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### Global Expert Mission South Korea and Japan Digital Health and Medtech 2019

**Contact** Dr Nee-Joo Teh Head of International and Development neejoo.teh@ktn-uk.org



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### Welcome

Innovate UK's global missions programme is one of its most important tools to support the UK's Industrial Strategy's ambition for the UK to be the international partner of choice for science and innovation. Global collaborations are crucial in meeting the Industrial Strategy's Grand Challenges and will be further supported by the launch of a new International Research and Innovation Strategy.

Innovate UK's Global Expert Missions, led by Innovate UK's Knowledge Transfer Network, play an important role in building strategic partnerships, providing deep insight into the opportunities for UK innovation and shaping future programmes.

The Digital Health and Medtech Expert Mission travelled to South Korea and Japan in March 2019. The findings and insights gathered from visiting Seoul and Tokyo over one week are shared in this report.

### 1. The South Korean Healthcare System

The South Korean healthcare system supports a population of 51.5 million people<sup>1</sup> through a publicly funded, national healthcare insurance system which is delivered through mainly private healthcare providers. Approximately 50% of the population live in the capital, Seoul.

The move to a single national healthcare insurance system was made in early 2000, when the original system operated through a number of separate insurance systems was slowly merged, to create a single provider, where effectively there is access to the entire Korean population data.

Although the system is publicly funded, there is a co-payment system where patients pay upwards of 20% for inpatient costs and outpatient costs could be as high as 60% depending on the provider<sup>2</sup>.

The health insurance system also requires people to have regular medical check-ups, depending on the type of work and work risk environment, leading to either biennial or biannual. This check-up includes a general consultation, blood pressure, lab test (including serum glucose, lipid profiles, renal and liver function and urine analysis), eye and oral examination and chest x-rays<sup>3</sup>. As part of the medical record, alcohol, smoking and exercise habits are collected by standardised self-reporting questionnaires. A national lung screening programme is currently being evaluated.

Seoul and the surrounding metropolitan area has five of the country's largest hospitals, referred to as the "Big 5" which dominate patient healthcare services. These hospitals are Samsung Medical Center<sup>4</sup>, Asan Medical Center<sup>5</sup>, Seoul National University Hospital (SNUH)<sup>6</sup>, Severance Hospital<sup>7</sup> and Seoul St Mary's Hospital<sup>8</sup>.

These hospitals have a total of 10,455 hospital beds or 12.1% of 86,630 beds in Seoul, with state-of-the-art facilities, and compete for highly-qualified medical staff. More than 90% of the beds are full at these hospitals, and in 2016 a total of 2.22 million visited the five hospitals. Despite the occupancy figures, 61% do not come from Seoul<sup>9</sup>. It is unclear

if these figures are due to Korean's living out of the city or the promotion of medical tourism by the South Korean Government. South Korea boasts the highest per capita rate of plastic surgery.

Whilst the public-facing side of the system appears efficient, with patients relatively at ease booking themselves in to see a doctor with limited waiting times, there are challenges in the system ranging from doctors seeing too many patients (up to 80-a-day), budgets not increasing proportionately, shortages of doctors in rural regions, to an ageing population and the rising cost of healthcare. From a Seoul perspective, there are some complaints about overcrowding in hospitals. This, in turn, is driving a private healthcare insurance market that sits uneasily alongside the state system.

South Korea suffers from similar mortality issues as western countries with malignant neoplasm (cancer), heart disease, cerebrovascular diseases and pneumonia as the top five conditions. Additionally, self-harm (suicide) comes in sixth followed by diabetes, as areas of concern. The major incidents of cancer are thyroid, stomach, large intestine, lung, liver and breast<sup>10</sup>.

Long term challenges for the country are an ageing population, a declining birth rate and pressure placed on social services. The healthcare system in Korea is fragmented and is not centred on senior-friendly care<sup>11</sup>, and co-morbidity complications require a more integrated medical and social care system.

The Ministry of Health and Welfare<sup>12</sup> is actively working on health promotion, supporting the healthcare industry, the modernisation of traditional Korean medicine and infectious disease prevention and control.

