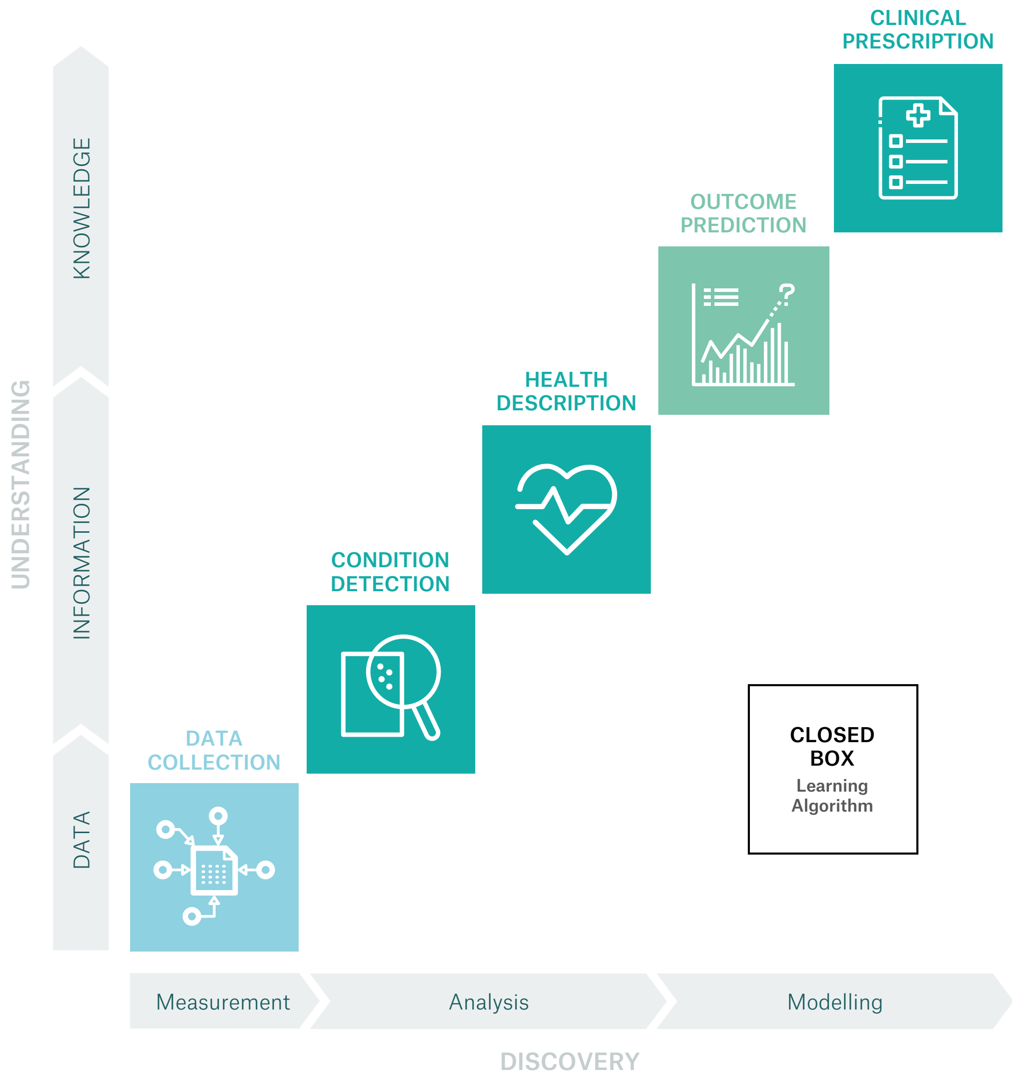
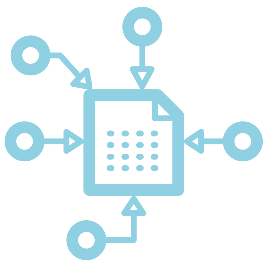


Figure 1: A five-step framework for value creation in digital medicine

The twin axes of 'understanding' and 'discovery' represent progression along independent components of health solution development. Understanding and insight increase as data evolves first into useful information and then medical knowledge. Discovery, or novelty, increases as we follow a process of invention. This process moves first from simple measurement, through analysing what the data means, to creating novel models, or simulations to explore how to drive outcomes.

Value escalates as activity progresses along these axes, deriving increasing benefits from the moment raw patient data is collected to the point of prescribed intervention. Each step brings various opportunities and challenges, requiring different types of input, such as applied science, hardware, and software expertise. Let's look at them in more detail.

