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Interoperable Digital Health Platforms can Drive Egalitarianism in Health Care Ecosystem

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Huma, the leading global digital health pioneering in the field of digital health innovations has achieved a key milestone by receiving the world's first and only multi-condition EU MDR Class IIb regulatory approval for its configurable SaMD disease management platform in March 2023. Huma's platform centres on Software as a Medical Device (SaMD) technology that powers digital health pathways that collect and assimilate data from patients. The ready-to-use platform reduces the time and cost for other companies to bring regulated SaMD products to market, democratising digital health innovation across the industry. Dan Vahdat, Founder and CEO, during his visit to Singapore shared his perspective on the evolving ecosystem of digital health in Asia.

- **How are emerging health ecosystems impacting Asian lives?**

During the pandemic, people the world over gained first-hand experience of digital health out of a necessity to be at a distance from healthcare providers. Post-pandemic, this experience has transformed into an expectation of patients to take greater control over their healthcare journeys using digital technology. Asia, and Singapore in particular, is no exception.

Singapore used digital technology very efficiently to cope with increased demands on the healthcare system during the pandemic, so much so that the amendments to the Healthcare Services Act (HCSA) were partly driven by the increase in telemedicine because patients are no longer confined to hospitals and clinics, but are being treated in their own home. Together with the breadth of ICT use here, and the government's Smart Nation policy, Singaporeans are a leading nation when it comes to patients being actively involved in their own health and driving their interaction with healthcare systems through digital channels. This embodies the emerging health ecosystem we see across Asia, and globally today, and it's precisely this consumer-centric digital health ecosystem that our technology platform at Huma is designed to support.

- **What are the most prevalent digitized care delivery models?**

Huma's platform centres on Software as Medical Device (SaMD) technology that powers digital health pathways that collect and assimilate data from patients. Clinicians can assess patients' biomarkers centrally or patients can self-monitor their health conditions.

The delivery model consists of remote patient monitoring (RPM), companion apps, health awareness and risk assessment tools, dose calculators, algorithms etc. It enables patients to take control of their own health, something they previously had to rely on a care provider for, and to gain access to a specialist anywhere in the world.

Today, in the healthcare space, there are two types of use cases for digital health models. One is aimed at addressing a specific problem and investing in launching an app to address the delivery of care for a single patient cohort and a given treatment. Perhaps thousands of companies are operating in this space now. In March. Huma became the first company in the world to gain EU-MDR Class IIb status for the proprietary disease-agnostic platform, and amongst so many other things that ClassIIb brings, it means we can solve the development problem for these companies because whether it's a multinational pharma, two doctors working to spin a solution from their clinic, or whoever else, can leverage our foundational platform and launch their solution.

And then there is a second category of companies focused on data capture from patients and creating a unique algorithm to generate insight that can diagnose and inform care, or provide data for clinical trials. This approach is also useful but it needs to sit within a platform technology that can collect the data. Now, for the first time, the algorithm players in the market can be housed in our ClassIIb platform and immediately benefit from data input and actions to deliver proactive care in ways that didn't exist before.

- **What are some potential sources of concern for the comprehensive digital healthcare industry? How is Huma endeavouring to ensure patient privacy protection?**

It's important to weigh the benefits and risks of all technological advances. Together with greater patient empowerment and engagement, digital health offers the potential for earlier disease diagnosis, personalised care, better symptom control, expanding clinical capacity, greater cost-effectiveness to healthcare systems, greater health equity to democratised access to care.

The concerns with technology in healthcare are similar to those with technology in other areas of our lives. One key example is data privacy and personal information being subject to unauthorised access, and Singapore has been working through its own challenges here with the TraceTogether app post-pandemic.

In Huma, protecting patient data is of the utmost importance, we take that responsibility very seriously. Regardless of jurisdiction, we seek a global approach to privacy compliance in all our products. By being compliant with UK and EU privacy law, including GDPR, plus HIPAA and the CCPA in the US we are expanding our use of the internationally industry leading privacy compliance tool OneTrust, which includes global templates. Implementing several robust, technical and organisational measures to ensure the protection of patient personal data to globally recognised standards is the key here, for example, ISO 27001:2013.

Over and above Huma's privacy compliance culture, it's important to acknowledge that compliance is not just adhering to the letter but also the spirit too, and we always seek a close working relationship with our customer privacy teams to support their needs in protecting their particular patient data. We rely on global law firms for expert advice on legislation in different countries.