<sup>2</sup> Soonma K, Republic of Korea, Health System Review, Health Systems in Transition 2015,

12 www.mohw.go.kr/eng/

<sup>&</sup>lt;sup>1</sup>www.statista.com/statistics/263747/total-population-in-south-korea

<sup>&</sup>lt;sup>3</sup> Kim S, Disparities in the utilisation of preventive health services by the employment status: An analysis of 2007-2012 South Korean national survey, PLOS One, https://journals.plos.org plosone/article?id=10.1371/journal.pone.0207737, 2018

<sup>&</sup>lt;sup>4</sup> www.samsunghospital.com/gb/language/m\_english/main/index.do

<sup>&</sup>lt;sup>5</sup> http://eng.amc.seoul.kr/gb/lang/main.do

<sup>&</sup>lt;sup>6</sup> www.snuh.org/global/en/main.do

<sup>&</sup>lt;sup>7</sup> www.yuhs.or.kr/en/hospitals/severance/Sev\_Intro/Gnr\_info/

<sup>&</sup>lt;sup>8</sup>www.cmcseoul.or.kr/en.common.main.main.sp

<sup>&</sup>lt;sup>9</sup> Song S, Korea Biomedical Review, www.koreabiomed.com/news/articleView.html?idxno=2778

<sup>10</sup> www.mohw.go.kr/eng/hs/hs0102.jsp?PAR\_MENU\_ID=1006&MENU\_ID=100602

<sup>&</sup>lt;sup>11</sup> www.kihasa.re.kr/english/publications/eng\_research/view.do?menuId=68&tid=34&bid=30&ano=1099

### 2. South Korea Digital Health Implementation in Hospitals

The recognition and importance of innovation and new technology in healthcare, particularly the use of digital healthcare technology, has been acknowledged by President Moon Jae-in. Since coming to power in 2017, his administration has been focusing on digital healthcare and pushing to drive deregulation to spur innovation<sup>13</sup>.

In 2015, the Korean digital healthcare market was estimated to be worth £2.4 billion and is expected to reach £4.4 billion by 2020. Whilst the segmentation for these statistics is unclear, the developments in information and communications technology (ICT), big data and AI were evidenced with a healthy digital healthcare start-up community. Korean conglomerate investments and leading hospitals such as the Asan Medical Centre, SNUH and The Catholic University of Korea are all developing their own in-house big data centres.

#### 2.1 Asan Medical Centre (AMC)

The Asan Medical Centre (AMC)<sup>14</sup> based in Seoul is the largest hospital in South Korea, with a number of satellite hospitals around the country. In addition to operating as a hospital the organisation also has its own Health Innovation Big Data Centre, Asan Institute for Life Sciences, as well as numerous research and development (R&D) programmes and projects with interests in augmented reality (AR) and virtual reality (VR).

In 2017 the Big Data Centre was set up to exploit the medical information the hospital holds in its own home-grown IT system that combines a range of different data sets from medical information sources such as PACS, ERP, EMR to research information for clinical trial data to hospital process systems.

The system is built on an open innovation platform, to position Asan as the "big data-generating hospital" and support workers and patients in improved patient care, reduced medical costs, development of new service models, efficiently-managed hospital resources and processes, and establishment of a collaborative network for R&D.

Leveraging its big data system, the hospital provides a range of services including:

BIRD Service – Big data innovation research and development

Sharing of research ideas with partners and VC-accelerators with the aim to shape a new type of medical industry by joint R&D. So far, this service has had 55 caseloads since October 2018, and has supported major digital healthcare starts up such as Vuno, Noom, Medipexel as well as MSD the global health and pharma company.

#### TREE Service (technology and research regulatory guidance)

By analysing regulatory requirements for big data, it is providing consultancy support on AI/big data usage in medical devices. It is also supporting the establishment of guidelines for big data research and commercialisation. It has had 128 clients since October 2018, mainly Korean government ministries.

Big Data Academy (health data education programme)

The hospital group offers a range of training courses in health data and bioinformatics for SMEs and start-ups.

Big data analytics competition

For the past couple of years, the group has been running competitions that utilise the data available in the hospitals to develop innovations. Topics that have been covered include; epilepsy seizure indicators, breast cancer MRI, brain tumour segmentation.

<sup>13</sup> South Korean Digital Healthcare Market, 2019, UK Department of International Trade, British Embassy Seoul

14 http://eng.amc.seoul.kr/gb/lang/main.do

As one of the leading medical institutes in South Korea, AMC has been chosen to lead in two major Al/big data projects. The development of Dr Answer as part of a larger consortium (see case study) and lead in conjunction with Seoul National University Hospital (SNUH), Severance Hospital of Yonsei University, to the development of the Ministry of Health and Welfare's ambition of Human-Centred Convergence Technology (HCT) for patient information. The HCT project aims to improve the communication between hospital providers and patients using a mix of hardware, software and app services for managing mental disorders and cancer care, with AMC receiving 22.5 billion won for R&D over nine years<sup>15</sup>.

