

Healthcare Taiwan

Digital Transformation and Advanced Therapies

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BRITAIN & NORTHERN IRELAND

*The Hamlyn Centre,
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1. Introduction

Taiwan has opportunities for UK digital health and advanced therapies companies, with its world-class information and communication technology (ICT) companies, mature healthcare system, and supportive government all investing into the sector. Taiwanese ICT companies see the digital transformation of healthcare as one of the next frontiers of business growth, whilst the government's health insurance system is looking for solutions to control costs, making Taiwan an attractive market for UK technology and solutions.

According to Taiwan's Ministry of Health and Welfare (MoHW), Taiwan's national health expenditure in 2018 totalled NTD 1.2tn (GBP 32bn), which grew 5% from 2017. This represents 6.6% of national GDP, which is lower than the OECD average of 8.8%. The single-payer system, despite offering comprehensive benefits to 99.9% of the population, has controlled costs in the past by proactively integrating and deregulating for new technology to improve efficiency. It also built a competitive ecosystem to force advancement among the predominantly private delivery system. The government's electronic medical records (EMR) system, for example, was deployed in 2004 and now covers over 90% of hospitals, compared to 12% of NHS Trusts as of 2019, according to OpenText research.

The already progressive healthcare system expects to continue with more digitalisation initiatives with the appointment of Audrey Tang in 2016 as the Digital Minister. She played a key role during Taiwan's successful COVID-19 pandemic response by spearheading the digitisation of mask inventory for mapping and ordering, as well as implementing a digital fence to manage quarantined cases. Currently the youngest minister without portfolio in Taiwanese history, she is tasked with facilitating digitisation efforts by leveraging her unconventional background as a software programmer, civic hacker, Silicon Valley entrepreneur, and Apple's digital advisor for artificial intelligence projects. For a

conservative industry such as healthcare, Ms. Tang is expected to promote and accelerate adoption of new technology by policymakers.

On the private sector side, the presence of mature ICT original equipment manufacturers (OEM) and well-trained healthcare professionals provides a strong foundation for digital healthcare and advanced therapies. The Taiwanese ecosystem allows collaborations between high quality talent in both medicine and engineering. All major hospitals are working with technology companies to improve care and efficiency through digitisation, whilst OEMs see medical IoT (MloT) and smart hospitals as strategic areas for investment.

We see opportunities for innovative solutions from the UK in telemedicine, MloT, AI, Big Data, blockchain, precision medicine, and cell therapy. As local competition builds market need through education and pilot projects that demonstrate tangible benefits, the willingness to invest and purchase solutions will continue to grow. With the launch of "Taiwanese Firms' Repatriation" - a plan to bring back manufacturing from China - 154 mainly export-oriented electronics businesses pledged to invest NTD 678bn (GBP 18bn) in manufacturing and R&D. We expect this to increase after the COVID-19 pandemic exposed weaknesses of a China-centric supply chain. Therefore Taiwan presents opportunities not only with its growing domestic market, but also through its integral role in the global ICT supply chain that makes it a strategic gateway into the digitisation of healthcare globally.

2. Taiwan: An Overview

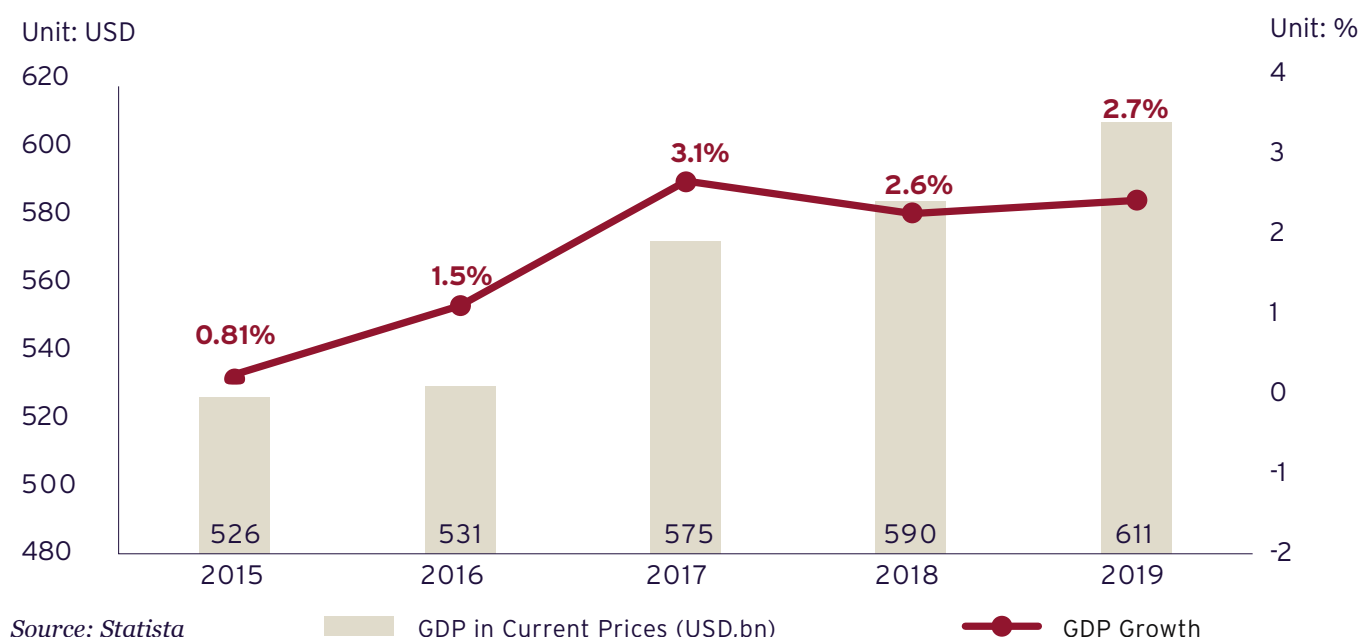
KEY POINTS

- Taiwan is a global powerhouse in technology manufacturing and has an export economy around electronics, machinery, and petrochemicals
- Taiwan's GDP is ranked 20th among 193 countries and regions tracked by IMF in 2020
- UK is Taiwan's third biggest trading partner in Europe

Taiwan is an island with a total land area of 36,193 square kilometres, which is roughly half of Ireland. It is located southeast of mainland China and is separated by the 180-kilometre Formosa Strait. With a population of 23.7 million people, its population density is 2.5 times that of the UK. Its economy is driven by industrial manufacturing, especially exports of electronics, machinery, and petrochemicals. According to Statista, Taiwan's national GDP reached USD 611bn (GBP 489bn) in 2019 and per capita GDP reached USD 25,008 (GBP 20,006) in 2018. The GDP growth of Taiwan was 2.7% in 2019, surpassing comparable neighbours South Korea (2.0%), Singapore (0.7%), and Hong Kong (-1.2%). Taiwan's GDP ranks 20th among 193 countries and regions according to the IMF's World Economic Outlook Database April 2020 report.

Taiwan is a global powerhouse in technology and has a significant lead as the world's most sophisticated producer of semiconductors. In 2019, the majority (75.6%) of worldwide integrated circuits foundry revenue was captured by Taiwan, according to Taiwan Semiconductor Industry Association. International trade in Taiwan is officially assisted by the Taiwan External Trade Development Council. The UK is currently Taiwan's third biggest trading partner in the European Union; UK exports to Taiwan grew by 40.8% from GBP 1.96bn to GBP 2.76bn and bilateral trade rose by 16.4% to GBP 6.6bn in 2018. In 2019 trade talks, the UK and Taiwan agreed to enhance cooperation and both see the uncertainty of Brexit as an opportunity to deepen ties.

Figure 1: Taiwan GDP (2015 - 2019)



2.1 Taiwan's Healthcare System

Taiwan's healthcare quality ranked number one among 93 countries in the 2019 Health Care Index released by Numbeo, which factored in skills and competency, speed, modern equipment, responsiveness, accessibility, and cost. The main regulatory body is the Ministry of Health and Welfare (MoHW) and the health insurance system is run by the National Health Insurance Administration (NHIA).

The National Health Insurance (NHI) is a single-payer universal health coverage scheme that provides comprehensive health insurance to Taiwan's 99.9% of citizens and foreign residents. NHI covers not only western medicine but also traditional Chinese medicine and dental care. Taiwan's healthcare delivery system is dominated by the private sector, with private ownership accounting for 83% of hospitals and 98% of clinics.

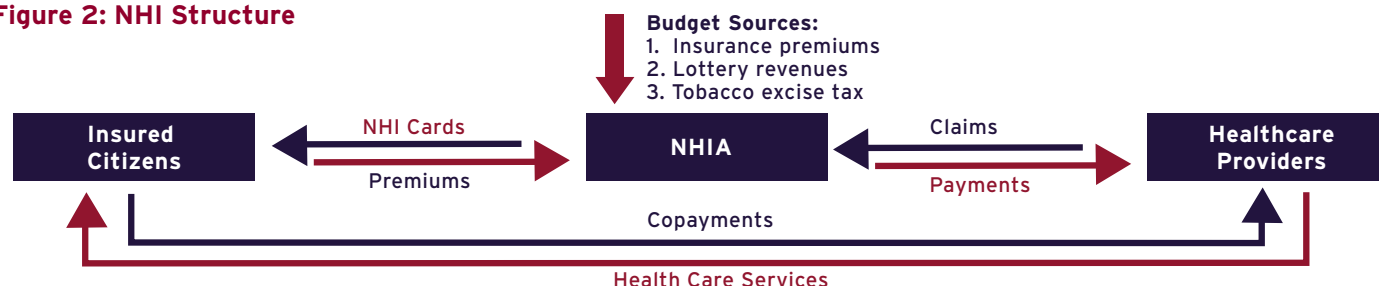
As of 2018, the delivery network included 483 hospitals, 11,580 western medicine clinics, 3,917 traditional medicine clinics, and 6,836 dental clinics. With more than 92% of clinics and hospitals contracted to the NHI, there are more than 44,000 doctors and 13,000 dentists available, giving patients a wide range of options for doctors and hospitals.