- **How is Huma staying relevant in an ever-evolving market?**

More than a decade ago we were a pioneer in digital health. During that period, healthcare companies increasingly began adopting mobile devices and sensors for health monitoring. Today, the entire healthcare and research sector has radicaly changed and been revolutionized. We have software and hardware technologies that not only enable us to generate insights but that can save lives because they are capable of predicting health complications.

In March this year, we became the first company in the world to gain EU-MDR Class IIb regulatory status for our platform which is disease-agnostic. This is an extraordinary leap. We operate in an ecosystem of health systems, governments, hospitals, clinics, life science and pharma companies; it's an environment that cares deeply about evidence supporting the decisions made for patients. ClassIIb certification prioritises verified evidence of safety and utility.

With ClassIIb capabilities our platform can drive clinical management up to critical condition patients, and triage or support diagnosis of serious condition patients. It turns data reporting into data insight. It allows patients to take certain actions regarding their own health for which they previously had to communicate with a care provider. This means significant value creation at the ecosystem level of patients and care teams, and when you have value creation for stakeholders, this is where a solution truly brings the impact that it's supposed to. The era of the next-gen digital health has began to create a true impact than ever before.

- **To accelerate global adoption of digital-first care & research, how is Huma contributing to the development of a technology platform essential to health systems and life sciences companies?**

For many years now, we've worked with the world's leading pharmaceutical companies and several leading healthcare systems and research institutes globally. Perhaps the biggest acceleration we will bring to digital-first care and research is the registration of our platform as ClassIIb certification.

Huma platform is disease-agnostic, and device agnostic and highly scalable. This enables life sciences companies and healthcare leaders with a regulated solution platform on which they can integrate their specifications and requirements for a particular disease condition, and instantly have a ClassIIb certified digital health solution.This configuration of an already approved solution saves them significant costs and years of development and it will drive huge innovation and growth in the field.

Huma is supported by leading life sciences and technology companies that share our vision as investors and shareholders, such as AstraZeneca, Bayer, Hitachi, Samsung Next, Sony Innovation Fund by IGV, Unilever Ventures, as well as individuals Nikesh Arora (former president of SoftBank) and Michael Diekmann (Chairman of Allianz).

- **What roles does Huma play to enable governments, healthcare payers, providers, and consumers to reimagine healthcare delivery and management?**

Huma's in-house clinicians and engineers work closely with healthcare system leaders around the world to understand their challenges, whether that is doubling the capacity of clinics by establishing virtual wards through remote patient monitoring, or driving patient engagement with medication adherence, or clinical trials participation, or enhancing care coordination through our interoperable technology platform.

For example, together with researchers from Stanford University School of Medicine, our Decentralized Trial in Atrial fibrillation Patients study was one of the first peer-reviewed assessments to examine whether a fully decentralised clinical trial (clinical trial participants being managed in their own homes instead of a clinic) would be feasible and effective for patients with a heart condition. The study, known as DeTAP, saw rapid recruitment (94% of patients signed up for the study in just 12 days), high engagement, and patients who otherwise failed to comply with their treatment regime showed an increased adherence to medication when linked remotely through a digital interface to their clinicians. Studies such as these show how healthcare can be managed differently.

In addition, recently we initiated an study to undestand National Health Service to drive engagement of hard-to-reach populations in bowel cancer screening in the UK. We are working with community leaders to tailor digital outreach so that the value of screening, and what's involved, is understood by these sectors of society.

At the population level, governments and payers are interested in preventative healthcare. For example, together with Bayer we currently have a campaign running across the United States encouraging people to take a brief web or app based cardiovascular assessment, underpinned by our peer- reviewed algorithm, which accurately estimates an individual's cardiovascular risk over the next decade. These types of risk assessment tools have historically required patients to visit clinicians for face-to-face consultations but our goal is to empower everyone, regardless of where they live, their background or socioeconomic status, to be able to assess their own risk of cardiovascular disease and initiate a conversation with a healthcare professional if necessary. The Bayer campaign aims to reach more than 100 million people with actionable insights to help improve their heart and overall health. This is helping people to reimagine what their own healthcare management looks like.

An essential part of healthcare in today's and tomorrow's world is health equity. The digital health revolution embodies patient-centered care, and emerging technological capabilities can drive egalitarianism.

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