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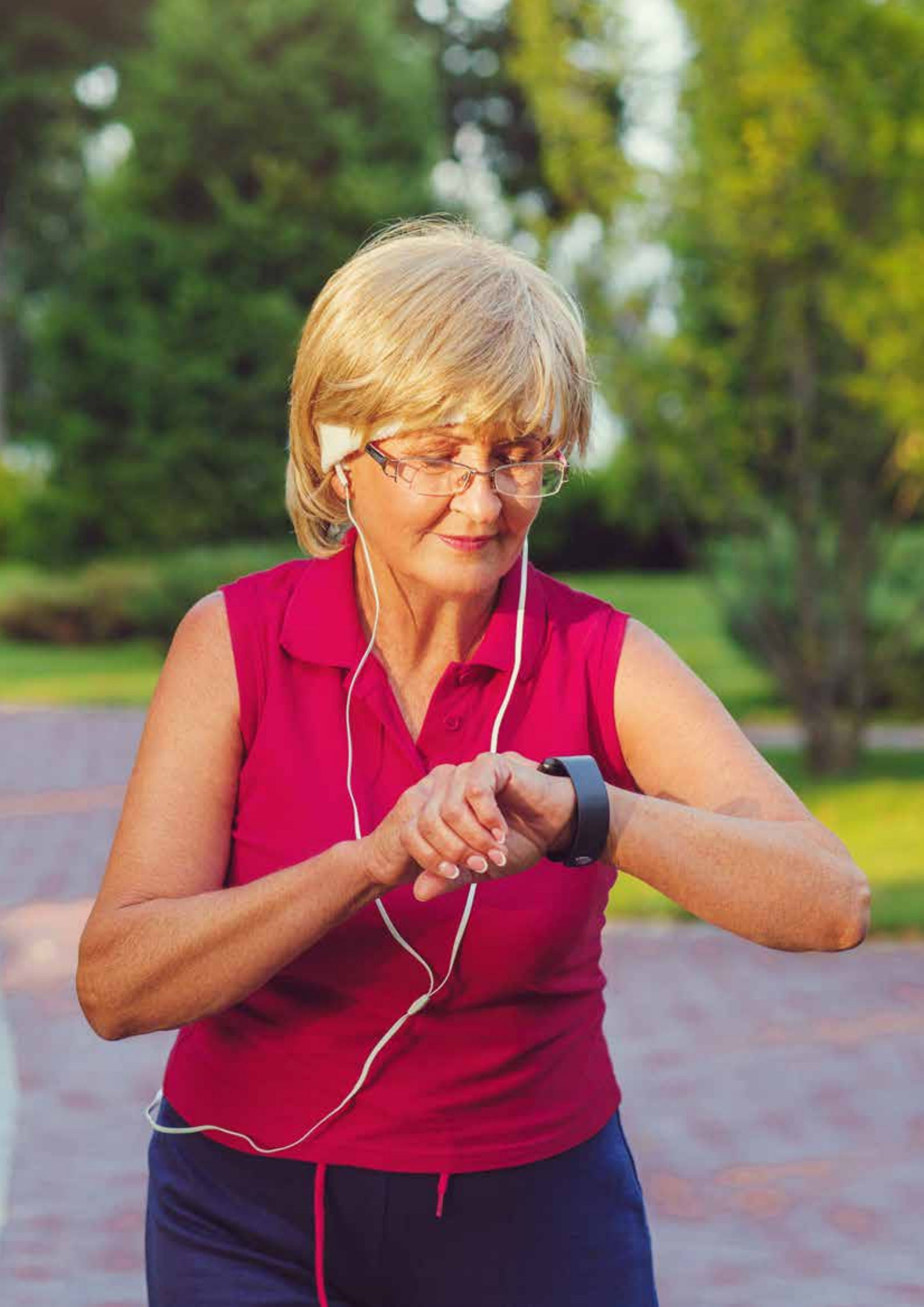
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Global Expert Mission Precision Medicine & Vaccines China 2018

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Welcome

Innovate UK¹ 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 (KTN)², play an important role in building strategic partnerships, providing deep insight into the opportunities for UK innovation and shaping future programmes.

The Precision Medicine and Vaccines Expert Mission travelled to China in December 2018. During the mission, a delegation consisting of government representatives and industry experts visited the cities of Shanghai and Wuxi to meet key stakeholders from the Chinese precision medicine and vaccines market.

The mission also visited the 3rd World Precision Medicine (China) Summit 2018 in Shanghai, under the theme of "Exploring the Recent Progress in Clinical Development and Industrial Innovation".

In this publication we share the information and insights gathered during the delegation's time in China. It is split into two main sections – Precision Medicine and Vaccines – and includes an appendix on the Chinese healthcare system.

UK MISSION DELEGATES:	KEY CHINESE STAKEHOLDERS ENGAGED:
Public sector stakeholders • Department for International Trade (DIT) • Innovate UK • Knowledge Transfer Network (KTN) Industrial stakeholders • AstraZeneca • Congenica • DIOSynVax • Genomic England • Oncimmune • Perspectrum	Public sector stakeholders • Shanghai Health Bureau • Wuxi Health Bureau Industrial stakeholders • AstraZeneca Innovation Centre (Wuxi) • Cloud Health Genomics • Dian Diagnostics • GeneTech • GSK • Polaris Bio • Simcere Research/Hospitals • Zhongshan Hospital

¹ www.gov.uk/government/organisations/innovate-uk

² www.ktn-uk.org

The mission was timed to build on the UK government's plan to build a Britain fit for the future through a new ambitious Industrial Strategy.

The Department for Business Energy and Industrial Strategy (BEIS) launched the ISCF to be delivered by UK Research & Innovation (UKRI) to bring together the UK's world-class research expertise with business investment to develop technologies and industries that can help the UK prepare for the challenge of an ageing society³.

The Industrial Strategy Challenge Fund (ISCF) has been invested in various health-related challenges⁴, but the most relevant in this contest are:

- **Data to Early Diagnosis and Precision Medicine ISCF** where the UK government will invest £210 million to ensure the UK will be a world leader in the development of innovative new diagnostic tools, medical products, and treatments. The main three strands of the challenge are:
 - o Digital Pathology, Radiology, and AI: £50 million has been allocated to five UK-wide centres of excellence and an additional £22 million allocated to integrated diagnostics.
 - o Digital Innovation Hubs: Health Data Research UK (HDRUK) will deliver a £37.5 million stream to enable the safe and responsible use of health-related data at scale for research and innovation.
 - o Genomics: The Wellcome Sanger Institute and the UK Biobank are among the key players to enhance UK capability in large-scale whole genome sequencing. Through sequencing of the 500,000 subjects of UK Biobank.
- The £98 million **Healthy Ageing ISCF**⁵ will drive the development of new products and services which will help people to live in their homes for longer, tackle loneliness, and increase independence and wellbeing. The programme will be investing in tackling some of the toughest medical challenges facing society today.