This creates a competitive market and encourages healthcare institutions to provide high quality care. The national total number of hospital beds is 167,521, which equates to 7.1 hospital beds for every 1,000 citizens. UK's national average is 2.5 beds per 1,000, according to OECD in 2017. Table 1 below provides an overview of the five largest hospitals in Taiwan.

Each NHI user holds an NHI IC card that contains the user's medical data. A swipe of the card gives the physician instant access to real-time medical records. Due to easy access and affordable cost, the number of annual outpatient visits per person averaged 15 times, and the number of hospital admissions per 100 persons averaged 14.4 times in 2017, which is significantly higher than OECD countries. Public satisfaction rose from 39% in 1995 to 89.7% in 2019 according to MoHW.

The combination of the comprehensive NHI and high hospital visit rate of Taiwan, in addition to Taiwan's advanced ICT infrastructure and government's push for integration of new healthcare solutions, asserts Taiwan as an excellent ecosystem for new digital healthcare applications and offers ample opportunities for innovative UK digital healthcare businesses.

Figure 2: NHI Structure



Source: Intralink Research

Table 1: Taiwan's 'Big 5' Hospitals

Hospital	Hospital Beds	Annual Outpatients	Annual Inpatients
Chang Gung Memorial Hospital (Linkou)	3,700	4M	100K
Taipei Vets General Hospital (Taipei)	2,800	2.5M	128K
National Taiwan University Hospital	2,600	2.9M	110K
Chang Gung Memorial Hospital (Kaohsiung)	2,200	2M	80K
China Medical University Hospital	2,100	2.2M	87K

Source: Intralink Research

3. Digital Healthcare Market Overview

KEY POINTS

- The Taiwanese government is leveraging technology in healthcare to decrease cost and improve efficiency as it prepares for Taiwan to become a super-aged society by 2026
- Private sector, especially major ICT manufacturers, sees digitisation of healthcare as the next frontier of growth as the traditional electronics market reaches maturity and saturation
- Key players include ICT companies Foxconn, Quanta, Compal, Wistron, Inventec, Asus, Acer, HTC, as well as publicly registered medical foundations with hospital networks and in-house engineering departments

Taiwan will become a super-aged society by 2026, where at least 20% of the population are 65 years-old or older. The rise of healthcare costs due to an ageing population and an increase in chronic disease prevalence will increase pressure for Taiwan's government to improve efficiency of care through leveraging technology. Without intervention, the National Health Insurance fund is expected to run into unsustainable income deficit levels within two years. As a result, healthcare digitalisation and collaboration between private and public sectors are widely encouraged.

On the private sector side, Taiwan is a global leader in supplying information and communications technology (ICT), with 23.7% of the world's smartphones manufactured by Taiwanese companies, according to Research and Markets, a leading market research firm. However, IT hardware industry growth was stagnant at 0.3% in 2018, causing major Taiwanese hardware companies to look elsewhere for growth. Many key players see digital healthcare, which includes smart hospital systems, medical equipment, and mobile health, as their future area of grow and have invested heavily.



3.1 Key Players

Taiwan's key players in digital health that influence market development include major ICT corporations and hospital networks owned by medical foundations. Due to Taiwanese ICT companies' heritage as contract manufacturers with strong original equipment manufacturer (OEM) as well as original design manufacturer (ODM) capabilities, most offer "total solutions" for private labelled hardware and software systems through leveraging their world-class research & development, manufacturing, and design talent.

“ Industry Insider's Thoughts

With merely 1% of the (Taiwanese) ICT gain invested in healthcare, the R&D investment would reach USD 4.2 billion (GBP 3bn) a year.”

Taiwan's Institute of Biotechnology and Medicine Industry (IBMI) - Vice-chairperson, Dr. Pan-Chyr Yan

Table 2: Major ICT Corporations with Digital Health Coverage

Corporations	Revenue '19	YoY Growth	Healthcare Subsidiaries and Businesses
Foxconn	USD 176bn (GBP 141bn)	+0.8%	Subsidiaries include digital healthcare solution systems company Heathera, medical equipment manufacturer Coning, cancer detection company Genconn, health management company Healthconn.
Quanta	USD 34bn (GBP 27bn)	+0.2%	QOCA is Quanta's smart healthcare solutions brand, which includes telehealth and smart ward & hospital solutions that leverage IoT, AI, and cloud computing.
Compal	USD 32bn (GBP 26bn)	+1.3%	Products and services include home and wearable IoT for the elderly & childcare, and fitness using edge computing and big data.
Asus	USD 12bn (GBP 10bn)	-1.0%	Subsidiary Asus Life is a joint venture with OmniHealth (Show Chwan) Healthcare System. It provides digital transformation products and services to hospitals, including the OmniCare platform, which integrates IoT medical devices and big data.
Wistron	USD 29bn (GBP 23bn)	-1.2%	Subsidiary Wistron Medical Technology (WMT) offers smart hospital and medical IoT platforms. Also offers exoskeleton, medical imaging, life science instrument and IVD solutions.
Inventec	USD 17bn (GBP 14bn)	-1.2%	Service includes design and manufacturing of diagnostics, life science, point of care testing instruments and devices.
Acer	USD 8bn (GBP 6bn)	-3.3%	Solutions include integrating AI into healthcare workflows to use software as a medical device. Key product VeriSee is an AI-assisted diagnostic software to identify diabetic retinopathy.
HTC	USD 333m (GBP 265m)	-57.8%	Subsidiary DeepQ is developing AI-powered mobile wireless diagnostic instruments. Products include virtual reality (VR) surgical training theatres and hospital AI chatbots.

Source: Intralink Research.

Key ICT players interviewed for this report, such as Quanta and Wistron, presented broad product and service portfolios with minimal emphasis on specific disease areas. Instead, they work with major hospitals and medical foundations to access healthcare specific expertise. Private clinics, though large in terms of number and coverage, are typically run as small businesses – they are cost sensitive and do not typically invest into research and development of new digital health solutions.

Within this report, we will focus on key areas where Taiwan presents opportunities for UK businesses, specifically: telehealth and medical IoT, medical AI and Big Data, and blockchain. However, the digital healthcare ecosystem is not limited to the above. Figure 3 below provides a summary of digital health areas in which large Taiwanese companies are investing to develop solutions, categorised by healthcare subsector.

Table 3: Digital Health Projects of Major Hospitals

Hospital	Beds	Area(s) of Focus
Veterans General Hospital (Taipei)	2,800	AI-supported diagnosis for oncology, osteopathology, and neurology related MRI. Smart hospital with digitised patient visit flow, resource planning, and medical devices connected to integrate HIS.
National Taiwan University Hospital	2,600	Telehealth for remote care of chronic diseases, especially cardiovascular and metabolic diseases such as hypertension, diabetes, and hypercholesterolemia.
China Medical University Hospital	2,100	Digitised ward through tablets for hospital staff and patients to access medical information, including automatically uploaded patient vitals, prescription instructions, hospital meal orders.
Changhua Christian Hospital	1,200	Unmanned vehicle delivery system to decrease cross-contamination and labor cost. Hemodialysis treatment big data for early warning system to predict acute hypotension.
MacKay Memorial Hospital (Taipei)	900	Smart hospital system to manage patient flow, security patrol, phlebotomy assistance, and medical supply with unique device identification (UDI).
Taipei Medical University Hospital	800	Blockchain-based patient record smart contract system “iTPASS” for inter-hospital transfer. Predictive AI algorithms for intensive care unit electronic dashboard (TED ICU) early warnings. Contact-less care with video AI algorithm and IoT for vital sign monitoring.
Chang Gung Memorial Hospital (Taipei)	300	Centre for Artificial Intelligence in Medicine supporting over 10,000 beds within its hospital network for diagnosis, disease prediction, medical imaging processing, and drug development by leveraging big data within its network.

Source: Intralink Research

Figure 3: Ecosystem Players and Digital Health Subsectors

Smart Hospital Systems	Medical Equipment	Mobile Health
		
<ul style="list-style-type: none">• AI medical solutions• Electronic medical records (EMR) & electronic patient records (EPR)• Mobile nursing systems• Smart wards & operating room• Medical monitors	<ul style="list-style-type: none">• 3D surgical navigation & VR training• X- ray/ultrasounds/Micro CT• Hemodialyzer• Assistive robots for surgery & rehabilitation• Capsule endoscopy• Clinical pathology analyzer• Molecular diagnosis• Physiology monitor	<ul style="list-style-type: none">• Telehealth• IoT equipment and solutions• Wearable devices• Health managements systems• Medical bioinformatic security

Source: IBMI

4. Key Areas in Digital Health

KEY POINTS

- Key areas in digital health include HIT, telehealth and MIoT, AI and Big Data, and blockchain
- Government is supporting digital transformation of healthcare through pilot projects, deregulation, and investment
- Industry strengths: high adoption of electronic medical records, high quality of medical data, strong foundation for hardware and software engineering, mature supply chain for IoT and medical devices
- Key opportunity areas:
 - HIT: platforms and tools to integrate fragmented EMR databases and share data securely
 - Telehealth and MIoT: software and protocol for use and management of medical IoT devices, especially for mobile and at-home care
 - AI and Big Data: foreign market approved AI for use as medical device, especially niche and/or rare disease areas
 - Blockchain: patient record management for inter-institution transfer, and supply chain security

4.1 Health Information Technologies (HIT)

Taiwan's healthcare system officially started its digital transformation after the implementation of electronic NHI IC cards in 2004. In November 2009, Taiwan's Executive Yuan (the executive branch of the ROC government) passed the "Plan for Accelerating the Implementation of Electronic Medical Record Systems in Medical Institutions (2010-2012)". The government allotted NTD 6bn (GBP 158m) to help hospitals and clinics with digital transformation. The focus of this plan was to establish the National Electronic Medical Record Exchange Centre (EEC). A hospital's information system connects to the EEC through an electronic medical record (EMR) gateway. This includes outpatient records, outpatients drug history, blood test, image reports, and discharge summary in the past six months. Inter-institution EMR exchange made it easier for people to access their medical records, reducing waste of

medical resources and improving the quality of medical care. The MoHW indicated that adoption rates of EMR and EEC system were 90% in hospitals and 70% in clinics at the end of 2015.