#### Case study: Dr Answer, South Korea's version of IBM Watson (Ji-young, 2018)

In May 2018, the South Korean Government announced plans to invest 35.7 billion won (\$33.4 million) over the next three years to develop an artificial intelligence system that could analyse patient's medical data to offer personalised diagnostics and treatment plans. The project aims to leverage the expertise of 25 hospitals, (including the Big 5) and 19 ICT companies as part of a single consortium known as K-DASH (Korean data and software-driven hospitals consortium) with Asan taking the lead. The hospitals and companies in the consortium are all responsible for different parts of the platform development from data handling, checking, labelling to API development. Collectively the K-DASH consortium has access to EMR, imaging, genomic and health screening data.

Dr Answer, as the project is called, targets eight medical conditions; cardio-cerebrovascular, cardiac diseases, breast cancer, colorectal cancer, prostate cancer, dementia, epilepsy and paediatric genetic rare diseases.

Prototypes in development are software packages for cerebral aneurysm and a readmission predictive service for cardiovascular diseases.



<sup>&</sup>lt;sup>15</sup> http://eng.amc.seoul.kr/gb/lang/about/news/langAboutNewsDetail.do?pageIndex=1&idx=1734

#### 2.2 Catholic University of Korea, St Mary's Hospital, Seoul

St Mary's Hospital is one of the Big 5 hospitals, treating 7% of the people in Korea. It is the single largest medical institution, with 12 hospitals that operate on the same EMR system, making it possible to construct the biggest medical health data record in Korea.

St Mary's is also part of the K-DASH consortium, where it is constructing its own customised databases that are open for external organisations to use. They are working on alcohol abuse and dyslipidaemia databases. For participants that want to access this data, the hospital has created a sandbox, whereby researchers/companies can access the data on hospital premises.

In a similar style to Asan Medical Centre, St Mary's offers a range of services from having their own internal start-up centre, business networks and education. Areas of service development include a patient-accessible personal health record (MyData), computer-aided diagnosis, teleradiology and developments in biomarkers for customised therapies.

The hospital group also has links to different industries from telecommunications companies to weather companies where they can access regular updates on pollution monitoring and feed this into the hospital system. It is unclear if this linkage is part of the K-DASH consortium.

#### 2.3 Seoul National University Bundang Hospital

Seoul National University Bundang Hospital is a 1,360-bed medical centre located in the southern suburb of Seoul. The hospital boasts its own Innovation Park, with SME companies on-site working in healthcare information technology, genomics, regenerative medicine, medical devices and nanomedicine.

Impressively, the hospital had gone paperless in 2003. The hospital has developed its own home-grown hospital management system BESTCare 2.0<sup>16</sup> which is the only non-US EHR system accredited to HIMSS Stage 7 and covers more modules than EPIC and at a lower price. Interestingly, SNUH is also making the source code available to organisations which want to take on this integrated software system for a hospital group. By embracing technology and digital health throughout the hospital, it has demonstrated a commitment to sharing medical records with its patients and presenting results in ways that they can understand.

<sup>16</sup> http://bestcare.ezcaretech.com/

### 3. South Korea Digital Health Start-up Community

South Korea has a vibrant start-up community in the digital healthcare sector. Whilst it is unclear how much commercial traction these companies have, there appears to be significant appetite to develop new products and services.

Whilst the national government schemes such as K-DASH supports the large hospitals and corporations, the start-up community looks able to access and be part of this big data ambition. One such company that is widely acknowledged as a leading start-up is Vuno.

#### 3.1 Vuno

Vuno is an AI-based company that supports physicians' detection rates in medical images such as CT and x-ray. The company has support platforms for bone age assessment, chest x-rays, lung nodule detection, fundus screening, neurodisease quantification, cardiac warnings and mental health.

The company was started in 2014 by three co-founders who originally worked for Samsung on a voice transcription algorithm. Since then, the company has pivoted to work with the medical imaging space. To date they have investments of over \$15 million , with significant support from the government but also local seed funding. They have more than 60 employees and built their own AI engine, differentiating themselves from other companies using the Tensor Flow platform. The company has already received regulatory approval by the KFDA for their chest x-ray product, is working with international hospitals for future partnerships and has CE approval for a bone age product.

Vuno isn't alone in this space with other companies also looking at image analysis, such as Lunit<sup>17</sup>.

#### 3.2 Selvas AI

Selvas AI is a leading disease prediction company that can generate disease risk scoring for diabetes, heart disease, stroke, dementia, liver, gastric, colon, breast and lung cancer using patient medical check-up data in conjunction with big data and their prediction algorithm. The company operates in a variety of industries with the goal of integrating AI solutions into all areas of our lives with the medical segment being one area of interest.