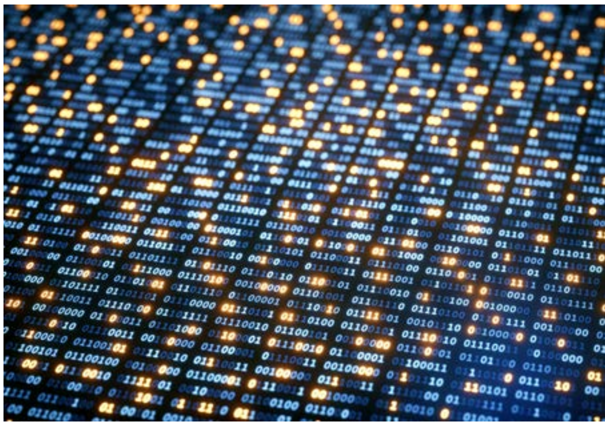


Step 1: Data collection

The first step is concerned with the collection and measurement of data on digital devices. Ones and zeros don't mean a lot in isolation, but collectively they form larger datasets from which more meaningful information can be extracted.

At the simplest level, this stage may involve the collection of biomarker and activity data via health kits and applications on wearables or smartphones. In clinical environments, there is scope for greater sophistication and complexity. Effective data collection may require the design and implementation of architectures including edge sensors for temperature, blood pressure and heart rate. Higher risk class, implanted sensors can also be introduced surgically, for example, as part of a smart implant to provide kinematic data on the longitudinal performance of a replacement joint. Intraoperative data on the surgical procedure itself can be collected for later combination with recovery metrics. The quality and reliability of sensors and other device technologies plays a significant role here. Connectivity and power engineering are key, with bioelectronic devices requiring implanted power sources, rechargeable batteries or kinetic energy harvesting technologies. Applied science expertise is required, as well as knowledge of hardware and human-centred design.

These measurable health indicators must be collected accurately, then segmented and stored in a way that enables effective analysis. Aggregation of data is a key aspect of collection too. This may involve combining the outputs from medical devices with healthcare professionals' notes and clinical, genomic, or behavioural data. In some cases, it will require the connection of hospital equipment with local networks and the cloud.



Step 2: Condition detection

Once relevant health data has been collected, detection of the condition, or *what it is* can be provided. Some sensing devices based on digital biomarkers can provide a result directly, perhaps performing basic data analysis at the network edge. This marks the first point of progression from raw data to more useful information, and in some scenarios, it provides enough insight for individual patients to receive a diagnosis and treatment recommendations. For example, a breathalyser device used to diagnose small intestinal bacterial overgrowth (SIBO) may use a molecular sensor to collect and analyse expired hydrogen and methane following the ingestion of a sugar substrate. Similarly, accelerometer data can be processed on a body worn device to determine patients' breathing cycles.

These capabilities are useful, but the true advantage of digital medicine is the ability to progress beyond this stage towards large scale data modelling and simulation. Data gathered at the individual level is combined and compared with data from the wider population or specific cohorts of people with shared physiological factors or medical conditions. Tracking disease indicators at scale, with big data techniques, can reveal patterns and trends which have the potential to enhance future detection, prediction, and treatment of health issues. It also unlocks new opportunities for early intervention.

Step 3: Health description

The next step is to better understand *what's happening* with descriptive analytic approaches, providing novel visualisation of complex, longitudinal data to gain insight on disease progression. With more advanced analytics, we can begin to answer *why*.

Opting for a cloud-based approach to analytics enables large amounts of data to be handled more quickly, securely, and cost-effectively than with traditional methods. Vast datasets can be broken down to reveal manageable, digestible insights for access on-demand. Analysis of patient journey data might reveal how the patient experience could be improved for enhanced satisfaction and better healthcare outcomes. Or device interaction data might be used to develop deeper behavioural insights, paving the way for strategies that encourage better patient engagement and compliance. Analysis of data from social media can provide a useful indication of what patient communities are saying about a given drug or illness, or any other topic of interest.

Building on condition detection, the ability to aggregate multiple datasets can be very powerful. For instance, overlaying information from electronic health records with biomarker data can facilitate integrated patient monitoring and alerts based on heuristic or derived thresholds. Complex surgical intervention might be supported too. For instance, combining data aggregation with capabilities such as 3D visualisation of digitised x-rays, MRIs, surgical device positioning and patient biomarker data could facilitate sophisticated visualisation with augmented realities.