Rather than outsourcing to a service provider, the majority of Taiwan's notable medical centres develop and maintain their own in-house healthcare information technology, including Chang Gung Memorial Hospital, Taipei Medical University Hospital, China Medical University Hospital, and Kaohsiung Medical University Hospital. Other smaller hospitals and private clinics buy healthcare information technology from the aforementioned hospitals or third-party suppliers such as Vision Asia Medical Information Company or Techgroup Integrated Design Company, which are both leading Taiwanese HIT system and service providers.

Market Gaps and Opportunities

In Taiwan, over 90% of hospitals have implemented EMR and EEC. However, inter-institution EMR exchange still requires handwritten and signed consent forms. Hospitals like Chang Gung Memorial Hospital and Taipei Medical University Hospital started digital transformation early and are on their way to go fully paperless, with many more hospitals expected to follow. To fully digitise the EMR exchange process, key gaps in technology products and services remain – as discussed below.

Medium and small hospitals and private clinics often operate as small independent businesses, so they typically do not have sufficient funding to support a full-time in-house IT team to develop their own information systems. They either purchase IT solutions from bigger hospitals or third-party providers such as Vision Asia. However, the pre-packaged solutions fall short in customisation options for a limited budget, especially as each clinic can offer different combinations of healthcare services to patients.

Even after implementing IT systems, self-funded hospitals and clinics typically minimise maintenance costs of IT since it does not directly increase revenue generation. With low investment into IT, networks and processing speed can be discouragingly slow for physicians. The study in Journal of Medical Informatics “An Assessment of the Interoperability of Electronic Health Record Exchanges among Hospitals and Clinics in Taiwan”, published in 2019 indicated that doctors identified the long wait time to load information as a reason to use the service less. Our research and interviews also found that due to use of different developers and systems by departments, the result is a confusing work environment. For example, doctors, nurses, radiology departments, and surgery department may all use different systems with different user interfaces and printed outputs within the same hospital. This is especially problematic for high-pressure emergencies and older doctors, therefore presents opportunities for cohesive IT solutions.

For large and well-funded hospitals, many have developed their own highly customised and comprehensive IT systems. However, the lack of coordination in format, structure, and architecture is a challenge for further use of the data, such as

Big Data analysis and insurance reimbursement. For additional details on Big Data applications, please refer to the AI and Big Data section of this report.

As a result, UK companies with hospital information system solutions that plan to enter Taiwan should be aware of the fragmented marketplace that is served by not only local third-party vendors but also large hospitals that package in-house solutions for resale. The key areas where we see opportunities for UK businesses are below, ranked loosely with most attractive opportunities on top:

1. Affordable IT systems for smaller hospital and clinics: solutions that can be configured easily and at low cost to suit individualised needs will be able to differentiate and compete with local vendors
2. Platforms that comply with the latest requirements: including requirements from government for EMR and EEC, as well as needs of physician and user operating environments
3. Data sharing and data security protocols or tools: especially with ability to quickly compress and encrypt, for EMR with images and audio/video recordings
4. Data consolidation and integration tools: especially for AI and Big Data analysis or insurance applications

In summary, the above solutions for HIT will have market opportunities in Taiwan with medium and small hospitals run as private businesses, as well as large hospitals funded by publicly registered medical foundations.

“ Industry Insider’s Thoughts

Data starts from doctors making decisions. We are trying to build a page of selectable routine options to help doctors documenting medical decisions and patient progress. This not only saves time for doctors but also will be easily recognisable for AI and big data analysis in the future. ”

Taipei Medical University Hospital Superintendent,
Dr. Ray Jade Chen

4.2 Telehealth and Medical IoT

Taiwan began developing telehealth in 1995. Initial efforts focused on supporting care of citizens off the main island, where healthcare resources are scarce. Medical centres on the main island used telecommunication technology to exchange information with off-island clinics through video conference of physician-patient consultations and physician-physician diagnosis discussion meetings, as well as sharing of medical history and images.

According to Taiwan's National Health Insurance Administration (NHIA) in March 2020, during the COVID-19 outbreak, there were 3,417 hospitals that offered telehealth services. This allowed video consultations with physicians to replace on-site visits for follow-up, but not first-time visits. For patient confidentiality concerns, physicians are required to be on-site during remote consultations and no recordings can be made. Readings from MIoT devices can be collected remotely and shared with physicians, who can then create medical records and prescriptions remotely.

Table 4: Telehealth Hospital Count by Geography

Region	Key Cities	Telemedicine Hospital Count
Northern Taiwan	Taipei, Taoyuan, Hsinchu, Keelung	335 (87 in Taipei)
Central Taiwan	Taichung, Miaoli, Changhua	826
Southern Taiwan	Kaohsiung, Pingtung, Chiayi	2,221 (2044 in Kaohsiung/Pingtung)
Eastern Taiwan	Hualian, Taitung	35
Total		3,417

Source: Taiwan NHIA

As telecommunication accessibility and acceptance in society improved with increased user-friendliness and exposure to internet-based services, the Ministry of Health and Welfare (MoHW) launched telehealth pilot projects in 2008 and 2010. The focus shifted from pure communication of information to administration of care through integrated community centres, private homes, and healthcare institutions. To accomplish this, telehealth services added medical IoT (MIoT) device-to-human for support.

The Medical Internet of Things (MIoT) market will mature because telehealth drives healthcare and patient monitoring out of hospitals and into communities and homes. Taiwan's key players in MIoT have strong backgrounds in hardware manufacturing and a broad range of devices and applications for smart hospitals, medical equipment, and mobile health (detailed in the Digital Healthcare Overview section of this report). On top of remote monitor of patients by human physicians, artificial intelligence (AI) and Big Data are also leveraged to manage workload and information, which is discussed in the next section of this report.

Market Gaps and Opportunities

As a rapidly ageing society, Taiwan focused its telehealth efforts on elderly care and chronic diseases. For elderly care, Taiwan's government published the "Long-term Care 2.0 Plan" (LTC 2.0) in 2017, with a budget of NTD 2bn (GBP 53m), which increased to NTD 30bn (GBP 791m) in 2018 to cover more people and services. The number of services covered by LTC 2.0 includes several items, and the most relevant for elderly care are dementia care, family-care support, community-based preventive care, and hospital discharge and transition care. LTC 2.0 was developed with Taiwan's cultural preferences in mind and to keep healthcare delivery costs down. Specifically, Taiwanese families generally prefer to have their elderly "age in place" instead of moving to a senior home. To fulfil localised care, three tiers of service centres were deployed: Tier A "flagship stores" for community-based service centres, Tier B "specialty stores" for

day-care service centres, and Tier C "corner stores" for stations dispersed in alleys. The goal is to offer physical and mental care within thirty-minute drive of homes.

Chronic disease care is typically focused around monitoring hypertension, hyperlipidaemia, and diabetes. Many companies are working with hospitals to develop remote monitoring systems that send data from Bluetooth connected medical devices to hospitals. Diabetes, for example, is only covered under the National Health Insurance for up to one check-up session every three months. However, through remote monitoring, physicians can receive daily data that alert them of abnormal events to trigger a proactive call to the patient to provide timely advice to change diet, exercise, or insulin routines.



Table 5: Examples of Telehealth Projects

Hospital Name	Partner	Description
Changhua Christian Hospital	Compal Electronics	Diabetes e-Institute is a cloud platform integrated into the hospital system for remote care of diabetic patients. Compal Electronics developed iDiabCare app with CCH so patients can record blood glucose before a meal, take a photo of the meal, then record blood glucose after the meal.
Taipei Medical University Hospital	SECOM	Various pilots, for example a community-based telehealth system with Taiwan SECOM. Includes 24-hour call centre that can be triggered by smart home system (MyCasa) in an emergency event. Other telehealth systems include pacemaker monitor, continuous glucose monitor, insulin pump, sleep apnea syndrome, wireless vital sign monitor, vital sign monitor.
MacKay Memorial Hospital (Taipei)	Rooti	Single-lead ECG for continuous and remote monitoring of heart health.

Source: Intralink Research

Taiwan is a global powerhouse for outsourced design and manufacturing of electronic hardware. As a result, there is strong local competition that can supply hardware needed for remote care of elderly and chronic diseases.

For UK businesses, there are opportunities in specialised software and services, because Taiwan's local players are focused more on hardware. According to a 2019 report by Taiwan's Industrial Technology Research Institute (ITRI), the country's national information and communications technology (ICT) spending is concentrated on devices (48.8%), which includes personal computers, tablets, and mobile phones. Taiwan's spending on services is small (18.2%) compared to United States (49.6%) and Japan (60.0%).

“ Industry Insider's Thoughts

We are developing next generation smart home systems for elderly care but cannot find good algorithm suppliers. For example, we want to analyse water and electricity usage patterns to create alerts if the pattern is unusual. We looked for IoT machine learning algorithms suppliers for this in Taiwan but could not find any. ”

SECOM Healthcare, R&D Manager

Robert Lien

Table 6: Ratio of Total National ICT Spending

Country	Taiwan	United States	Japan
Data Centres	11.7%	9.7%	6.6%
Services	18.2%	49.6%	60.0%
Software	21.3%	23.6%	11.4%
Devices	48.8%	17.1%	22.0%

Source: ITRI 2019 Report

As a result, UK companies with telehealth and MloT solutions that plan to enter Taiwan should be aware of local ICT hardware competition. The key areas where we see opportunities for UK businesses are below, ranked loosely with most attractive opportunities on top:

1. Telehealth software platforms: includes telehealth business-to-business platforms as well as business-to-consumer platforms to connect healthcare devices and caregivers, especially to improve interoperability of a fragmented market with no clear leader
2. MloT protocols and infrastructure: includes backend solutions for medical device use, such as low latency for immediate feedback, high frequency and high-volume processing, and advanced encryption for data privacy.
3. Medical education tools and services for non-professional caretakers: includes software and services to train and facilitate healthcare administration by community or family as patients are given medical care outside of hospitals
4. Mobile healthcare tools: includes remote diagnosis and treatment, for example in a moving ambulance, to facilitate immediate data sharing, decision, consent, and treatment
5. Edge computing solutions: includes systems for immediate feedback, such as ECG wearable devices with integrated alert algorithm for abnormal cardiac activity, for improved prognosis

In summary, the above solutions for telehealth and MloT will have market opportunities in Taiwan for remote monitoring and care of chronic diseases, such as diabetes and hypertension, as well as aging associated diseases, such as dementia, functional limitations and disabilities, or frailty issues.