Whilst Selvas AI is not a start-up company in the conventional sense, it is a new entrant into the use of AI in healthcare. The company, listed on KOSDAQ with 172 employees, is part of the Selvas Group and Selvas Healthcare which also makes BP and body composition analysers.

#### 3.3 Medipixel

Medipixel is an AI-based surgical robot performing automated surgery. The company is developing an algorithm that allows a catheter-driven robot to navigate through the arteries and perform stent placement.

The company was established in 2017 and currently has nine employees. It has been the recipient of a number of funding awards from angel investment groups to government grants.

#### 3.4 Showcased Digital Health Start-ups

The South Korean digital health start-up environment is similar to the UK with perhaps a more balanced hardware and software mix. Other companies met during the visit included more traditional medtech.

| Company       | Activity   | Website              |
|---------------|--|----------------------|
| Neurophet     | Computerise neuromodulation planning and guide software using Al-<br>based brain modelling     | www.neurophet.com    |
| Olive Union   | Smart hearing aid solution   | www.oliveunion.com   |
| SkyLabs       | Atrial fibrillation detection using a finger ring  | www.i-skylabs.com    |
| FRT           | Exoskeleton development for the elderly  | www.frtechnology.com |
| Soundmind     | Computerised cognitive training solution to delay the onset of Alzheimer's                     | www.soundmind.life   |
| Omnifit       | Healthcare management platform using a range of devices including a smart ring and head sensor | www.omnifit.co.kr    |
| The.Wave.Talk | Bacterial counting and differentiation device  | N/A                  |

17 www.lunit.io

Whilst a number of SME and start-up company solutions were discussed, it is unclear how these are tackling the challenges that the healthcare system faces and how this is linked to insurance reimbursement with some companies, indicating that they are "still looking for a payer".

#### 3.5 Data Play

The competitive position of many of the companies and institutions visited was based on their access to clinical data and expertise in AI.

The Big 5 hospitals appear to have significant access to clinical data that is based on well-structured electronic patient records within the same hospital groups. However, it didn't appear that this data was shareable across the different hospital groups. Companies such as Vuno and Selvas AI have enjoyed significant access to these records; however, the "patient consent" and legal position is unclear. Vuno claimed easy access to training data at a time when the regulations were more relaxed. Since then the government has become stricter in managing these rights. There was an indication from the companies that they had a revenue sharing scheme in place with the hospitals to support access to data rights.

At the time of visiting there didn't appear to be a coherent policy or consent framework for accessing clinical data. President Moon's government was expected to pass a law in late 2018 to provide greater access to this data, but this has been postponed to the first quarter of 2019. To date the law has not been passed (March 2019), and it has not been possible to verify the current situation.

From a medical device regulatory position, the country seems to have adopted a fast track approach to approving updated algorithms within their technology, enabling frequent releases.

### 4. South Korea Medtech Developments

In 2018 the total number of medical device imports was \$3.5 billion; however the demand for advanced foreign manufactured devices has slowed recently. This is said to be caused by increasing competitiveness with domestic manufacturers and the challenges of importing medical products and reimbursement processes.

Over 1,200 domestic and international manufacturers displayed their products at the annual medical device trade show, KIMES, in 2019. From an international perspective, the show demonstrated a broad range of medical products that would fit more comfortably in the health and wellness space compared to a traditional medtech show. Reflecting South Korea's cosmetic surgery interest, there was considerable space devoted to products ranging from surgical applications to stem cell treatments.

Whilst the domestic-manufactured products were all registered with the KFDA, it was not clear how widely these manufacturers also held European or USA regulatory approval.

# 5. South Korea National and Industrial Priorities

The South Korean Government has regularly expressed a belief that their country needs to change its industrial strategy towards the emerging technologies of the Fourth Industrial Revolution<sup>18</sup> such as smart technology, artificial intelligence and big data. The country needs to diversify from its current technology expertise in ICT, mobile phones and LCD displays.

Part of the national strategy puts AI at the forefront of its healthcare strategy; with the vision of "making a society where everyone is healthy with Korean technologies leading the global market"<sup>19</sup>. This ambition includes healthcare big data products, new drug development using AI, smart clinical trial systems, smart fusion medical devices and an innovative ecosystem linking regional biohealth clusters<sup>20</sup>.

Another part of the strategy is to support start-ups, since this is where the government believes real innovation will take place. As such, President Moon has committed \$10 billion for start-up companies over four years. It is unclear how this will be allocated across healthcare and the other industrial sectors. This opens up the possibility of companies relying on government funding despite not necessarily developing a technology of commercial value. The developments being made as part of the K-DASH consortium and the companies that are taking advantage of this data, go some way to developing the government's healthcare and industrial commitment.