The mission also builds on China's:

- World-leading Precision Medicine Initiative which will see the Chinese Academy of Sciences investing over US\$9.2 billion by 2030 in the sector and which is seeking to make the country the world leader in precision medicine utilising both private sector and government resources⁶.
- Application of Fourth Industrial Revolution technologies in data collection, analysis tools and artificial intelligence (AI) in the healthcare sector.
- Beijing Genome Institute which is a world-leading genome sequencing capacity (Million Chinese Genome project⁷).

Definition of Precision Medicine

Innovate UK defines precision medicine as “technology that enables early and accurate diagnosis to inform patient treatment, as well as the availability of targeted therapies. This includes combining clinical biomarker knowledge with advances in diagnostic technologies, data analysis and tailor-made therapeutics. Precision medicine is also commonly referred to as stratified medicine or personalised medicine”.⁸

³ www.gov.uk/government/collections/industrial-strategy-challenge-fund-joint-research-and-innovation

⁴ For more information, see www.gov.uk/government/collections/industrial-strategy-challenge-fund-joint-research-and-innovation.

⁵ <https://www.ukri.org/innovation/industrial-strategy-challenge-fund/healthy-ageing>

⁶ <https://www.nextbigfuture.com/2016/06/chinas-92-billion-precision-medicine.html>

⁷ <https://db.cngb.org/cmdb/>

⁸ apply-for-innovation-funding.service.gov.uk/competition/201/overview#scope

1. China - Precision Medicine

1.1 Overview

The People's Republic of China "is a socialist state under the people's democratic governing system"⁹. China is the most populated country in the world and is the fourth largest by land area. The total population in China was estimated at 1390.1 million people in 2017, according to the latest census figures. Looking back, in the year of 1950, China had a population of 552.0 million people¹⁰.

The country's economy has developed rapidly over the last two decades and consists of a mixture of state-controlled and private enterprises. Economic reforms initiated since 1978 have created a highly diversified economy and, despite its development, China is highly uneven with the major cities and coastal areas being far more prosperous compared to rural and interior regions. China has grown to be the world's second-largest economy in terms of GDP (behind the USA).

In the last decade, China has exhibited the fastest country growth of GDP per capita (Figure 1)¹¹.

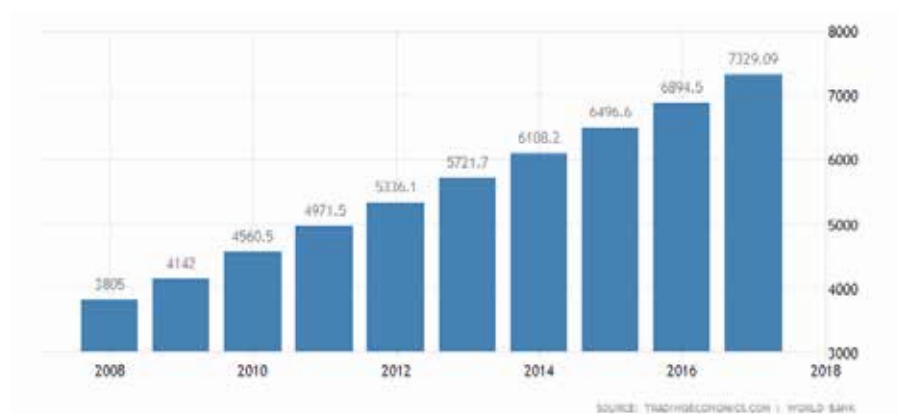


Figure 1: China GDP per capita

China is also emerging as a leader in the international innovation landscape. The country's spending on R&D has grown massively since 2000 and is expected to overtake the USA as the largest investor in 2019. This reflects China's ambition to become a leader in technology, as set out at the 19th National Congress of the Communist Party of China in October 2018. In addition, the country is home to 25% of the world's R&D workforce, and in the past 15 years, the number of foreign-run R&D centres in China has increased from 200 to over 1,500¹². China's economic growth and investments in science and innovation are being translated into the growth of the population's disposable income driving the rapid expansion of the middle classes which is seeking a better quality of healthcare services (Figure 3)¹³.

⁹ Constitution of the People's Republic of China: www.npc.gov.cn/englishnpc/Constitution/2007-11/15/content_1372962.htm

¹⁰ tradeeconomics.com/china/population

¹¹ tradeeconomics.com/china/gdp-per-capita

¹² <https://www.mta.org.uk/system/files/resource/downloads/Made%20in%20China%202025%20Booklet%20One.pdf>

¹³ tradeeconomics.com/china/disposable-personal-income

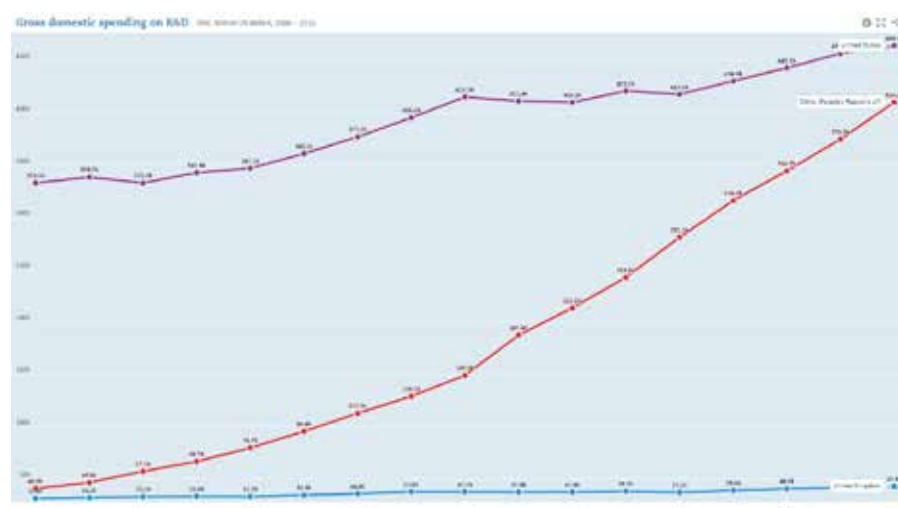


Figure 2: Gross domestic spending on R&D - Total, million US dollars, 1998– 2018¹⁴