Health description can be taken further still with the use of algorithms to identify patterns that can be displayed via dashboard solutions or other insight tools. Applications where this capability adds value include the continuous monitoring of respiratory and heart data to enable earlier detection of health deterioration. It also enables the detection of abnormal activity based on established patterns of normal behaviour, allowing crisis events to be identified earlier and managed more effectively.

The above factors mark an important shift towards a deeper understanding of patient condition, which can progress in two ways. At the point of care, it facilitates more informed clinical decisions about individual patients. In terms of the wider health ecosystem, it accelerates learning about health conditions and how they manifest and progress across wider cohorts or populations.

Step 4: Outcome prediction

From here, with advanced data science and more sophisticated modelling, it's possible to make the transition from descriptive to predictive analytics, answering *will*, and even more helpfully *when,* a condition might manifest in the future. Cloud capability plays an essential role at this stage, enabling scalability and enhancing interoperability between data of different types and from different sources. Modern cloud engineering skills are required to architect cloud-based applications to store and process multidimensional and multimodal data securely, efficiently and effectively. This capability underpins advanced data modelling for better understanding of disease progression, enabling clinicians to anticipate what's likely to happen and when with greater certainty.

One area that will benefit from these techniques is exacerbation prediction, for example, health issues associated with chronic obstructive pulmonary disease (COPD). Sensors tracking breathing quality, lung sounds and physical performance (for example, the time taken to climb the stairs at home) could enable imminent exacerbation of the condition to be identified before it happens. This approach could also prove useful in hospital wards, predicting patient deterioration before it manifests. By identifying the combined warning signs that preclude a downturn in patient condition, it may be possible to make earlier interventions for improved patient outcomes. Critical conditions such as heart failure, septic shock, or dangerous drops in blood pressure, which lead to breathing problems, organ failure, or stroke could be forecast and mitigated in this way.

Surgery spotlight

Patient recovery after surgery is a key area where predictive analytics is gaining ground. Patient rehabilitation can be greatly enhanced when the likely trajectory of recovery, and recovery goals, are tailored to the individual and remodelled as rehabilitation progresses. For instance, precision physiotherapy following joint replacement might consider data related to a range of motion as the patient goes about activities of daily life. Predicting levels of outcome such as the ability to climb stairs against, playing a particular sport again offers meaningful opportunities for intervention that effectively shape the rehabilitation journey towards improving those outcomes.

Predictive approaches can add value to surgical workflow too. Analysing composite datasets of patient pre-condition, surgical parameters and patient recovery data may reveal correlations between causative factors, such as surgical decisions, and outcomes of interest for example, patient recovery metrics. Robot assisted surgery in particular offers great opportunity to relate rich, real world, interoperative data to postoperative patient outcomes, and drive predictive models to help future surgical planning.

For approaches like those outlined above to make the journey from ideation to commercialisation, proof of concept or clinical trial implementations are needed. Gaining approval or authorisation from the relevant regulatory bodies requires evidence around safety and efficacy. Cloud comes to the fore again here. Hosting trial implementations on cloud-based platforms allows greater freedom to prototype and sandbox predictive models that can be deployed at a small scale. This accelerates the product development lifecycle and paves the way for more seamless progression to the final step of our digital medicine value creation journey.