#### 5.1 Government Ministries and Agencies

A plethora of ministries and agencies are involved in supporting the national strategy, and it can be challenging to understand how their functions differ.

A summary of national bodies involved in innovation or the promotion of new technology is covered below but is not intended to be exhaustive.

| Ministry/Agency  | Activity  | Website         |
|--|---|-----------------|
| KHIDI, Korea Health<br>Industry Development<br>Institute       | Raise the competitiveness of the health and medical industry  | www.khidi.or.kr |
| KOTRA, Korea Trade-<br>Investment Promotion<br>Agency          | Support SMEs to export to overseas markets  | www.kotra.or.kr |
| KITA, Korea<br>International Trade<br>Association              | Private association to promote Korean trade overseas  | www.kita.org    |
| Ministry of Science and ICT                                    | Accelerate innovation in the Fourth Industrial Revolution in Korea  | www.msit.go.kr  |
| Ministry of SMEs and<br>Start -ups                             | Strengthening SME and micro-enterprises competitiveness   | www.mss.go.kr   |
| KIAT, Korean Institute<br>for the Advancement<br>of Technology | Promotion of technological policy, construction of industrial technology infrastructure and tech transfer | www.kiat.or.kr  |

<sup>18</sup> President Committee on the Fourth Industrial Revolution, www.4th-ir.go.kr/home/en

<sup>19</sup> https://pharmaboardroom.com/articles/korea-prioritising-ai-in-healthcare-innovation/

<sup>20</sup>www.koreaherald.com/view.php?ud=20181210000652

### 6. South Korea Innovation Landscape

The South Korean start-up and innovation environment has changed significantly over the past few years. There are more than one hundred accelerators; numerous co-working spaces such as FastFive and hundreds of start-up events. There is also a growing angel venture network; global investors from the USA, Japan and China; significant government support from various ministries as well as corporate investors. The fastest-growing sector by funding is virtual reality, followed by fintech and cybersecurity. Whilst the environment is supportive of domestic companies, it is more challenging for foreign start-ups to enter, requiring a financial investment of \$100,000, patenting locally and attendance of a three-week government course<sup>21</sup>.

The Bloomberg Innovation Index placed South Korea as number one in 2019, with the UK being positioned eighteenth and Japan in ninth position<sup>22</sup>. The index is made up of a number of weighted categories from patent, education to R&D expenditure.

The IMD index is less generous in placing South Korea at number twenty-seven in its competitive index. Their position was that the country still requires a weakening of management, innovation in a broader sense (not just products), investment in developing global talent, improvement in governance, and managing the intergeneration gap. The report also found that executives needed to be more open and positive in attitudes<sup>23</sup>.

Despite there being a number of co-working spaces, companies face stiff competition to enter the more favourable locations. As an example, the Seoul City local government funds a hub which is free of charge – requiring companies only to pay maintenance costs. Entry requirements include interviews and documentary applications. However, once approved the centre provides business mentoring and financial support.

Whilst the start-up community is vibrant, most companies have an immediate global strategy with companies looking first at the USA and China, followed by the UK market. The entrepreneurs are well-educated with many having been educated overseas, especially in the USA. Going global, however, has its own challenges for these early-stage startups; from accessing international networks, funding and language challenges – though English is now widely spoken amongst the younger generation.

In Korea, for the corporates such as Samsung or LG, success has long been based on being fast followers. They have also been accused of stifling local competition, and therefore there is still some suspicion from start-ups entering into partnerships with these players.

<sup>21</sup> Korea Start Up Ecosystem, G3 Presentation

<sup>22</sup> www.bloomberg.com/news/articles/2019-01-22/germany-nearly-catches-korea-as-innovation-champ-u-s-rebounds

<sup>23</sup> TURPIN D, Korea's Global Competitiveness, IMD World Competitiveness Center

### 7. The Japanese Healthcare System

Japan's population peaked in 2008 with a total of circa 128 million people. Since then there has been a gradual decline, and in 2016 the population was recorded at 126.9 million. Over 27% of the population is over 65 years of age, and the country has a population growth rate of -0.17% with a fertility rate of 1.44 children per women. In 2015, 93.5% of the population was considered urban due to a sharp decline of rural communities.

The health system since 1961 has been supported by universal healthcare access to all citizens through a mix of employee and community health insurance plans. This system works through a co-payment approach, where users of the health system pay a percentage contribution depending on their age for their medical treatment. This payment can vary between 10-30% depending on the age of the claimant.