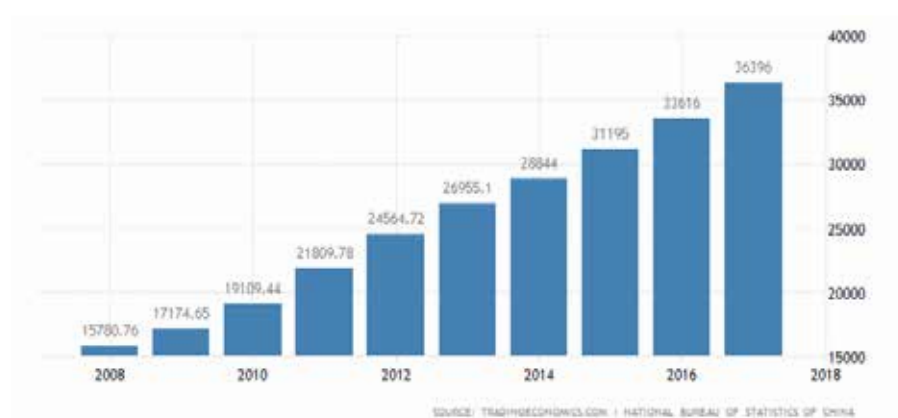


Figure 3: China disposable income per capita

China's population profile is also shifting. In 2010, 9.7% of Chinese were aged 60 or older, and this is set to grow to 26% by 2050, making China the world's fastest ageing society. Elderly citizens have a higher incidence of diseases, which is increasing the demand for healthcare services.

The previously-mentioned factors are driving the growth of China's healthcare industry. In 2016, China's health spending totalled RMB 4.6 trillion at a compound growth rate of 13.5% over the past three years accounting for only 6.2% of China's GDP. This percentage should rise from 6.5% to 7% of the GDP by 2020 as proposed in the 13th Five-Year Plan (see section 1.3).¹⁵

One of the fastest-growing markets in the healthcare industry is pharmaceuticals. In 2016 the Chinese drug market was valued at US\$17 billion, second only to the USA. Although Chinese consumers are not able to pay the same prices as in the USA, the number of patients means that China will soon be the number one market in the world. This is driving a "discovered in China" drug industry as established pharma companies, such as Roche and Novartis, invest in drug discovery research and clinical trials. Currently, China contributes only 4% of global drug innovation, compared with 50% for the USA but that proportion is predicted to grow rapidly with the increased investment by both government and venture capital in the sector¹⁶.

¹⁴ OEDC Data (2019).

¹⁵ Deloitte, 2017. China Life Sciences and Health Care Investment Promotion Report

¹⁶ Chinese biopharma starts feeding the global pipeline, Nature Reviews Drug Discovery, June 2017

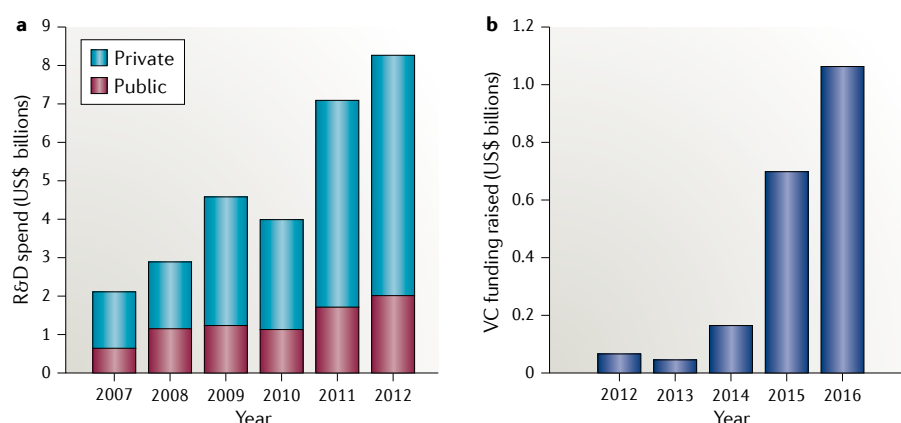


Figure 4: Biopharma investment in China

1.2 Precision Medicine in China

China is actively targeting the creation of a precision medicine sector. In 2015, as part of China's Five-Year Plan¹⁷, the country launched the China Precision Medicine Initiative (PMI) which is a 15-year project that aims to build the country as a world leader in this field. With this initiative, the Chinese healthcare industry is investing in scientific research to deeply understand the genetics and biological make-up of people, cutting-edge data collection and analysis tools, and powerful computing capabilities to make discoveries from large quantities of data.

Along with Healthy China 2030 (see Section 1.3), PMI is providing large investments in infrastructure, people and services to expand and develop the precision medicine sector in the next decade. This investment is driving the creation of new precision medicine centres at research institutes and universities across China.

Recently, the Chinese Academy of Sciences (CAS) issued detailed application guidance for projects under the China PMI, which is widely expected to be funded with ¥60 billion (US\$9.2 billion) by 2030. In its bid to make the country a leader in "precision medicine," the initiative is utilising both private sector and government resources.

This investment has already generated a dramatic improvement in China's genome sequencing capability, in both the public and private sectors. This capability, alongside the continued government investment and access to millions of patients, suggests that China will be one of the leading countries in the precision medicine sector as new diagnostics and therapies are developed.

1.2.1 Genomic Sequencing

Genomic sequencing is at the core of the Chinese PMI. The first step of the initiative will be to assemble a database of genomic data from the Chinese and international populations. A cross-disciplinary team coordinated by the Beijing Institute of Genomics (BGI) will first collect genetic information from about 2,000 volunteers and aim to develop new treatment concepts. WuXiNextCODE¹⁸ will then focus on the application of sequence data to improve disease diagnosis, develop better and more targeted drugs, and to provide informed, personalised scientific wellness regimes that can help people to stay healthier longer. In addition, the telecommunications giant Huawei Technologies Company will develop cloud infrastructure to facilitate the handling of genomic data associated with the PMI.

Although the PMI was launched in 2015 the details of how the initiative will progress and what it will deliver remain unclear. While China has significant sequencing capacity, for example, Cloud Health, BGI, and WuXiNextCODE¹⁹, the whole genome sequencing part of PMI has not yet begun. There have been a number of announcements of WGS projects, but few have yet delivered significant sequence datasets.

1.2.2 Infrastructure – Computing and Analytics

China is also investing in creating a world-leading position in the development of computational power and artificial intelligence programmes both to discover new drugs and treatments as well as identifying and targeting the appropriate patients. For example, iCarbonX is a Chinese company founded in 2015 that collects data on the genetics, environment, and behaviour of millions of patients. It uses artificial intelligence and data mining to formulate the best treatments based on a digital, holistic view of each patient.