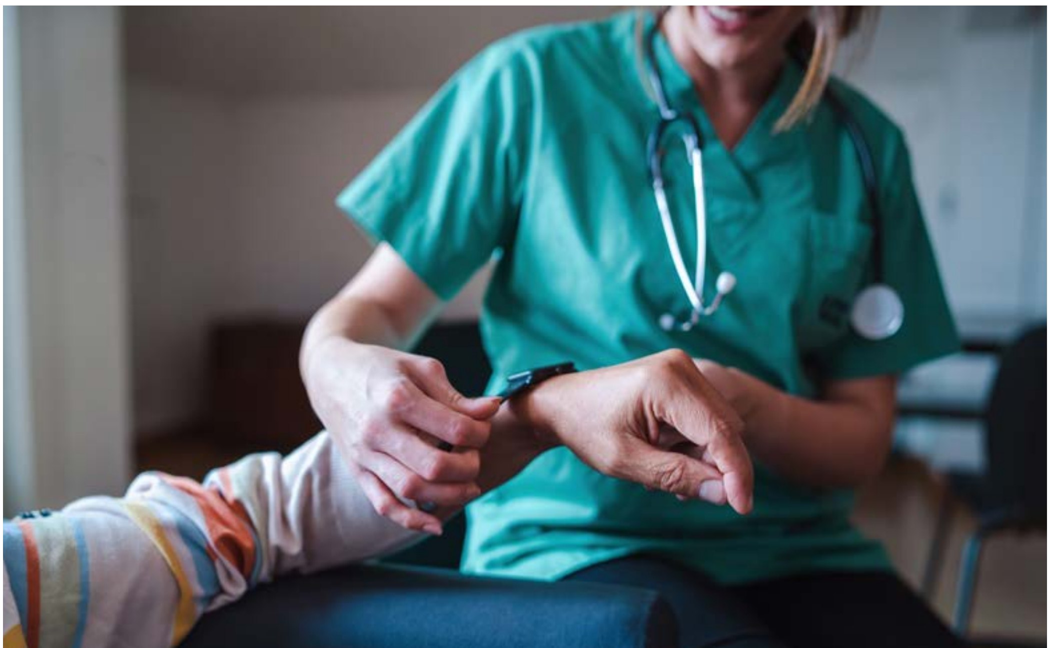
Step 5: Clinical prescription

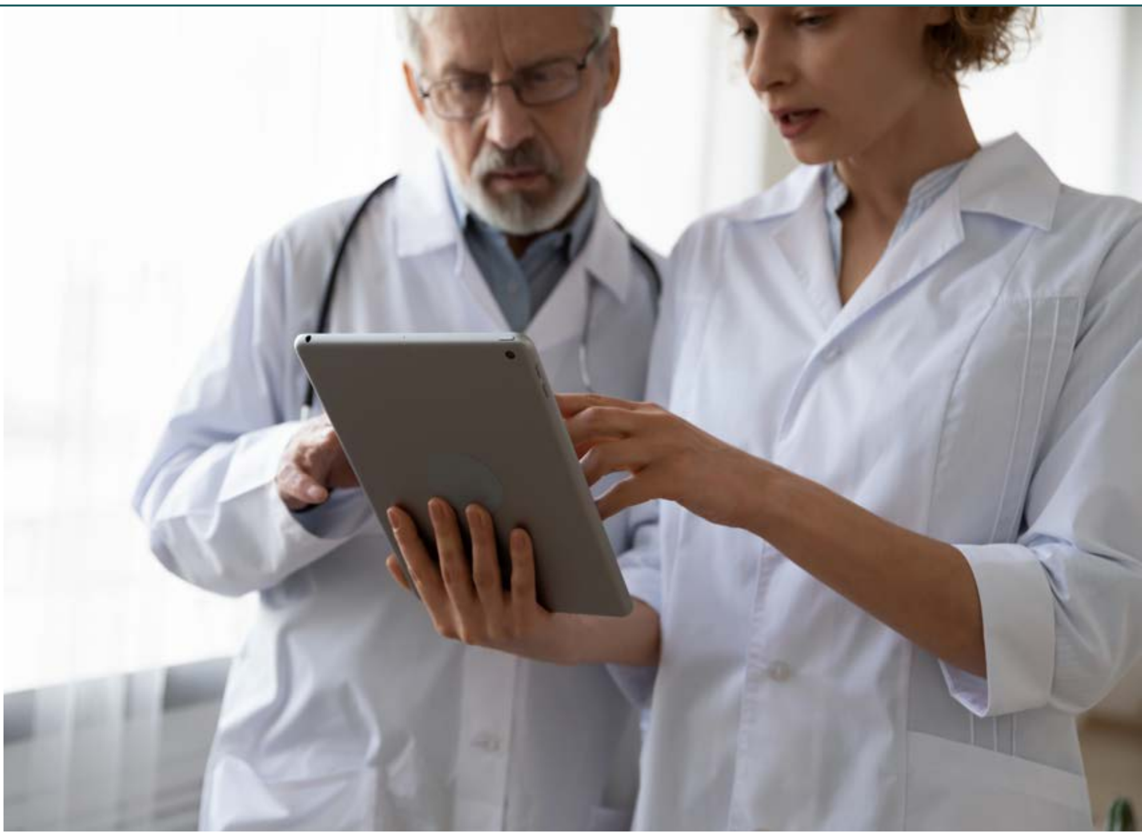
This final stage turns insight into action, effectively answering 'so *what*?' by helping clinicians decide what interventions to make to improve patient health through proactive measures customised to the individual. Digital medicine offers deep insight based on rich and varied data that is harnessed and leveraged using the power of modern computing. Clinicians are empowered to make better decisions at different stages of the patient journey, offering intelligence-led healthcare instead of reactive care of patients in advanced states of illness.