The major causes of death in Japan reflect that of an ageing, developed nation with cerebrovascular disease, ischaemic heart disease, lower respiratory infection, Alzheimer's disease and lung cancer as the top five conditions. Diabetes, whilst not listed as a major cause of death, is one of two major chronic diseases which also includes hypertension. The prevalence of diabetes is 12.1% and has remained stable over the years in all age categories except for the elderly, which has steadily increased. Japan's healthcare system was designed during an era of prosperity and population growth and has managed to effectively support the healthcare of a nation, notably with achieving one of the world's highest life expectancy. The challenge is that the country has one of the fastest ageing populations in the world, with a shrinking economy and workforce. This places significant financial pressure on the system, and the general population's healthcare requirements have changed considerably since the boom years. The government has been forced to introduce reforms, and different service delivery offers from the Long-term care insurance, Integrated Community Care System to developing a Regional Healthcare Vision<sup>24</sup>.

<sup>24</sup> SAKAMOTO H, et al, Japan Health System Review, Health Systems in Transition, 2018, Vol 8, Number 1

### 8. Digital Health in Japan

Until recently, remote medical treatment was not allowed under Japanese Law, except for rural regions. This was changed in 2015 by the Ministry of Health, Labour and Welfare to open up this area of healthcare provision, forced largely by the need to manage a "super-ageing" population. It is now possible to acquire vital-signs data and receive certain medical services through digital services. Anecdotally, whilst a number of start-ups were offering to provide services in this area, the reimbursement was lower than expected, and therefore the service providers entering the market were fewer than initially expected<sup>25</sup>.

In 2017, the government revised the Act on the Protection of Personal Information, which allowed for personal information to be utilised by anonymising the data. The hope is that this can lead to improved services and the creation of new businesses. This has already opened up the opportunity for remote consultations using apps such as Curon, Pocket Doctor, YaDoc and Clinics<sup>26</sup>.

The Prime Minister has announced that he wants Japan to have a national medical database with patients being able to easily access their data by 2020.

Whilst the use of electronic health records was not explored on the Japan leg, it was noted that large IT vendors such as Fujitsu and Hitachi operated the largest healthcare record systems. So far, it does not appear these vendors/hospitals are doing anything to utilise the data.

One company that looks like it is trying to utilise data from nursing homes is the Care Design Institute, where they are looking at the history of senior patients and their treatments and using AI and improving the link between the care manager and the person or family that needs the care.

#### 8.1 National Institute of Informatics (NII)

The National Institute of Informatics (NII)<sup>27</sup> is an academic research institution focused on creating future intelligence through big data, the Internet of Things and information security. The aim is to promote practical research to solve social problems and research the fundamentals in informatics. In addition, the institute aims to develop the next generation of IT personnel in inter-university research environments.

The Institute's scientific interests are broad and include research interests in medical data. They are currently working with AMED<sup>28</sup> (Agency for Medical Research and Development) to explore opportunities in medical images in pathology, endoscopy and radiology. The aim is to develop research that will ultimately lead to helping doctors automate diagnosis. To achieve this, they have teamed up with academic institutions that are skilled in image analysis and medical societies that can access anonymised medical images across Japan. Current research is in gastric and colorectal cancer, supporting doctors in making a more accurate diagnosis.

Despite all of this research, the NII cannot commercialise their algorithms because they are a research institution and the data they are accessing has been obtained on an opt-out scheme which means that data can only be used for research and not commercial purposes. The NII has strict conditions about how they can receive and utilise data from public institutions, but with private companies this is less rigorous. They have indicated that they are open to conversations with commercial organisations.

<sup>25</sup> YAMAMOTO, Digital Health in Japan, www.yuasa-hara.co.jp/wpcontent/uploads/2017/10/The\_Patent\_Lawyer\_Yuasa\_Hara\_REV.pdf

<sup>26</sup> KOBAYASHI M, Telemedicine via smartphone apps gaining in popularity in Japan, Japan Times, www.japantimes.co.jp/news/2018/09/18/national/science-health/telemedicine-viasmartphone-apps-gaining-popularity-japan/#.XKCnMOtKi8U, 2018

<sup>&</sup>lt;sup>27</sup> www.nii.ac.jp/en/ <sup>28</sup> www.amed.go.jp/en/

### 9. Japan Digital Health Start-up Community

There are estimated to be 100-200 digital health start-up companies in Japan working in a variety of areas of the digital healthcare spectrum, from support for an ageing population to risk of disease onset predictions. It was estimated that there are probably around ten companies working in the area of AI image analysis in the radiology field. According to Forbes, digital healthcare is expected to grow in Japan because it is seen as a perfect place to test new technologies in healthcare for the ageing society<sup>29</sup>.