¹⁷ www.bioworld.com/content/china-initiative-would-pour-billions-precision-medicine-0

¹⁸ For further information on WuXiNextCODE, refer to section 1.3.1

¹⁹ More information about these organisations is provided in section 1.3.1

BGI

BGI (see section 1.3.1) is the world's largest sequencer and repository of genetic material and, in 2010, it hosted more sequencing capacity than the whole of the USA. Since then, Illumina sequencing equipment has been installed in at least three further sites including, WuXiNextCODE, CloudHealth (both based in Shanghai), and Novogene (Beijing). BGI is also collaborating with Zhongshan Hospital to create a centre for clinical precision medicine to be operated by Fudan University²⁰.

In 2018, BGI announced that it had completed a genome study of more than 140,000 people (this was partial genome sequencing via non-invasive prenatal testing)²¹. The study was the largest of its kind for the Chinese population to date and covered all 31 provincial-level administrative units in the Chinese mainland and represents Han Chinese and 36 ethnic minorities. It discovered the genetic structure of the various ethnic groups, found six genes that display significant differences across latitudes, and identified the gene flow patterns between Europeans, South Asians, East Asians, and Chinese. In the next three years, BGI plans to further expand the database to 1 million genomes. BGI started its Million Chinese Genome Project in 2016 and this study represents its first phase.

1.2.3 Digital Health

China has committed to embedding digital health in its health reforms. The 13th Five-Year Plan (2016) committed to promoting telemedicine and using informatics to improve population health and alleviate poverty. It is also committed to accelerating the development of health apps, expand e-commerce platforms in the health sector and using internet plus and telemedicine to enhance development along the Belt and Road initiative (see section 1.3).

Large amounts of government funding have been allocated to research and development in this area, including an RMB 100 billion fund to look at artificial intelligence in Tianjin. China's large conglomerates have forged ahead creating subsidiaries to pick up the digital health challenge, among these are Tencent (sixth largest internet company in the world) and Alibaba (fifth largest) which are notable for their activity.

Independently, hospitals have excellent digital solutions. Many have internal systems allowing patient data to be shared with various departments across apps; electronic patient apportionment booking systems; videoconferencing that allows thousands of doctors to dial in simultaneously; virtual surgery equipment that allows a surgeon to view the patient's internal organs and manipulate them using effectively an Xbox Connect. However, many of these inventions have not been commercialised outside the individual hospital. Furthermore, at the primary care-level digital solutions are much less frequently used.

Many provinces and municipal governments claim to be leading the way with big data centres looking at digital health. However, China's health infrastructure, with a lack of referrals between hospitals, and very little primary care, means that

data collection tends to be sporadic and compartmentalised, making population health solutions difficult. While China may have some of the largest health databases in the world, only a small percentage of the data is in a usable format and accessible to those who could use it effectively.

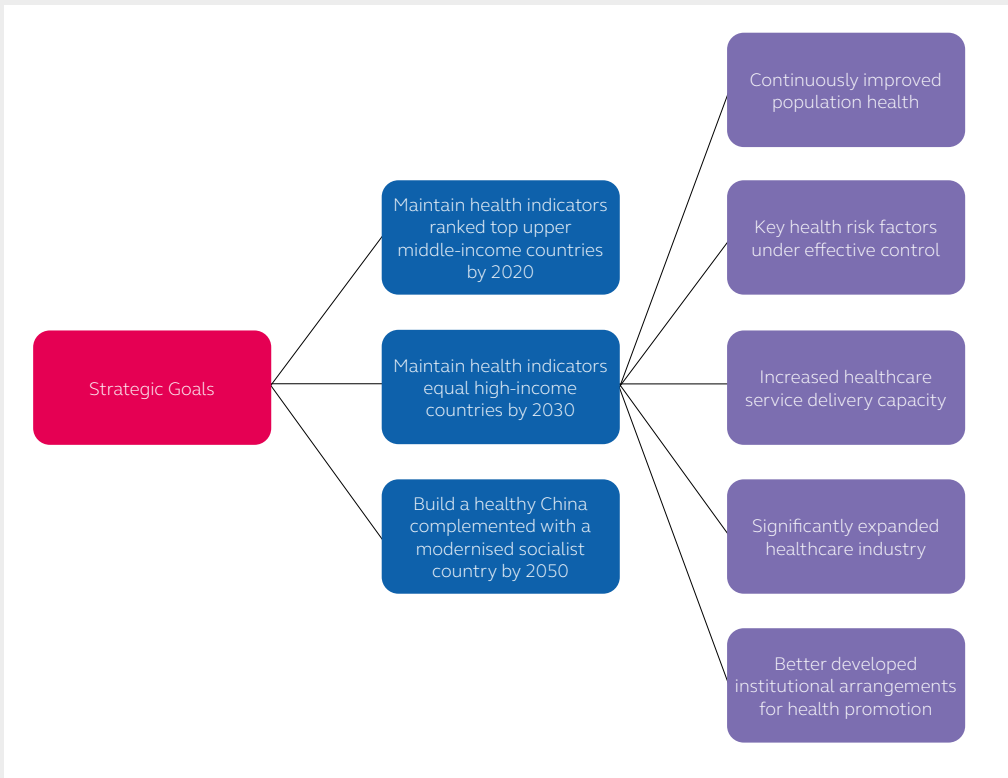
Recent cyber laws prohibit Chinese patient data leaving the country (see section 2.3.1). This has raised questions for international organisations about the practicalities of R&D using shared big data sets; the challenges to telemedicine; and the risks to international companies trying to support crowdsourced diagnostic tools. International companies wanting to work with Chinese patient data are required to set up servers in the mainland which raises concerns around intellectual property of algorithms. This has led to companies such as Google-owned Deep Mind to decline the offer of Chinese opportunities.

²⁰ China embraces precision therapy, Nature, 2017, vol 259, 10-11

²¹ www.chinadaily.com.cn/a/201810/11/WS55bbe8bb2a310eff303281adc.html

1.3 Key Policies and Mechanisms Supporting Precision Medicine in China

Listed in the table below are the other key policies and mechanisms beyond the PMI implemented by the Chinese government to create the precision medicine sector.