“ Industry Insider’s Thoughts

With a focus on prevention over treatment, Taiwan’s government spending on medical devices (for early detection) grows at 3-5% annually, versus pharmaceutical spending is relatively flat. Our National Health Insurance covers telehealth so hospitals can justify the investment on our telehealth hardware, such as Bluetooth connected endoscopes, otoscopes, and dermoscopes. ”

MiiS (remote medical image solutions startup in Taiwan)
- CEO, Stefan Cheng

4.3 Artificial Intelligence and Big Data

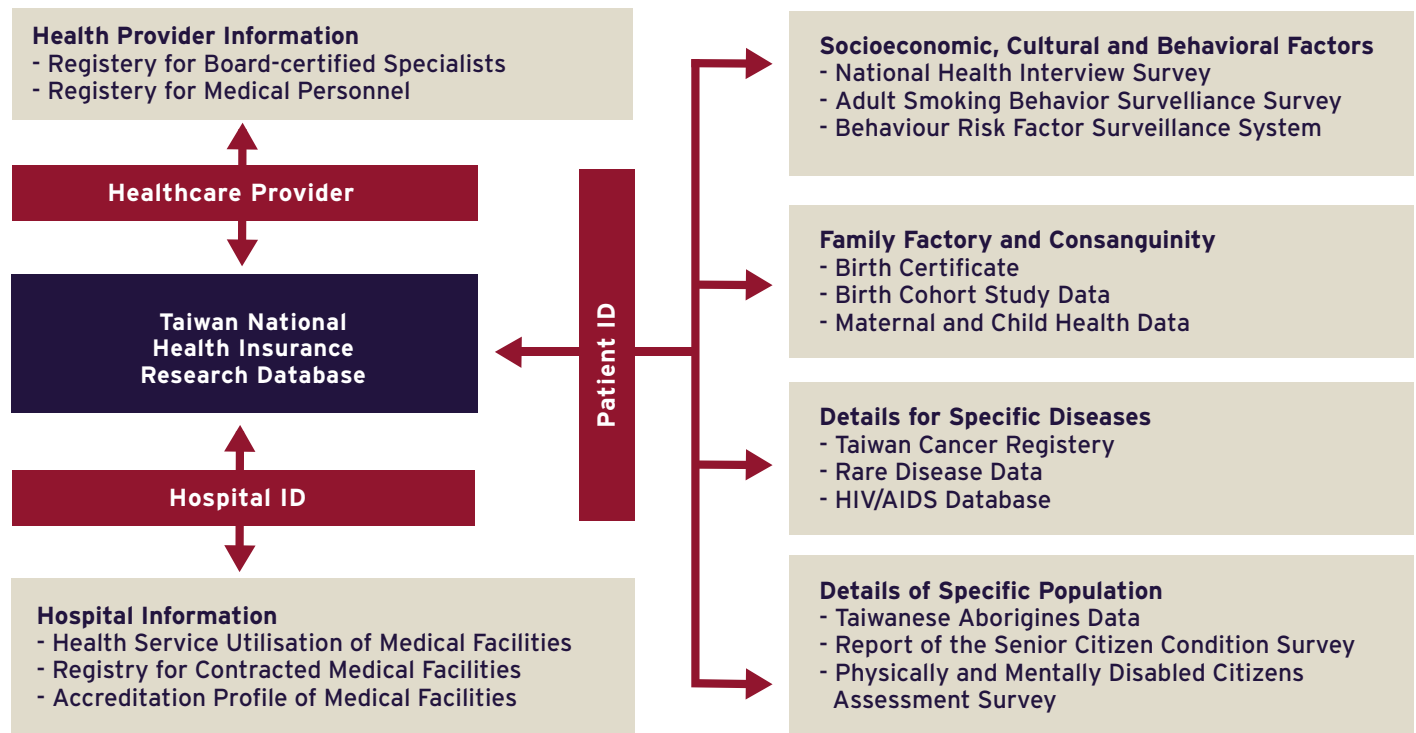
On January 18th, 2018, the Executive Yuan published a four-year “AI Action Plan” with a budget of NTD 38bn (GBP 1bn) and the Ministry of Science and Technology (MoST) published a five-year “AI Strategy” with a budget of NTD 16bn (GBP 422m). The investments aim to grow Taiwan into one of the world’s leading smart nations by focusing on five components: developing AI talent, promoting Taiwan’s leading role in AI, building Taiwan into an AI innovation hub, liberalising laws and opening test grounds, and transforming industry with AI.

In the same year, global AI leaders including Google, Microsoft, IBM, and Amazon, all announced major investment and expansion of their AI research and development capabilities in Taiwan. A key reason is the high calibre of local engineering talent that rivals their western counterparts, but at one-fifth of US salaries in 2018, according to AppWorks Ventures, one

of Asia’s largest accelerator networks that is focused on early stage investments. For example, the foundational DeepMind research for AlphaGo was co-authored by Taiwanese born and raised computer scientist Aja Huang, along with David Silver, in 2016.

Other than great R&D talent, the other precursor needed for strong AI solutions is accessibility to high quality training data. Taiwan’s Ministry of Health and Welfare (MoHW) established a Health and Welfare Data Centre (HWDC), which is a centralised data repository that includes National Health Insurance Research Database (NHIRD) and nearly seventy other health-related databases, according to 2019 Clinical Epidemiology Journal paper “Taiwan’s National Health Insurance Research Database: Past and Future”. The database was started in 2002 for public research use, and covers 99.9% of Taiwanese population’s healthcare, demographic, and behavioural data.



Figure 4: Taiwan National Health Insurance Research Database

Source: 2019 *Clinical Epidemiology Journal*, Taiwan's National Health Insurance Research Database: Past and Future

The NHIRD database was used to develop applications that include disease research and treatment to improve medical care. Other than research use, the government has also developed:

- **MediCloud:** launched in 2013, it is a centralised patient information system for physicians, which is updated on a rolling daily basis. It includes prescription information, lab results, CT scans, MRIs, ultrasounds, colonoscopies, X-rays from clinics and hospitals. The key goal is to reduce waste of medical resources through sharing medical information.
- **My Health Bank:** launched in 2014, it is a personal healthcare information mobile app for patients. Users can access their health records that covers record histories of the past three years. The goal is to enable users to manage their own health through convenience and education.

- **AI Analysis of NHI Data:** launched in 2019, the pilot program allows researchers, including hospitals, universities, or research institutes, to access NHIRD through submitting applications. After signing data privacy agreements and receiving approval from the Institutional Review Board (IRB), researchers can access data of up to 10% of Taiwan's population, which is roughly 2.3 million. The goal is to give the Taiwanese biotechnology and healthcare industry a data quality advantage in research for sectors such as precision medicine – a topic discussed later in this report.

Market Gaps and Opportunities

Enthusiasm from the government and market to leverage AI and Big Data for healthcare creates opportunities for UK companies where local suppliers fall short. Though there are data privacy regulations and restrictions, which are covered in the Regulations section of this report, Taiwan's market accessibility for foreign companies is relatively high compared to mainland China. To compete successfully against local companies, UK companies will need to offer differentiated AI and Big Data solutions. Specifically, many end users such as large hospitals or research institutes will have dedicated information systems departments with strong AI and Big Data engineering teams that are developing their own solutions based on existing mainstream AI frameworks.

“ Industry Insider’s Thoughts

We have a team of 22 engineers dedicated to the digital transformation of our hospital. It started when we visited the US and saw an ICU solution that used AI to manage medical orders and monitor vital signs. We really liked it, but it costs two million US dollars to implement plus additional maintenance cost, so we took the concept and custom built it for our needs. We built our “TED ICU” system for cheaper and now are planning to sell it overseas to generate additional income for the hospital. ”

Taipei Medical University Hospital Superintendent,
Dr. Ray Jade Chen

Table 7: Examples of AI Companies

Company	Established	Description
iXensor	2012	World's first US FDA approved smartphone camera-based blood test system. PixoTech uses colour sensing AI and a hardware module with biochemical test strip for HbA1c and lipid panel. Eveline is the world's first AI-powered ovulation prediction kit based on PixoTech.
Aether AI	2015	AI-powered web platform for medical image analysis in pathology, radiology, and haematology. Preparing for US and Taiwan FDA clearance under Class II fixed model (non-learning) AI.
Deep01	2017	First Asia Pacific AI start-up to obtain US and Taiwan FDA clearance. AI-powered brain CT image analysis to detect and localise intracerebral haemorrhage within 30 seconds, surpassing Israeli competitor's five minutes processing time.
Ever Fortune AI	2017	AI-powered systems for bone age assessment, breast ultrasound tumor classification, liver cancer metastatic risk assessment, liver fibrosis assessment, and atrial fibrillation detection. Preparing to submit to US and Taiwan FDA for clearance in 2020.
AI Explore	2017	AI with high performance computing (HPC) for real-time gigapixel analysis for pathology, radiology, cytology disease detection and classification using 1D, 2D, 3D, or multi-dimensional data.

Source: Intralink Research.

Additionally, Taiwanese ICT companies are also another source of strong competition offering AI and Big Data capabilities as part of their total system solutions. Many will work with local startups to codevelop solutions, especially for relatively mature AI use cases such as medical imaging, as there are many strong local vendors.