<sup>29</sup> How Japan's Ageing Society Paves the Way for the Era of Digital Health Care, www.forbes.com/sites/japan/2019/03/28/how-japans-aging-society-paves-the-way-for-the-era-of-digitalhealth-care/#587b9f126e26, Forbes, 28 March 2019

### 10. Japan Medtech Developments

Japan is the world's second largest medtech market, with the majority of products imported from overseas. Most Japanese medtech manufacturers blame the Japanese regulatory system for the lack of domestic innovation, citing the time it takes to get products approved, and physicians tending to steer towards overseas products. The challenging length of time for approvals has meant that Japan has often been criticised for not having access to the latest medical devices and being stuck in "version 1.0". The government has made structural changes in the approvals process, and Japan should start to see more innovative products entering the market faster. It is hoped that this will also encourage the domestic industry to start innovating in this area. The Japan Association for Clinical Engineers<sup>30</sup> (JACE) is supporting this initiative with the training of more clinical engineers<sup>31</sup>.

The medical trade show, Medtech Japan 2019 represented a number of overseas and domestic manufacturers, and in contrast to the KIMES exhibit in Korea was more focused on traditional medtech. There were a very limited number of companies at the show in digital healthcare.

Disappointingly the show did not demonstrate developments such as the Smart Cyber Operating Theatre (SCOT) utilising robotics and AI to perform groundbreaking brain surgery. The development came out of the consortium effort of Tokyo Women's Medical University, the Institute of Advanced Biomedical Engineering and Science and private institutions funded by AMED<sup>32</sup>.

<sup>30</sup> www.ja-ces.or.jp/english/

<sup>&</sup>lt;sup>31</sup> IGETA H, Roles of CE in Medical Device Development, www.who.int/medical\_devices/global\_forum/3rd\_gfmd/RolesofCEmedicaldevice.pdf?ua=1, WHO

<sup>&</sup>lt;sup>32</sup> Open Innovation in Japan Breaks New Group in the Operating Room, www.forbes.com/sites/japan/2019/03/08/open-innovation-in-japan-breaks-new-ground-in-the-operatingroom/#4ca9aae214a8, Forbes 8 March 2019

### 11. Japan National and Industrial Priorities

#### 11.1 Japan 2035

Japan 2035<sup>33</sup> is the Ministry of Health and Welfare's vision of the type of healthcare system that needs to be built over the next 20 years. The vision is based on the three pillars of lean healthcare; life design and global health leader.

The lean healthcare approach is making headway in introducing health technology assessments into the system, with the aim of improving quality and efficiency in delivering better care and reduced costs.

The life design pillar aims to empower society and support personal choice. This essentially means that the system must recognise that health is influenced by environmental and social factors that extend beyond individual choice. An ambitious goal under this pillar is to have a tobacco-free Tokyo 2020 Olympics.

The third pillar is to be a global health leader supporting regional countries in areas such as universal health coverage and drug approval processes.

#### 11.2 Society 5.0

In 2017, the Japanese Prime Minister announced the country's vision for Society 5.0<sup>34.</sup> Leveraging the Fourth Industrial Revolution, the aim is to create a society that can benefit from the areas of AI, Internet of Things, big data and robotics.

The vision for healthcare is to connect and share information between medical data users, including medical check-ups, treatment and nursing care records. It aims to put remote medical care services into practice and use AI and robots in nursing-care facilities to support people's independence.

#### 11.3 Japan Healthcare Innovation Policy, METI

An early stage policy document by the government department METI<sup>35</sup> (Ministry of Economy, Trade & Industry) illustrated how they were working on the strategic planning for the future of medical welfare in an ageing society. The focus for the ministry is that ageing is an economic issue as well as a health issue and that Japan needs to understand how businesses and society will be affected by these changes. With projections that people will live to 100 years, society needs to provide a way to keeps these people occupied, leverage their experiences and ensure they do not become a burden.

#### **11.4 Government Ministries and Agencies**

Government ministries and agencies involved in digital healthcare and innovation are shown below.

| Ministry/Agency  | Activity  | Website        |
|--|---|----------------|
| MWHL, Ministry of<br>Health, Labour and<br>Welfare                         | Ministry responsible for health and welfare policy                                      | www.mhlw.go.jp |
| METI, Ministry of<br>Economic, Trade and<br>Industry                       | Ministry responsible for the economic welfare of the country                            | www.meti.go.jp |
| AMED, Japan Agency<br>for Medical Research<br>and Development              | Agency responsible for the promotion of integrated research and development in medicine | www.amed.go.jp |
| AIST, National Institute<br>of Advanced Industrial<br>Science & Technology | Responsible for the creation and practical realisation of technologies useful to Japan  | www.aist.go.jp |