MECHANISM	SUPPORTING POLICY/SCHEME
Healthy China 2030 Strategy	The Healthy China (HC 2030) blueprint was announced by President Xi Jinping in 2016²². The strategy makes public health a precondition for all future economic and social development. The HC 2030 blueprint, released in Beijing by the Chinese government, includes 29 chapters covering public health services, environmental management, the Chinese medical industry, and food and drug safety. The HC 2030 blueprint has been established as a national strategy and sets a goal of enabling everyone to be involved in health, share health, and be responsible for health. The blueprint is based on four core principles, that is, health priority, reform and innovation, scientific development, and justice and equity. There are five specific goals to improve the level of health nationwide: control major risk factors, increase the capacity of the health service, enlarge the scale of the health industry, and perfect the health service system.  Specific actions include enhancing health education in schools, promoting healthy lifestyle, encouraging exercise, enhancing universal healthcare access, improve service quality of healthcare providers, special attention to the elderly, women, children and disabled, reforms in health insurance, pharmaceutical and medical instruments systems. The Healthy China 2030 strategy is a major driver for the development of the healthcare system and industry in China. It catalyses major investments that are developing new facilities and services. By 2030 China will have significantly improved its healthcare services and will have developed a medical industry to compete with the current pharma and medtech industry, which is dominated by the USA, EU, and Japan.

²² www.cn-healthcare.com/article/20161107/content-487000.html

Made in China 2025	The Made in China 2025 plan was launched in 2015. It aims to break China's reliance on foreign technology and pull its high-tech industries including the pharmaceutical industry, up to Western levels. The plan identifies the goal of raising domestic content of core components and materials to 40% by 2020 and 70% by 2025. The plan highlights ten priority sectors including biopharma and advanced medical products.
1000 Talents	In 2008, China's central government announced the Thousand Talents Plan: a scheme to bring leading Chinese scientists, academics and entrepreneurs living abroad back to China. In 2011, the scheme grew to encompass younger talent and foreign scientists, and a decade later, the Thousand Talents Plan has attracted more than 7,000 people overall. For Chinese scientists, the scheme has given them a strong financial incentive to return home. For foreigners, it's an opportunity to join the Chinese system with major administrative hurdles removed. The scheme is open to Chinese scientists under 55 years of age, and foreigners younger than 65. All applicants must have worked at renowned universities outside China and have a strong publication record. All successful applicants receive a 1 million yuan (US\$151,000) starting bonus, and the opportunity to apply for a research fund of 3–5 million yuan. Foreign scientists receive additional incentives, such as accommodation subsidies, meal allowances, relocation compensation, paid-for visits home and subsidised education costs. Employers are also obliged to find jobs for foreign spouses or provide an equivalent local salary. In addition, the Thousand Youth Talents Plan targets foreign and expat Chinese scientists under the age of 40. Unlike the main Thousand Talents Plan, Chinese returnees receive the same benefits as foreign recruits under the Thousand Youth Talents Plan.
Belt and Road Initiative	China's Belt and Road Initiative (BRI) is an ambitious programme to connect Asia with Africa and Europe via land and maritime networks along six corridors with the aim of improving regional integration, increase trade and stimulate economic growth. The name was coined in 2013 by President Xi Jinping, who drew inspiration from the concept of the Silk Road – an ancient network of trade routes that connected China to the Mediterranean via Eurasia for centuries. The BRI comprises a Silk Road Economic Belt – a trans-continental passage that links China with Southeast Asia, South Asia, Central Asia, Russia and Europe by land – and a twenty-first-century Maritime Silk Road, a sea route connecting China's coastal regions with South East and South Asia, the South Pacific, the Middle East and Eastern Africa, all the way to Europe. The programme is expected to involve over US\$1 trillion in investments, largely in infrastructure development for ports, roads, railways and airports, as well as power plants and telecommunications networks.

²³ www.csis.org/analysis/made-china-2025

²⁴ www.1000plan.org/en/

1.3.1 Stakeholder Organisations in the Precision Medicine Sector

The following tables outline the stakeholders relevant to the development of the precision medicine sector in China.

GOVERNMENT	
State-Level Agencies (Health)	NATIONAL HEALTH COMMISSION (NHC) The National Health Commission (NHC) is the most powerful ministry for health and is led by Minister Ma Xiaowei. NHC is responsible for formulating national health policies, coordinating reform and supervising public health, health emergencies and family planning. Government restructuring earlier this year saw a name change from the National Health and Family Planning Commission which suggests a relaxing of the family planning policies as the country grapples with a rapidly ageing society and a shrinking labour pool. The one-child policy was relaxed in 2015 and replaced with a two-child policy which may be abolished completely in the near future although this is unlikely to have the desired effect of increasing the fertility rate.
	NATIONAL MEDICAL SECURITY ADMINISTRATION The National Medical Security Administration (NMSA) is a newly-created bureau which sits at Vice-Minister level (Hu Jingling). It is responsible for managing health financing, including medical insurance policies and the pricing of medical products.
	NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA) The National Medical Products Administration (NMPA) is the regulatory body responsible for the registration of medicines, medical devices and cosmetics. Previously called the China Food and Drug Administration (CFDA), this bureau sits under the State Administration of Market Supervision and is Vice-Minister level.
	MINISTRY OF CIVIL AFFAIRS The Ministry of Civil Affairs is responsible for social and administrative affairs. Since restructuring, its healthcare portfolio has been reduced to the regulation of elderly care facilities.
	MINISTRY OF SCIENCE AND TECHNOLOGY (MOST) The Ministry of Science and Technology (MoST) is the central government ministry which coordinates science and technology activities in the country. It formulates and facilitates the implementation of strategies and policies for innovation-driven development, and plans and policies for science and technology development and the attraction of foreign talent. MoST coordinates the development of the national innovation system and works with relevant government departments to improve incentive mechanisms for technological innovation. MoST endeavours to improve the national R&D system, facilitate the reform and development of research institutes, enhance the innovation capabilities of enterprises, promote military-civilian integration, and develop the consulting system for major national S&T decision-making.
Regional and Local Agencies	CITY GOVERNMENTS During the mission, meetings were held with officials of both the Shanghai Health Bureau and Wuxi Health Bureau. These represent the city-level health authorities responsible for implementing central government health policies and for providing healthcare services. They are also responsible for investing in key infrastructure and initiatives, e.g. research facilities, science parks, to develop precision medicine and diagnostic services in the future.