As a result, UK companies with AI or Big Data solutions that plan to enter Taiwan should be aware of local competition from startups and ICT companies, as well as the internal engineering departments of hospitals. The key areas where we see opportunities for UK businesses are below, ranked loosely with most attractive opportunities on top:

1. AI solutions for niche or specialised applications: especially where it requires prohibitively high cost to get expertise, such as rare disease diagnosis, for hospitals and research centres to build in-house
2. AI-powered assistive or automated alert systems: especially to increase efficiency and decrease workload and error of healthcare systems, personnel, and community or family caregivers
3. AI with government approval: foreign market traction, such as US FDA clearance, will help accelerate Taiwan FDA clearance to capture local market share through device makers and system integrators
4. Big Data mining tools: especially to process multi-dimensional data, such as NHIRD, to help policy makers, health administrators, public health authorities, drug development, and clinical research
5. Big Data security and infrastructure tools: especially to manage growing digitised health data from MIoT devices, hospital health records, public health data, for consumers and businesses
6. AI and Big Data for healthcare education and customer service: especially to decrease public health and hospital burden, such as AI chatbot engines to translate healthcare data, for patients and doctors

In summary, the above technologies are most sought after by the Taiwanese market for chronic disease management, elderly care, cancer early detection, and public health disease prevention and management.

“ Industry Insider’s Thoughts

Our system integration business unit works with corporates and hospitals to build complete IT solutions. Though there are many Taiwanese medical AI companies, most of them are not approved by the Taiwanese FDA (TFDA) so it is limited to research use and not clinical use. This means we cannot commercialise them for at least another two to three years. If there are foreign approved solutions, the pre-approved status will expedite TFDA’s approval time, so we are happy to consider these, because it is more likely to generate revenue for us within the next six to twelve months.”

FarEasTone (major telecom operator in Taiwan)

- Smart Healthcare Product Manager,

Eric Chen

4.4 Blockchain in Healthcare

Taiwan's blockchain applications in healthcare are in their infancy, but experiments and projects are underway. Fintech applications, specifically cryptocurrencies and distributed ledgers, are currently the most mature use of blockchain in Taiwan. Following the UK's lead on creating a regulatory sandbox for financial applications, blockchain-based technology in Taiwan was also given a sandbox in 2018 with the Financial

Trusted Blockchain Applications (INATBA). The platform's goal is to enhance communication and collaboration between academia, government, and the blockchain industry's private sector service and solution providers.

Though healthcare related uses for blockchain have not reached their full potential, an ecosystem is formed with notable players from the application layer, to software, and protocol infrastructure.

Figure 5: Taiwan Healthcare Blockchain Ecosystem

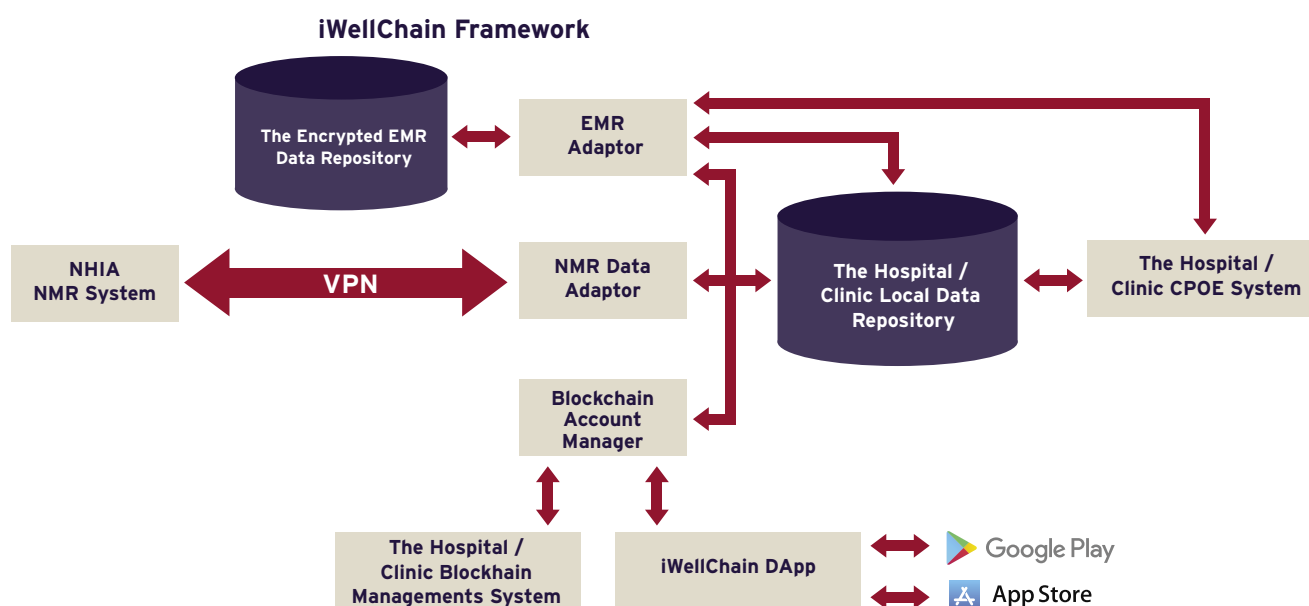


Source: Intralink Research

Technology Development and Innovation Experiment Act. The regulatory sandbox is a supervised testing environment for blockchain businesses to trial new business models that may not be covered or protected under existing regulation. This allows new blockchain applications to rapidly experiment without going through official regulatory approval that are often complex and time consuming. In July 2019, Taiwan's National Development Council (NDC) announced the launch of the government-backed Taiwan Blockchain Alliance, which has a similar function to European Union's International Association for

Market Gap and Opportunities

As described above, blockchain is still in the early stages of development, especially for healthcare. At the time of writing, we found that Taipei Medical University Hospital (TMUH) has the most well developed blockchain solution. TMUH partnered with DTCO, a Taiwanese blockchain integration service provider, to build Personal Health Records Operating System (phrOS) to solve the problem of electronic medical record transfer during patient referral between hospitals and clinics. Patients can enrol by visiting a hospital running phrOS to open an account, then they can access and authorise the sharing of their personal data through the iWellChain DApp (decentralised application).

Figure 6: iWellChain Blockchain Ecosystem Architecture

Source: Taiwan Medical University Hospital (TMUH)

TMUH identified the opportunity to use blockchain's decentralised and secure encryption properties to build its smart contract system. This reduced administrative costs by giving patients full access and control of their medical records, including high-resolution medical images, lab results, and health exams. For patients, it not only simplifies inter-institution transfer procedures, but will also create an opportunity to generate revenue in the future by selling their data for clinical research. TMUH is partnering with Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA) for drug development, and plans to build a patient medical data marketplace for clinical research.

Taichung Veteran's General Hospital (VGHTC) on the other hand, partnered with iOne Technology, a Taiwanese company that provides Blockchain as a Service (BaaS), to build blockchain-enabled solutions for supply chain and logistics management. The system allows real-time and secure order tracking to prevent fraudulent drugs and medical supplies from entering the supply chain.

As a result of TMUH and VGHTC blazing trails to introduce blockchain technology into healthcare, other institutions are expected to begin deeper investigations into potential applications for blockchain. As the market is still maturing, we identified no significant local competition. Instead, there will be many opportunities to increase blockchain's general development and understanding. The key areas where we see opportunities for UK businesses are below, ranked loosely with most attractive opportunities on top:

1. Training and consulting services
2. Outsourced contract development services
3. Complete solutions and products
4. Joint development or research projects

In summary, the above services and products will be most sought after in medical record management for patient referral, drug development, supply chain management, and applications with decentralised databases.

5. Key Areas in Advanced Therapies

KEY POINTS

- The government is supporting the development of the advanced therapies market via approving key projects and regulations
- Industry strengths: Strong NGS technology, cell harvesting and storage, medical centre support, transparent and safe regulatory measures
- Key opportunity areas:
 - Precision Medicine & NGS: Data integration, unique molecular diagnostic tools
 - Cell Therapy: Cell production facility supply chain, cell processing technology

Advanced therapy in this report refers to new medical products that use cell therapy and tissue engineering. The rise of genomics technologies over the past two decades made it possible to determine the sequences of genetic material, and the resulting data can be mined for genetic mutations that cause disease and affect drug response.

As a relatively new area in healthcare, Taiwan's Food and Drugs Administration sees gaps in its understanding of the space. The Taiwan FDA therefore minimises risk in clearance of

new technology by closely following policies in countries that are more advanced, instead of completely denying clearance. For novel drugs and therapies, especially cell therapy, Taiwan defers to US FDA and Japan's Pharmaceuticals and Medical Devices Agency. In 2018, Taiwan became second only to Japan in Asia to approve clinical cell therapy treatments for various types of cancer. This provides foreign investors a platform to explore advanced therapy markets in the Asia Pacific region.



5.1 Precision Medicine

Taiwan's ageing population led to increased prevalence of chronic diseases and rise of medical expenditure. To treat patients in the most efficient way – the right treatment for the right person at right time and every time – the medical world is evolving away from the one-size-fits-all medicine to precision medicine. The goal of precision medicine is to use genomics and Big Data analysis to prevent, predict, and cure diseases. Several countries including the USA, UK, France, and China, have devoted national resources towards developing precision medicine.

The global precision medicine market is expected to register 12.48% CAGR from 2015 to 2022 and is anticipated to reach USD 126bn (GBP 101bn) by 2025. Asia Pacific makes up 14% of the global market in 2017 according to forecasts by Market Research Future, a market intelligence firm.

Taiwan Biobank (TWB) was established by Academia Sinica with the goals of preventing, diagnosing, and treating a wide range of common but life-threatening diseases. In 2012, it began collecting data of 200,000 healthy volunteers, in addition to 100,000 samples from major hospitals, to focus on specific conditions such as cancer, stroke, and Alzheimer's disease. Data collection includes body measurements, blood and urine test results, blood pressure, heart rate, lung function, drug history, on top of surveys of social habits, education level, work and family history. Taiwan, with its comprehensive national health insurance coverage, advanced electronic medical record adoption, and excellent R&D in electronic information, is well-positioned to pursue precision medicine.