So, what are the opportunities for high value innovation?

From a preventative healthcare perspective, historic data related to patient biomarkers, genomics, phenotyping and disease diagnosis holds much potential. It might be used to build models which lead to lifestyle and dietary recommendations that may prevent or delay the onset of disease. Patients with undiagnosed or misdiagnosed chronic disease – or a high likelihood of developing chronic disease – could be identified, enabling patient specific prevention intervention. To return to the earlier COPD example, catching an exacerbation before it happens enables a pharmaceutical intervention to be prescribed at a much lower level than would otherwise be needed. Better still, non-pharmaceutical, behavioural changes might be implemented to avoid exacerbation and hospital treatment altogether through better management of the condition.

As highlighted in the previous section, there is great scope for the improvement of surgical procedures and outcomes using data-driven, digital approaches. Combining data about historic procedures with patient pre-condition and recovery data enables the creation of more targeted surgical plans. For postoperative patients, progress can be more closely monitored and potentially accelerated using data from wearable sensors or smartphone apps to build a movement profile. In a joint replacement scenario, predicting rehabilitation pathways and stratifying outcomes offers the opportunity to prescribe changes to physiotherapy in recovery time, remodelling the approach, so it's profiled more precisely to achieve an individual's optimised outcome as they progress. For patients staying in hospital, the risk of hospital acquired infections could be greatly reduced through the monitoring of high-risk patients coupled with intervention strategies based on patient-specific factors. The core opportunity for technology developers is to win the race to drive solutions that significantly reduce the burden on hospitals.





Closed box, learning algorithms

Algorithms rooted in Artificial Intelligence (AI) are the nucleus of advanced digital medicine. However, the nature of closed machine learning techniques challenges current regulatory thinking in the medical sector. Regulatory authorities need to understand the precise mechanism of operation behind a medical product when authorising or approving it for market. This means showing a product works in a known way, safely, reliably, and repeatably.

But adaptive algorithms are at odds with this paradigm as their power lies in their ability to continually evolve based on growing data – often in highly novel and unpredictable ways – which may obscure understanding of the basis for their conclusions. The implications are clear: learning algorithms must not only create novelty but also progress clinical understanding of how they work. Overcoming this paradox to harness the power of AI for medical software is a complex challenge that needs to be addressed.

Digital medicine and the cloud

Patient data is at the heart of these new possibilities, and it's important to acknowledge both the power and the extreme complexity of this raw material.

One of the primary objectives of digital medicine is delivering better health outcomes for individuals in a way that can be replicated and adapted across many thousands of people. Digital health data is the key to unlocking this vision. Cloud computing will facilitate its secure and effective use across prophylactic, diagnostic and therapeutic solutions that build value for patients, payers and providers of healthcare.

Large scale implementation of digital medicine is heavily reliant on the capacity and capabilities of cloud providers like **Microsoft Azure**. The ability to develop, then 'drag and drop' proof of concept solutions onto commercially available platforms is one of the defining features of this new paradigm. Experienced software developers and engineers are instrumental here, leveraging cloud capabilities to account for vital factors such as governance, security, and cost-efficiency. For digital medicine to fully deliver on its promises, extensive collaboration and cohesion across disciplines will be required. Experts in life sciences, genomics and other fields of science will need to work alongside hardware, cloud and software engineers as well as data scientists and regulatory professionals. The road ahead will be complex and challenging, yet full of opportunity. We are at the start of a healthcare revolution which will benefit the global population for years to come.

Medical device companies ready to exploit the value offered by these changing approaches to healthcare will have a clear digital strategy backed up by strong technical capability. If you'd like to discuss your digital journey with our team, please contact info@sagentiainnovation.com.

About Sagentia Innovation

Sagentia Innovation provides independent advisory and leading-edge product development services focused on science and technology initiatives. Working across the medical, industrial, chemicals and energy, food and beverage, and consumer sectors, Sagentia Innovation works with a broad range of companies from some of the world's leading and best-known brands, to start-up disruptors, new to the market. It is part of Science Group (AIM:SAG), which has more than ten offices globally, two UK-based dedicated R&D innovation centres and more than 400 employees. Other Science Group companies include Leatherhead Food Research, TSG Consulting and Frontier Smart Technologies.

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