INDUSTRY	
Genomics	WUXINEXTCODE²⁵ WuXiNextCODE was formed in 2011 and is a subsidiary of WuXi PharmaTech²⁶. It offers a gene sequencing platform and analysis software for genomic research. It is headquartered in Shanghai with facilities in Boston, USA and Reykjavik, Iceland. In 2018, WuXiNextCODE announced the acquisition of Genomics Medicine Ireland (GMI) as part of a \$400 million investment in precision medicine in Ireland²⁷. GMI aims to enrol 400,000 people and for whole-genome sequencing alongside medical and health datasets. This will be utilised for identifying drug targets, conducting stratified clinical trials, disease risk models and new diagnostic tests.
	CLOUDHEALTH GENOMICS²⁸ CloudHealth Genomics Ltd, headquartered in Shanghai, provides whole-genome sequencing and genomics-based precision medicine studies to understand, diagnose and provide solutions to treat diseases. The company has certified clinical genetic testing labs and high throughput sequencing centres (HiSeq X10 platform, NovaSeq and Pac Bio Sequels systems) located in Shanghai and Nanjing, China. CloudHealth Genomics is part of a larger CloudHealth Medical Group ecosystem, comprising of CloudHealth Life Center, CloudHealth High-End Clinic Center, CloudHealth Big Data Center, CloudHealth Genomics Research Institute, Academician Experts Workstation and CloudHealth Club of Medical Doctors. During the mission, a meeting was hosted by CloudHealth at their Shanghai facility. CloudHealth is seeking to investigate the effect of Traditional Chinese Medicine (TCM) on the individual patient level, i.e. the pharmacogenomics of TCM. They were interested in the potential for collaborations in this area.
	NOVOGENE²⁹ Novogene is a leading provider of genomic services and solutions with cutting-edge next-generation sequencing and bioinformatics expertise. It claims to have the largest sequencing capacity in the world. The company has 1,800 employees in multiple locations including USA, UK, Singapore, and China. Novogene is headquartered in Beijing and has sequencing facilities in both Nanjing and Tianjin.
	BGI GROUP BGI is a leading provider of genomics sequencing services (known as the Beijing Genomics Institute prior to 2008)³⁰. The company was founded in 1999 to participate in the Human Genome Project and is reported to have sequenced approximately 1% of the genome. BGI provides a wide range of next-generation sequencing services and a broad portfolio of genetic tests for medical institutions, research institutions, and other public and private partners. BGI has particular strengths in prenatal screening, hereditary cancer screening, testing for rare disease and in aiding precision medicine research, and initiatives (e.g. a centre for clinical precision medicine at Zhongshan Hospital). In 2013, BGI bought US-based Complete Genomic for US\$118 million. In 2017, BGI Genomics, a division of BGI Group, completed an RMB 547 million (\$81 million) initial public offering on the Shenzhen Stock Exchange³¹. BGI is headquartered in Shenzhen, China, with offices and labs in Beijing, Tianjin, Wuhan, Shanghai, and Guangzhou. BGI also has offices and laboratories located in London, Boston, Seattle, Singapore, and Brisbane.

²⁵ www.wuxinextcode.com

²⁶ www.wuxinextcode.com/about-us/

²⁷ www.prnewswire.com/news-releases/in-ireland-wuxi-nextcode-embarks-on-unprecedented-effort-to-enable-precision-medicine-at-national-scale-with-global-impact-300755670.html

²⁸ <http://www.chgenomics.com/En/>

²⁹ en.novogene.com/

³⁰ www.bgi.com/global/

³¹ www.genengnews.com/topics/omics/bgi-genomics-raises-81m-in-ipo/

INDUSTRY	
Diagnostics	YOURGENE HEALTH
	Yourgene Health is an international molecular diagnostics group which develops and commercialises genetic products and services.³² Yourgene Health's first commercialised products are non-invasive prenatal tests (NIPT) for Down's syndrome and other genetic disorders. Yourgene Health is headquartered in Manchester, UK with offices in Taipei, and Singapore. During the meeting with mission delegates Dr Chang, CSO, indicated that Yourgene Health had been visiting China for 10 years but had not yet found a commercial partner. Intellectual property issues were raised as a barrier. Another barrier identified was the fact that it takes time to build appropriate relationships and trust.
	DIAN DIAGNOSTICS
	Dian Diagnostics was founded in 1996 and is a top independent laboratory-test company.³³ It has more than 9,000 employees in 37 testing facilities covering every province of China. In 2017, total revenue was \$859 million. Dian Diagnostics also has a product redistribution channel and in vitro diagnostics manufacturing facility. Since 1996, it has been a distributor of Roche diagnostics and also co-manages testing laboratories within hospitals. Dian Diagnostics are involved in "Medical Malls" that are being developed across China to improve direct-to-consumer (DTC) community health monitoring³⁴. The UK is investing in similar "out of the hospital" initiatives, e.g. the use of screening trucks to improve the detection of lung cancer³⁵. There is potential for the UK and China to share learning and experiences from these initiatives. Dian Diagnostics are also collaborating with John Hopkins Medicine to utilise the Hopkins pathology lab services at DIAN labs in 17 Chinese cities. Hopkins pathologists will help train Chinese doctors, who will also have access to a Hopkins diagnostic iPad application³⁶.
	GENETECH
	GeneTech (Shanghai) Co Ltd is a subsidiary of Gene Group Holding Ltd (GGH).³⁷ GGH was founded in 1992 and currently has 18 offices across China and over 650 employees. GGH provides R&D, manufacturing, marketing and distribution of immunological and molecular diagnostic products in the fields of oncology, pathology, haematology, and cytogenetics. GeneTech is focused on developing a range of molecular and companion diagnostic products to use in precision, diagnosis and medicine. In 2018 Oncimmune, one of the UK companies participating in the mission agreed an investment and licence agreement with GeneTech for the manufacturing, marketing and distribution of EarlyCDT®-Lung diagnose test.³⁸

³² www.yourgene-health.com

³³ www.dazd.cn/en/index.aspx

³⁴ sino-us.com/117/21534095166.html

³⁵ www.england.nhs.uk/2019/02/lung-trucks/

³⁶ www.healthleadersmedia.com/strategy/hopkins-medicine-forms-collaboration-offer-diagnostic-lab-services-across-china

³⁷ www.genetech.com.cn/en/

³⁸ www.consilium-comms.com/news-insights/client-news/client-news/2017/oncimmune-completes-first-tranche-of-10m-equity-investment-from-genosics/