In 2019, Academia Sinica further partnered up with 13 hospitals across Taiwan and launched the Taiwan Precision Medicine Initiative (TPMI). Its goal is to profile the genetic makeup of one million participants, especially to improve the understanding of Asian origin genetics because currently most genetic studies and literature are

focused on western populations. Furthermore, in November 2019 the National Health Research Institutes (NHRI) of Taiwan announced a plan to embed whole genome and exome sequencing into Taiwan's health system by 2025 through a partnership with Illumina, a global leader in genetic sequencing technology development and manufacturing. The first milestone is to complete the G2020 Population Genomics Pilot, which has two goals. The first goal is to complete a production scale and accredited genome sequencing facility. The second goal is to implement Big Data platforms to support exchange of genomic and health data with various industry participants.

Currently 31 biobanks in Taiwan of various sizes store personal data of more than 70% of Taiwan's population. To promote efficiency and generate actionable of biobanks, the Executive Yuan actively coordinated with MoHW and NHRI to unite all biobanks. As a result, the National Biobank Consortium of Taiwan (NBCT) officially launched in October 30, 2019. The goal of the NBCT is to consolidate all biobanks, totalling 4.5m samples and data from 460,000 participants. As of today, 21 of the 31 biobanks have agreed to join forces and form a comprehensive database network to enhance Taiwan's biomedical industry ecosystem and improve its competitive edge.

For consumers, genetic testing services can be offered directly through hospitals, and are focused on cancer screening and prenatal testing for genetic diseases. Examples of major test providers include ACT Genomics, Sofiva Genomics, Yourgene Health, GGA Corp, Genomics, and Libogene. NGS supply chain in Taiwan is strong and contributes 20-25% of semiconductors and more than 20% of sequencing chips to the world, according to a report by National Human Genome Research Institute (NHGRI, US).

Market Gaps and Opportunities

Taiwan will be a super-aged society by 2026, therefore early cancer detection and prevention will be a key area of focus. For treatments, Taiwan closely follows the U.S. in the field of precision medicine. With decreasing cost of gene sequencing, Taiwan accumulated large amounts of genetic data. However, with the growing database, gaps are emerging in the market for processing technology, which includes software and hardware.

A whole human genome sequence is large and difficult to interpret, containing 100GB to 1,000GB worth of data. Our interviews with stakeholders suggests that Taiwan lacks professionals in decoding and translating DNA sequence. Despite having strong IT industries, software engineering, and medical expertise, the field of bioinformatics in Taiwan did not receive enough attention from the government and academia until recently. UK companies with strong bioinformatic expertise will have opportunity in either offering the service directly or offering training and consulting services.

Before 2018, less than half of the 31 biobanks had opened their data due to privacy and security concerns. Today, 21 of the 31 banks have agreed to consolidate through National Biobank Consortium of Taiwan (NBCT). Outside of biobanks, precision medicine also requires the participation of pharmaceutical companies, insurance companies, bioinformatics and Big Data analysis to capture its full potential. Hence, security and efficiency interdisciplinary data sharing is a crucial but an unfulfilled gap in Taiwan's market.

On top of the software gaps, the maturing of the physical supply chain also present UK companies with opportunities, such as supply of specialised DNA extraction kits, high quality reagents, and unique biomarkers for detection of disease, especially cancer.

Lastly, as an immigrant society, Taiwanese people's genetic makeup presents interesting opportunities for research collaborations. With the large migration from mainland China into Taiwan in 1949, the majority of the population has Chinese ancestry. This presents opportunities to study the Chinese genome outside of China, where human genetic material is tightly regulated and guarded as a national security issue. UK companies can

leverage Taiwan's relatively more open ecosystem towards foreign companies to develop precision medicine related treatments and databases.

In summary, the above-mentioned solutions are highly sought after in the Taiwanese market, especially for interdisciplinary and/or government administrations and oncology and chronic disease research institutions. The key areas where we see opportunities for UK businesses are below, ranked loosely with most attractive opportunities on top:

1. Genomic data sharing and integration platform and tools
2. Bioinformatics and genomic data interpretation software, services, and training
3. Specialised DNA extraction kit, high quality reagents, and unique biomarkers for cancer detection
4. Precision medicine treatment research & development looking for a gateway into Chinese genomic data

“ Industry Insider's Thoughts

Precision medicine is a tailored medical treatment based on individual's DNA makeup, however most Taiwanese doctors are not traditionally trained to interpret large volumes of genetic sequence data. When understood fully, the data is indicative of the individual's prognosis and can be a significant advantage in not only diagnosis but also treatment advancement. ”

Taipei Medical University - President, Yan Yen

5.2 Cell Therapy

Cell therapy is defined as a medical treatment using viable cells to regenerate functions of tissues or organs impaired by disease or injury. Cell therapy can be applied in treating cancer and degenerative disease, which was previously prohibited in Taiwan and triggering terminal cancer patients seeking cell therapy in other countries, such as Japan and the US, where treatments cost over NTD 1m (GBP 26k). On Sept 6, 2018, the Ministry of Health and Welfare

(MoHW) issued amendments to the “Regulations Governing the Application of Specific Medical Examination Techniques and Medical Devices”. This opened up six areas to cell therapy technology, detailed in the table below. Since then, 100 cell therapy applications for treatment of cancer, degenerative joint diseases, and skin problems, have been submitted by 27 medical institutions and are awaiting approval.

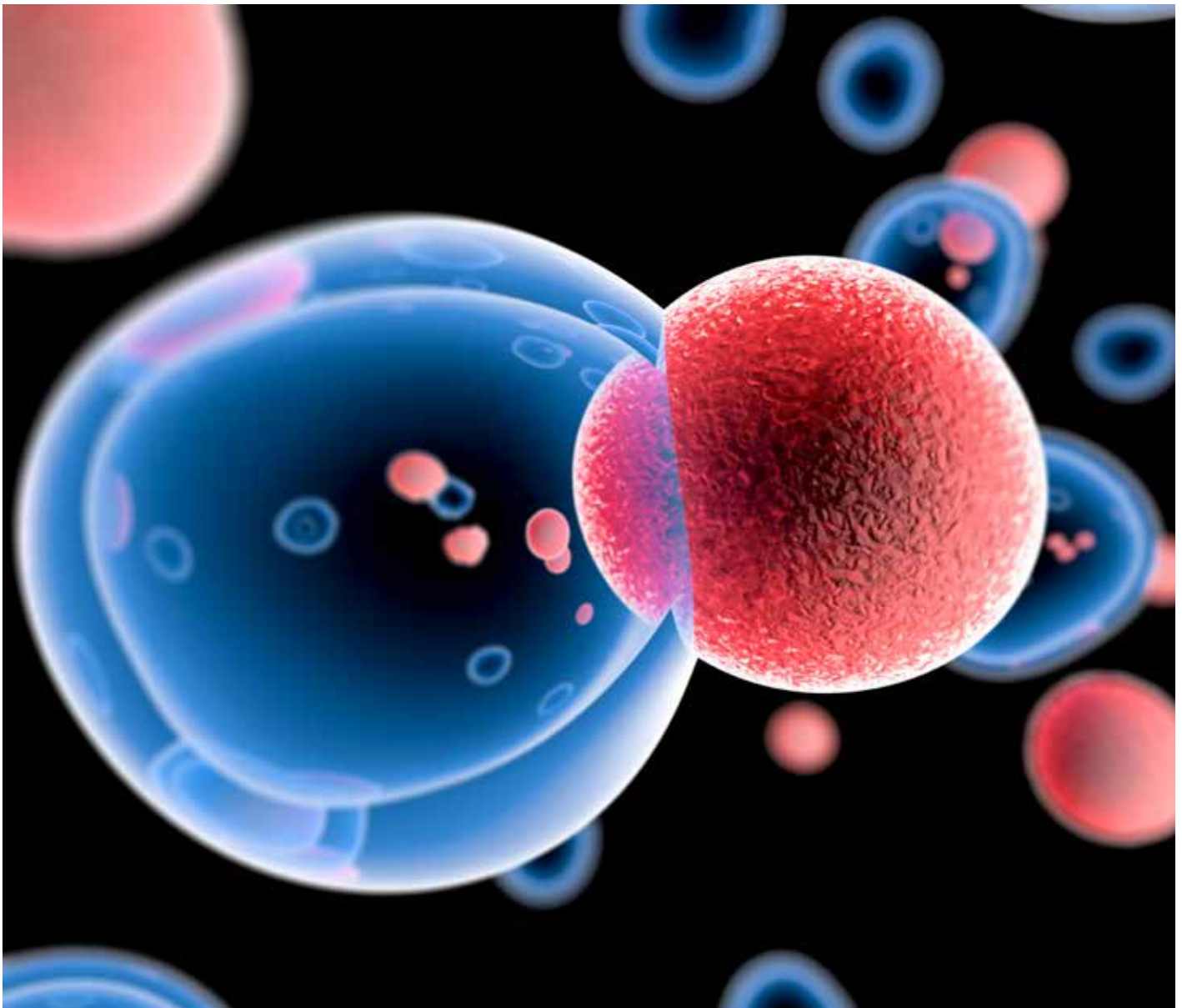


Table 8: Approved Taiwan Cell Therapy Treatments

Project	Description
Autologous CD34+ selection peripheral blood stem cell transplantation	<ul style="list-style-type: none">• Haematological malignancies: leukaemia (excluding chronic phase of chronic myeloid leukaemia), lymphoma, multiple myeloma• Chronic ischemic stroke• Severe lower limb ischemia
Autoimmune cell therapy	<ul style="list-style-type: none">• Haematologic malignancies are ineffective by standard treatment• First to third stage solid cancer, invalid by standard treatment• Solid cancer phase IV
Autologous adipose stem cell transplantation	<ul style="list-style-type: none">• Chronic or difficult wounds that have not healed for six weeks• Large area burns or skin wounds that account for more than 20% of the total surface area• Subcutaneous and soft tissue defects• Degenerative arthritis and knee cartilage defects• Combination or adjuvant therapy for other superficial minimally invasive techniques
Autologous fibroblast transplantation	<ul style="list-style-type: none">• Skin defects: filling and repair of wrinkles, pits, and scars• Subcutaneous and soft tissue defects• Combination or adjuvant therapy for other superficial minimally invasive techniques
Autologous bone marrow mesenchymal stem cells	<ul style="list-style-type: none">• Degenerative arthritis and knee cartilage defects• Chronic ischemic stroke• Spinal cord injury
Autologous chondrocyte transplantation	<ul style="list-style-type: none">• Knee articular cartilage defect

Source: Ministry of Health and Welfare

Fior, a market research firm, estimates that the global market of cell therapy will reach USD 34.4bn (GBP 27.5bn) by 2025 at a CAGR of 16.8% from 2018 to 2025. According to Economy Daily News of Taiwan, the value of the cell therapy market in Taiwan was NTD 16.5bn (GBP 435m) in 2019 and it will increase to at least NTD 40bn (GBP 1.1bn) in 2023. Speedy approval by MoHW and increasing investments from private firms are driving rapid growth.