<sup>33</sup> Japan 2035, www.mhlw.go.jp/seisakunitsuite/bunya/hokabunya/shakaihoshou/hokeniryou2035/future/en/ , MHWL 2015

<sup>34</sup> Society 5.0, www.japan.go.jp/abenomics/\_userdata/abenomics/pdf/society\_5.0.pdf , Japanese Government, 2017

<sup>35</sup> www.meti.go.jp/english/

### 12. Japan Innovation Landscape

The innovation landscape in Japan is growing but is fragmented with numerous startups almost hiding under the radar. The visibility issue appears to be because Japan, alone, represents a large market, with many start-ups not necessarily focusing on international markets (though this is changing). Whilst the investment scene is not as developed as other Asian markets, the many Japanese corporates (such as Rukten, Softbank) are supporting their own start-up accelerators or providing corporate funding, though this was not explored during the visit.

In digital healthcare, this area has slowly begun to grow; the much larger medtech companies remain cautious because of the difficulty in obtaining regulatory approval. However, METI and organisations such as JOMDD<sup>36</sup> see a bright future for digital health start-ups.

METI's interest in boosting the competitive nature of the healthcare business is reflected in their involvement in a number of initiatives:

- a) Running their own annual Japan Health Business Contest since 2016. This competition draws significant publicity and support for start-up companies in the healthcare industry.
- b) Over 25% of the companies involved in METI's J-Start Up<sup>37</sup> programme are reported to be medical, bio and healthcarerelated. The programme supports the export of Japanese

ideas and at the same time supports overseas start-up ventures in Japan with "start-up" visas.

- c) In April 2019, METI will establish a Healthcare Innovation Hub (Ino Hub) as a one-stop consultation point for information on start-up venture support.
- d) The international conference, the Well Ageing Summit will run for a second year in October 2019 providing an opportunity for corporates, start-ups, investors and government agencies to discuss global efforts and solutions for a super-aged society.

Adding to the steady mix of activities, in March 2019, a new start-up accelerator, Bio-Labs launched a share wet lab facility<sup>38</sup> (Blockbuster Tokyo, 2019) for life sciences-based start-ups.

<sup>&</sup>lt;sup>36</sup> https://jomdd.com/company\_en/

<sup>&</sup>lt;sup>37</sup> www.j-startup.go.jp/about/

<sup>&</sup>lt;sup>38</sup> www.blockbuster.tokyo/

### 13. Conclusion

South Korea and Japan both have universal healthcare for their populations, with effectively single payers, which makes the market commercially attractive but comes with its own complications.

Both countries also have similar healthcare challenges driven by an ageing population, and therefore increasing demand being placed on the system. Both see value in leveraging value from data, driving out costs in delivery care and moving care out of hospitals into a self-care or primary care environment.

However, the approaches to these challenges and skillsets in managing these conditions seem to be slightly different. From an innovation point of view, South Korea has embraced a digital health start-up culture that is looking at innovative ways to utilise the big data systems that the large hospital groups can provide. The South Korean start-up community also appears to be more visible with numerous accelerators and shared working spaces in Seoul. The adoption and support from South Korean's limited number of corporates is less clear but offers significant opportunity for start-ups success.

Japan's digital health start-up sector appears smaller and perhaps not as developed, but there are signs that this is changing fast with diverse sectorial corporates rising to the challenging of supporting these companies. At the forefront of the push for digital healthcare start-ups in Japan is the Ministry of Economy, Trade and Industry (METI) supporting these companies to become global.

To be successful in either market requires local expertise and cultural understanding. Both countries offer opportunities that could benefit the UK start-up digital healthcare and innovation industry.

## **Annex 1** List of UK Participants

Cambridge Respiratory Innovations Ltd

Healthcare Consultants

Innovate UK

Knowledge Transfer Network

Trichrome Health

West Midlands Academic Health Science Network

### List of Japanese Participants

Japanese Organization for Medical Device Development

Medtech Tokyo

Ministry of Economic, Trade and Industry

National Institute of Informatics

Olympus

Tokyo Medical University Hospital

### List of South Korean Participants

| Asan Medical Centre                                |
|--|
| British Chamber of Commerce in Korea               |
| Bundang Hospital                                   |
| FR Technology                                      |
| FRT  |
| G3 Partners  |
| Korea Health Industry Development Institute        |
| Korea International Trade Association              |
| Korean Institute for the Advancement of Technology |
| Medipixel  |
| Neurophet  |
| Olive Union  |
| Omnifit  |
| Selvas AI  |
| SkyLabs  |
| Soundmind  |
| St Mary's Hospital                                 |
| The.Wave.Talk                                      |
| Vuno   |