Pharma	SIMCERE Simcere is a 4,000-employee listed pharmaceutical development company (NYSE: SCR) focused on medicines and generics based in Nanjing. Simcere has over 50 products that cover oncology, cardiovascular and cerebrovascular, anti-infection, rheumatology and other therapeutic areas. In recent years, Simcere has established high-quality international cooperation through various partnership models. In March 2018 the company's precision medicine division, Simcere Diagnostics, formed a strategic partnership agreement with Agena Bioscience focusing on expanding the use of Agena's MassARRAY System for companion diagnostics and pharmacogenetic testing in China. Simcere is also collaborating with European-based biotech Merus to develop and commercialise in China three bispecific antibodies and with Amgen to codevelop and commercialise a series of biosimilars in China. Simcere Diagnostics is a precision medicine solution provider. They provide direct-to-consumer (DTC) testing with an innovative service model (mainly HPV testing for women's health) and also perform cancer diagnostics (run 1,600 samples on TS170 Illumina panel and will soon be utilising OGP500 in China). They are running respiratory infections disease analysis on Oxford Nanopore equipment. This is in collaboration with top three hospitals e.g. Huashan Hospital in Shanghai. Simcere also supports the Nanjing BioSciKin facility, an open investment and incubation platform in China for life science innovation. The innovation facility in Nanjing has 100 small incubator companies and might be a start-up site for UK companies in China.
Med Tech	POLARIS BIO Polaris Bio is a medical technology company specialising in the development and clinical application of cell-level precision diagnostic technology.³⁹ Support for clinical tumour diagnosis and treatment is provided by studying individual and dynamic changes in tumours at the cellular level. Polaris Bio is collaborating with ThermoFisher on single-cell diagnostics. During their meeting with the mission delegates, they highlighted their interest in opportunities to collaborate with the UK, e.g. they are seeking a single molecule antibody-based assays to replace flow cytometry. They also highlighted that international collaborations could be difficult as at least part of the particular technology platform needs to have been manufactured in China.
OTHER	
Hospitals	ZHONGSHAN HOSPITAL Hospitals in China are organised according to a three-tier system that recognises a hospital's ability to provide medical care, medical education, and conduct medical research. Tier three hospitals are the largest and provide the widest range of services, including specialist new services such as precision medicine. During the mission, a meeting was held with Zhongshan Hospital, Shanghai. Zhongshan Hospital has 1,700 beds serving 84,000 inpatients and 3,111,000 outpatients and emergency in 2013. In collaboration with BGI, the hospital also hosts a clinical precision medicine centre.

³⁹ www.polarisbiology.com

2. Synergies, Collaboration Opportunities and Barriers

2.1 Existing Mechanisms for Collaboration between China and UK

2.1.1 China Joint Strategy for Science, Technology and Innovation Cooperation

The UK and China have collaborated on science initiatives for 40 years. The UK-China Science & Technology Cooperation agreement was signed in 1978, and regular UK-China Joint commission meetings on science, technology and innovation commenced in 1998.

The UK-China Research and Innovation Cooperation Partnership Fund, part of the Newton Fund, was launched in 2014⁴⁰ and has supported more than 460 projects and partnerships across more than 40 funding initiatives⁴¹. The Newton Fund is part of the UK's official development assistance (ODA) commitment, administered in the UK by BEIS. The original cooperation agreement was renewed and updated in 2017 with the publication of the UK-China Joint Strategy for Science, Technology and Innovation Cooperation. This represents the first bilateral science and innovation strategy China has developed jointly with another country.

The strategy sets the framework for future cooperation to jointly tackle global challenges and drive economic growth until 2028. It also outlines new cooperation mechanisms, including an annual Flagship Challenge Programme. In 2018, the programme focus was on agricultural technologies and will be on healthy ageing in 2019. The strategy outlines three core principles to guide its implementation:

1. Respect for intellectual property rights.
2. Project-focused bilateral cooperation.
3. Engaging research and innovation communities.

With China's continuing economic development, the country is rapidly approaching the point where it will no longer be eligible for Newton Fund investment.

2.1.2 UK-China Collaboration to Tackle Antimicrobial Resistance

In 2018, Innovate UK launched a collaborative competition for UK-based researchers to work with Chinese partners to

tackle the growing threat of antimicrobial resistance⁴². The competition is investing up to £10 million of ODA funding on behalf of the Department of Health and Social Care (DHSC). Additionally, MoST will invest up to RMB 60 million to fund the Chinese partners.

The competition aims to encourage innovative partnerships between business and academics in the UK and China to carry out novel projects that neither country would be likely to conduct within the same timeframe and without the expertise of the other. These should result in new products and services to address antimicrobial infections in humans and animals, providing that the infection being addressed constitutes a significant threat to human health. The research competition will be looking to support projects that specifically target the development of novel antimicrobials and alternative approaches, including exploring opportunities from traditional Chinese medicine for treatment or prevention of infectious bacterial diseases in human or animals, as well as diagnostics.

2.1.3 Global Health Research Programme

The DHSC Global Health Research (GHR) Programme⁴³ was established following an allocation of £429.5 million from the UK's ODA budget to commission and fund internationally outstanding applied global health research delivered through the National Institute of Health Research (NIHR). Through a combination of NIHR GHR projects and partnerships with established UK and global funders, the programme has invested ~£16 million in equitable research partnerships involving Chinese partners and institutions.

The GHR programme provides funding for a total of twelve projects in China and has supported the establishment of partnerships between researchers from eight internationally-recognised UK research centres with colleagues from ten institutions in China on a wide portfolio of research.

These partnerships harness both UK and Chinese research expertise to address global health challenges, with funding strategically targeted to support research that is of both regional relevance and global importance. This portfolio includes a significant investment into research on non-

⁴⁰ www.newtonfund.ac.uk/about/about-partnering-countries/China/

⁴¹ UK-China Joint Strategy for Science, Technology and Innovation Cooperation, www.gov.uk/government/news/joint-uk-china-strategy-for-science-technology-and-innovation-cooperation-sets-new-horizons-for-closer-international-collaborations#documents

⁴² apply-for-innovation-funding.service.gov.uk/competition/98/overview

⁴³ <https://www.nihr.ac.uk/funding-and-support/global-health-research/>

communicable diseases (NCDs), such as stroke, diabetes and respiratory diseases, as well as projects on road safety, antibiotics and vaccines and immunisation.

2.1.4 BIA China Special Interest Group

The China Biotech Special Interest Group⁴⁴ is a joint initiative with the China-Britain Business Council (CBBC) and supported by the Department for International Trade (DIT). It provides a discussion platform for BIA and CBBC members in the biotech sector, exploring the opportunities for business growth in and with China, via trade and investment. The group's objective is to increase the number of UK biotech companies collaborating with, generating revenue from, and receiving investment from the Chinese market.

2.1.5 China-Britain Business Council

The China-Britain Business Council (CBBC) helps British and Chinese businesses and organisations work together in China, the UK and third markets around the world. It has a membership of over 1,000 UK and Chinese companies and organisations. The CBBC also works closely with cities and local enterprise partnerships to help forge the links to drive local economic development.

2.1.6 Prosperity Fund

The Prosperity Fund⁴⁵ was announced as part of the UK Government's 2015 Strategic Defence and Security Review. The fund aims to remove barriers to economic growth, promote the economic reform and development needed to reduce poverty in partner countries, and, as a result of this economic growth, looks to create opportunities for international business. China has been identified as a recipient country for Prosperity Fund programming. The China Prosperity Fund Programme is expected to include projects in at least four thematic areas: infrastructure alliance; financial services; rule of law for businesses; and energy and low carbon. Other thematic areas may be included at a later date.