To date, 12 hospital partnerships with local biomedical companies have received approvals from MoHW, detailed in the table below. The majority of the projects approved are for cancer indications. However three out of the four most recent approvals were for degenerative knee treatments.

Table 9: Hospital Cell Therapy Partnerships and Projects

Hospital	Partner	Description	Approval
Tri-Service General Hospital	Ivy Life Science	<ul style="list-style-type: none"> • CIK cell for hematologic cancer that are ineffective by standard treatment • CIK cell for stage IV liver and lung cancer 	2019/05/03 2019/07/22
China Medical University Hospital	Ever Supreme Bio Technology	<ul style="list-style-type: none"> • DC for stage IV solid tumour • DC for Stage I-III solid tumour that are ineffective by standard treatment 	2019/05/15 2019/09/16
Hualien Tzu Chi Hospital	Taiwan Advance Bio-Pharmaceutical	<ul style="list-style-type: none"> • CIK cell for stage IV lung cancer, oesophagus cancer, colorectal cancer, breast cancer, liver cancer, brain tumour and renal cancer 	2019/08/22
Taipei Medical University Hospital	Guang-Li Biomedicine	<ul style="list-style-type: none"> • CIK cell for stage IV colorectal cancer, breast cancer, lung cancer, cervical cancer, ovarian cancer, kidney cancer, liver cancer, pancreatic cancer, nasopharyngeal cancer, stomach cancer, oesophageal cancer, and cholangiocarcinoma 	2019/11/15
Kaohsiung Medical University Chung-Ho Memorial Hospital	Ever Supreme Bio Technology	<ul style="list-style-type: none"> • DC for stage IV breast cancer, liver cancer, lung cancer, colorectal cancer 	2019/12/16
Asia University Hospital	Ever Supreme Bio Technology	<ul style="list-style-type: none"> • DC for stage IV breast cancer, liver cancer, lung cancer, colorectal cancer 	2019/12/18
Kuang Tien General Hospital	Ever Supreme Bio Technology	<ul style="list-style-type: none"> • DC for stage IV breast cancer, liver cancer, lung cancer, colorectal cancer 	2019/12/18
Tainan Municipal An-Nan hospital -China Medical University	Ever Supreme Bio Technology	<ul style="list-style-type: none"> • DC for stage IV breast cancer, liver cancer, lung cancer, colorectal cancer 	2019/12/18
E-Da Hospital	MetaTech	<ul style="list-style-type: none"> • Autologous regenerated cartilage sheet transplant at the knee 	2019/12/18
Far Eastern Memorial Hospital	EMO biomedicine	<ul style="list-style-type: none"> • Adipose stem cell transplantation for degenerative disease of knee 	2019/12/26
Chang Gung Memorial Hospital-Linkou	Unicocell	<ul style="list-style-type: none"> • Adipose stem cell for degenerative knee arthritis and cartilage defects. 	2020/01/14
E-Da Cancer Hospital	Medigen Biotechnology Corp	<ul style="list-style-type: none"> • NK cell for stage IV solid cancers, including colorectal cancer, lung cancer, breast cancer, liver cancer, head and neck cancer, prostate cancer and pancreatic cancer 	2020/02/04

Source: Intralink Research. Note: CIK=Cytokine Induced Killer cell, DC=Dendritic Cell, NK=Natural Killer.

Key players such as Bionet, Medigen Biotechnology, MetaTech, Taiwan Advance Bio-Pharmaceutical, and Ever Supreme Bio Technology, are experienced in prenatal testing, neonatal stem cell storage, molecular diagnostics, and construction

of cell manufacturing facilities. With speedy approval by MoHW, these companies are in a good position to supply cell processing equipment to medical institutions and help them with cell processing and storage.

Market Gaps and Opportunities

After the initial implementation of “Regulations Governing the Application of Specific Medical Examination Techniques and Medical Devices” in 2018, more medical centres are receiving approvals from MoHW for the use of cell therapy in end stage cancer treatment and degenerative diseases.

Cord blood banking—harvesting and storing new-born infant’s cord blood as a potential treatment option for diseases - started in early 2000’s. Biomedical companies including TABP, Bionet Corp, and Guang-Li Biomedicine have more than 20 years of experience in the field and are capable of harvesting, processing, and storing good quality cells and tissues. Under the strict regulations, Good Tissue Practices (GTP) and Good Manufacturing Practices (GMP) define the core requirements for handling products regulated as human cells and tissues.

As of 2019, there is no international large-scale GMP cell processing facility in Taiwan to satisfy the future needs of cell therapy. Japan is the leading country in cell therapy research and supply chain. However, the production cost in Japan is reportedly at least double in Taiwan. Hitachi Chemical of Japan and Metatech of Taiwan are now working together to build Asian’s largest cell processing facility in Hsinchu Biomedical Science Park, which is to be completed by 2023. The new facility will have automated systems for increased production capability for large number of patients. The large pipeline of new projects and high value of cell therapy will generate interest and opportunities for manufacturing solutions and capacity.

“ Industry Insider’s Thoughts

Currently cell processing relies on manual work of specialists. Production capacity is low and will not be sustainable for larger number of patients. A qualified cell processing facility with automated workflow is essential for cell therapy.”

Taipei Medical University Hospital

- **Chief of Cell Therapy Centre**, Dr. Kuan-Der Lee

Unique cell preserving and cell proliferation methods, and unique genetically engineering methods such as CAR-T cell are welcomed in Taiwan. Most cell therapies currently focus on the cancer market using

CAR-T cell. The worldwide market for CAR-T therapies is expected to reach USD 3bn (GBP 2.4bn) by 2025, according to Polaris Market Research, a global market intelligence company. Commercial and technological developments have also driven a huge rise in patent filings in Taiwan. Our interview with TMUH’s cell therapy centre and Cardinal Tien Hospital research centre reveals that Taiwan is particularly interested in the UK’s unique and mature genetic engineering methodologies.

Although Taiwan is relatively small, research institutions or biomedical companies in the UK can take advantage of Taiwan’s highly regulated healthcare and mature legal systems, which allow clinical trials with relatively less IP breach concerns compared to mainland China. Furthermore, Taiwan’s genetic pool can act as a pilot site for the mainland China market as well as the south East Asia market.

In summary, the Taiwanese market for cell therapy is growing and the government aims to transform Taiwan into a hub for regenerative medicine in Asia. The key areas where we see opportunities for UK businesses are below, ranked loosely with most attractive opportunities on top:

1. Cell production facilities, especially with automation for high quality and efficient manufacturing
2. Equipment and materials for the entire supply chain to process and administer cell therapies
3. Mature and unique cell processing technology
4. Genetic engineering tools and training

“ Industry Insider’s Thoughts

We are going to create biotech and medical technology industries integrated with the rest of the world. Throughout this (COVID-19) pandemic, Taiwanese teams have proven that they are capable of working with world-class technologies to produce reagents and develop new drugs and vaccines. We are going to give these industries our utmost support, and transform Taiwan into a key force in the global battle against infectious diseases.”

Inauguration Address (May 20, 2020)

- **President of Taiwan**, Tsai Ing-wen

6. Regulations

KEY POINTS

- Medical data sharing regulations are vague but closely monitored, presenting uncertainty for digital healthcare solutions
- Telehealth services are permitted for follow-up consultation of specific disease areas, but accelerated deregulation is expected due to the COVID-19 pandemic
- Taiwan allows clinical cell therapies with special approvals from MoHW
- Gene therapy is not yet approved

Taiwan's National Health Insurance Administration (NHIA) contains medical information on almost the whole population, which is vital to the development of health IT and Big Data (AI, deep learning)based technologies as well as precision medicine. Taiwan has several laws that act to regulate the use of such personal data.

Currently the guidelines pertaining sharing and using personal health data are vague, leaving healthcare providers and companies at risk if they were to interpret the guidelines the wrong way. This stalled the advancement of medical development in Taiwan. However, the current administration has committed to relaxing the regulations for data management to boost growth, particularly in the medical field.

6.1 Personal Data Protection

In Taiwan, there are two categories of data in healthcare that are regulated - personal data and sensitive data. Personal data includes identity and social information: names, dates of birth, ID card numbers, passport numbers, fingerprints, marital status, family, education, occupation, medical records, medical treatment, genetic information, sexual life, health examinations, criminal records, contact information, financial situation, social activities and other information that may be used to identify a person, both directly and/or indirectly. Sensitive data refers to any personal data related to medical records, medical treatment, genetic information, sexual life, health examinations and criminal records.

To regulate the collection, processing and use of personal data so as to prevent harm on personal rights, and to facilitate the proper use of personal data, Taiwanese government implemented "Personal Data Protection Act (PDPA)" in 2010, amended it in 2015, then further published the "Enforcement Rules of the Personal Data Protection Act" in 2016. PDPA applies to all government agencies and non-government agencies that are collecting, processing, and using personal data. The Taiwanese government is planning to further amend PDPA to meet General Data Protection Regulation (GDPR) standards and to obtain an adequacy status decision from the EU. Currently the National Health Insurance Administration (NHIA) can release data collected through National Health Insurance (NHI) to third-parties for research use only.

6.2 Medical Care Quality

The “Medical Care Act” regulates matters related to the quality of medical services, requirements for hospitals and medical records as well as prohibition against disclosure of confidential patient information, such as treatment options and drugs prescribed.

6.3 Medical Diagnosis and Treatment by Telecommunication

Telehealth in Taiwan started in 1995, with the focus on remote areas and places lacking medical resources. The government began its pilot program in 2008, which gradually grew to cover major regions all over the country. On May 11, 2018, the MoHW implemented “Rules of Medical Diagnosis and Treatment by Telecommunications”, which specifies areas where telehealth applies under particular circumstances. Physicians are required to conduct telehealth within a medical institution to protect the privacy of patients. Patients must visit in-person for initial diagnosis and consultation, then move to telehealth for follow-up consultations.

Due to COVID-19, the MoHW implemented electronic medical services on Feb 26, 2020 specifically to enable those undergoing home isolation and quarantine to seek medical assistance remotely. More than 3,000 medical institutions across Taiwan offer remote diagnosis and treatment by means of telecommunications technology. After the COVID-19 scheduled consultation, family members then take the patient’s NHI IC card to the designated clinic or hospital to pay and collect prescriptions.



6.4 Medical Examination Techniques and Medical Devices

On Sept 6, 2018, the MoHW issued amendments to the “Regulations Governing the Application of Specific Medical Examination Techniques and Medical Devices”. This regulation allows medical institutions to apply to MoHW for specific treatment plan using “patient’s own cells” under “minimum-to-none” alteration. Once approved, medical institutions can enrol and charge patients for cell therapy. The medical institutions must submit an implementation report every year, documenting the number of treatment cases, treatment effects, adverse reactions or abnormal events. Moreover, the results of the treatment conducted in medical institutions would be disclosed whenever necessary to remain open and transparent to professionals for research purposes.

As of the time of this report, only autologous cell therapy –using patient’s own cells – is allowed in Taiwan. The next step is to progress to allogeneic cell therapy, in which cells from a donor can be used, as the nation is seeking to excel in the field of stem-cell therapy, according to Dr. Shih Chung-liang, head of Taiwan’s Department of Medical Affairs.

6.5 Regenerative Medicinal Products

As of Oct 1, 2019, “Regenerative Medicinal Products Act” (RMP) is under legislative process. The key goal is to have a complete framework of regulation and to facilitate the development of innovative medicine whilst promoting patient rights, ensuring the quality, safety and effectiveness of cell and gene therapy products. This will then enable cell therapy to be applied to patients in need as soon as possible through effective management.

7. Market Entry Strategies

KEY POINTS

- Partnering with local systems integrators, distributors, or resellers is advised for foreign companies
- Using a sales team based outside of Taiwan is difficult due to language and cultural barriers, along with high expectations of after-sales support
- Foreign companies can apply to participate in government-led projects, but should note:
 - Culture, language, business environment, etc.
 - Preference towards local businesses adding at least some value to products or services

Taiwan presents opportunities for UK digital health and advanced therapies companies. Increase in investment from government, major hospitals, and large ICT companies is helping the sectors to mature and create space in technology, supply chain, and expertise for UK companies to monetise. As Taiwan's population demographics develop into super-aged society by 2026, the increasing healthcare cost is forcing NHIA to adopt and invest in new solutions. Additionally, large ICT companies pressured by stagnant growth in their traditional electronics business are proactively looking into the healthcare sector to invest heavily as their next area of growth. British businesses can approach the Taiwanese market through direct sales from the UK, by appointing a local partner, or by setting up an office in Taiwan.

In addition, Taiwan can also be leveraged as a springboard into Mainland China. With common language and culture, Taiwanese businesses were among the first to invest and expand into China when China opened its doors. Taiwan's close link to China, along with its developed legal system and business environment that functions closer to western practices, makes Taiwan a strong candidate for a UK company's first venture into the Asian region. Taiwan's Food and Drug Administration, for example, reached an agreement with China's National Medical Products Administration to accept clinical trial data from a select list of hospitals from both regions without repeating the costly and time-consuming clinical trial.

Direct Sales from the UK

The simplest option is direct sales of a particular digital health or advanced therapy solution from UK into Taiwan. The main downside is the lack of local time-zone support. This can be mitigated by using a local agent or business development consultancy, capable of bridging time-zone, language and cultural gaps without the long-term commitment of local incorporation and hiring. Market-specific factors to consider include:

- Do we have a strong differentiator - something that sets us apart from our competitors in the market?
- Do we have a strong track record in other major markets?
- Are we willing to localise the product for the market and/or for local regulations, if necessary?
- Are we ready to provide a Proof of Concept (PoC) at little or no cost to the customer? Taiwanese government-led initiatives, for example Taipei Smart City, do not pay suppliers for PoCs.
- How do we provide after-sales support?
- Do we understand the local regulations, particularly in relation to data? Do we need to adjust our business model to adapt?

Appointing a Reseller or Distributor

A more common way to approach the market is to seek a partnership with an established local company that complements your product, has experience in the target sector and can help navigate the legal environment. A local channel partner can provide services such as certification, registration, pre-sales, sales, consulting, installation, technical training, service maintenance and technical support in the Taiwanese market. Even large multinationals take this route in the early stages of market entry. Market specific factors to consider when seeking a partner include:

- Does the partner already serve the type of customer that we do?
- Does the partner have a good understanding of the market in general and my particular application?
- Does the partner already offer solutions similar or complementary to our offering?
- Is the partner focused on short-term wins or will they be able to drive our business in the long run?
- Does the partner have specific experience with public sector projects?
- Are we comfortable communicating with the local partner and are they transparent with us?

Establishing a Local Presence

There are broadly three ways of establishing a local presence: (1) a liaison office, (2) a branch office or (3) a local corporation through foreign direct investment (FDI). Setting up a liaison office is a simple process; but a liaison office can only perform non-profit generating activities in Taiwan such as market surveys, research and development and quality assurance. Setting up a branch office can be a complicated process that requires documentation to be translated, but it allows for sales activities and the exchange of revenues with the head office. The most common process for an overseas company to open a branch office in Taiwan is through FDI, where an initial investment is made by the head office, which in return owns stock in the branch. The local corporation leads independent activities and is authorised to perform direct transactions. Market-specific factors to consider when establishing a local presence in Taiwan include:

- Is our business generating enough revenue in Taiwan to consider a local presence? Businesses usually consider establishing a local presence after several years of sales (either direct or through a partner)
- Is Taiwan a strategic market for us, either in terms of securing use-cases or securing further funding?
- Do we need to engage in profit generating activities?
- Will we transfer staff from our head office or hire local staff?
- What location shall we pick for our local presence? Scouting, negotiating, and conclusion of contracts are time-intensive processes that often are hard to conclude without local support.

8. Appendices

8.1 Acronyms

Table 10: Acronyms and Definitions

Acronym	Definition
AI	Artificial Intelligence
CAGR	Compound Annual Growth Rate
CAR-T	Chimeric Antigen Receptor T Cell
CIK	Cytokine Induced Killer Cell
COVID-19	Coronavirus Disease 2019
CPOE	Computerized Physician Order Entry
CTH	Cardinal Tien Hospital
Dapp	Decentralized Application
DC	Dendritic Cell
EEC	National Electronic Medical Record Exchange Centre
EMR	Electronic Medical Records
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GB	Gigabyte
GBP	British pound sterling
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practices
GTP	Good Tissue Practices
HIT	Health Information Technology
HPC	High Performance Computing
HWDC	Health and Welfare Data Centre
IBMI	Institute of Biotechnology and Medicine Industry
IC Card	Integrated Circuit Card
ICT	Information and Communication Technology
INATBA	International Association for Trusted Blockchain Applications
IoT	Internet of Things
IRB	Institutional Review Board
ITRI	Industrial Technology Research Institute

LTC 2.0	Long-term Care 2.0 Plan
MIoT	Medical Internet of Things
MoHW	Ministry of Health and Welfare
MoST	Ministry of Science and Technology
NBCT	National Biobank Consortium of Taiwan
NDC	National Development Council
NGS	Next-Generation Sequencing
NHGRI	National Human Genome Research Institute
NHI	National Health Insurance
NHIA	National Health Insurance Administration
NHIRD	National Health Insurance Research Database
NHRI	National Health Research Institutes
NK	Natural Killer
NMR	National Medical Referral
NTD	New Taiwan Dollar
OECD	Organization for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
PDPA	Personal Data Protection Act
PoC	Proof of Concept
RMP	Regenerative Medicinal Products Act
ROC	Republic of China
TFDA	Taiwan Food and Drug Administration
TMUH	Taipei Medical University Hospital
TPMI	Taiwan Precision Medicine Initiative
TRPMA	Taiwan Research-based Biopharmaceutical Manufacturers Association
TWB	Taiwan Biobank
UK	United Kingdom
USA	United States of America
USD	United States Dollar
VGHTC	Veteran's General Hospital Taichung
VPN	Virtual Private Network

8.2. Up to Date Regulations

Table 11: Up to Date Regulations

Regulation	Source
Personal Data Protection Act	https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=I0050021
Enforcement Rules of the Personal Data Protection Act	https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=I0050022
Medical Care Act	https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021
Rules of Medical Diagnosis and Treatment by Telecommunication	https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020197
Regenerative Medical Products Act (Open for public comment until June 2020)	https://www.ey.gov.tw/Page/9277F759E41CCD91/a602e0f5-ee02-40cb-a955-25e31c4c4cc5
Regulations Governing the Application of Specific Medical Examination Techniques and Medical Devices (Reviewed draft)	https://gazette.nat.gov.tw/egFront/detail.do?metaid=114573&log=detailLog

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