2.1.7 UK Universities Presence in China

A number of UK universities have established links in China, including teaching and research campuses; and the UK is the second most popular partner for Chinese researchers after the US⁴⁶. These linkages cover a wide range of disciplines and areas of activity, e.g. from engagement between academics to large scale investments in branch campuses and joint research

centres. Examples of UK universities presence in China include:

1. In 2018, Oxford University and Suzhou Industrial Park (SIP) in China's Jiangsu Province signed an agreement to jointly establish the Oxford-Suzhou Centre for Advanced Research⁴⁷. This will house a multidisciplinary research, innovation, and technology centre with research focused around the areas of biomedical engineering, biomedicine, advanced functional materials, environmental technology and energy, financial mathematics, computer science and health.
2. The University of Lancaster has a longstanding history with China, including teaching, student exchange and research collaborations with leading universities including the Chinese Academy of Sciences, Guangdong University of Foreign Studies and South China University of Technology.⁴⁸
3. In 2017, Imperial College London and Beijing's Tsinghua University launched a \$300,000 joint seed fund to support early-stage bold scientific ideas⁴⁹. The fund aims to kick-start innovative research projects and concepts that are showing signs of promise but are at an early stage in development and need funding to progress.
4. The University of Liverpool and Xi'an Jiaotong University established the Xi'an Jiaotong Liverpool University in 2006, which now hosts over 7,400 students.
5. The University of Nottingham founded the first Sino-foreign university in Ningbo in 2004. It has since signed a £25 million cooperative agreement in a Marine Research Centre, which will foster new collaborations with industry in China.⁵⁰
6. The York-Nanjing Joint Centre for Spintronics and Nano Engineering combines research strengths of both institutions, attracting funding from the Engineering and Physical Sciences Research Council and Chinese businesses.⁵¹

2.1.8 UK Industry Presence in China

2.1.8.1 AstraZeneca

AstraZeneca has been in China since 1993 and has established a series of science, innovation and manufacturing centres including a global R&D centre in Shanghai⁵². The Shanghai HQ site includes commercial operations, a biopharmaceutical R&D centre and, academic training. R&D focuses on cardiovascular

⁴⁴ www.bioindustry.org/bia-membership/developing-your-company/china-biotech-sig.html

⁴⁵ www.gov.uk/government/publications/cross-government-prosperity-fund-programme

⁴⁶ International comparative performance of the UK research base 2016: www.elsevier.com/data/assets/pdf_file/0018/507321/ELS-BEIS-Web.pdf

⁴⁷ www.ox.ac.uk/about/international-oxford/oxfords-global-links/asia-east/china?wssl=1

⁴⁸ www.lancaster.ac.uk/study/international-students/find-your-country/china/

⁴⁹ www.imperial.ac.uk/news/183597/imperial-tsinghua-university-launch-seed-fund/

⁵⁰ www.nottingham.edu.cn/en/About/index.aspx

⁵¹ www.ynjc.org

⁵² careers.astrazeneca.com/locations/china

and metabolic disease, oncology, respiratory, inflammation and autoimmunity, and infection and neuroscience. Manufacturing facilities are located in Wuxi and Taizhou.

AstraZeneca is working with AliHealth (the health arm of online retail giant Alibaba) to develop a smart city response to chest pain management in Wuxi. They are using the Internet of Things (IoT) to support emergency care to chest-pain patients and refer them to clinics in good time.⁵³ Astra Zeneca is also collaborating with Tencent and the NMPA, to develop online tracking systems to fight counterfeit medicines.⁵⁴

Astra Zeneca is also partnering with the Wuxi government in a health innovation demonstration centre where it pilots new approaches, often in partnership with other companies.

2.1.8.2 GSK

GSK also has a long history of working in China and has established two joint ventures:

1. Sino-American Tianjin SmithKline & French Laboratories (TSKF). Established in 1987, TSKF is one of the earliest foreign-invested joint-venture consumer healthcare companies by GSK, Tianjin Zhong Xin Pharm.Ltd. and Tianjin Medicinal Corporation⁵⁵.
2. Zhejiang Tianyuan Bio-Pharmaceutical Co Ltd (Tianyuan). Tianyuan is one of China's leading vaccine manufacturers and joined GSK Group in 2015 as a result of the three-part deal with Novartis⁵⁶.

In 2017, GSK formed a strategic partnership with AliHealth to launch an innovative adult vaccination service system.⁵⁷ The platform aims to cover 1,500 community healthcare service centres in more than one hundred cities nationwide, including Beijing, Shanghai, Guangzhou, Shenzhen, Hangzhou, Nanjing, and Wuhan.

2.1.8.3 Congenica

Congenica was spun out of Cambridge's Wellcome Trust Sanger Institute and works with the National Health Service to help support genomic medicine on a national basis. It has also worked closely with Genomics England's 100,000 Genomes project. Congenica has established a presence in China supporting whole-genome sequencing processing and analysis for China's 100K Wellness Pioneer Project.

In 2018, Congenica announced it would develop a version of its Sapia platform specifically for the market in China and signed Digital China Health Technologies Cooperation Ltd (DCHealth) as a strategic partner to help market the product to hospitals throughout the market.⁵⁸ DCHealth has participated in a variety of national health initiatives including the National Rare Disease Registry System of China and has experience working with hospitals in the country to build IT systems that enhance patient care. DCHealth has built a reputation as one of the leading companies in China leveraging big data for precision medicine via its work establishing a nationwide data network that connects 30 specialised cancer hospitals and 174 municipal cancer hospitals across the country.

2.1.8.4 Oncimmune

As discussed in section 1.3.1 Oncimmune has announced an investment and licence agreement with GeneTech for the manufacturing, marketing and distribution of EarlyCDT®-Lung diagnose test.

From the meetings held during the mission with companies, health bureau officials and hospitals, it was clear that Oncimmune's lung cancer diagnostic kit was of great interest. Lung cancer is one of the biggest priorities in China and Oncimmune's technology provides an opportunity for earlier diagnosis and treatment.

Although Oncimmune has established a relationship with GeneTech it participated in the mission. This provided an opportunity to expand its understanding of the Chinese healthcare market and to develop new relationships in the rapidly developing precision medicine market.⁵⁹

2.1.8.5 Oxford Nanopore

Oxford Nanopore⁶⁰ is a UK-based provider of genome sequencing equipment. It has China-based commercial and support staff operating from offices in Shanghai. NextOmics (Wuhan), GrandOmics (Beijing) and Biomarker Biotechnology Corporation (Beijing) operate certified sequencing laboratories using nanopore sequencing.⁶¹

⁵³ www.china.org.cn/business/2018-02/06/content_50430004.htm

⁵⁴ uk.reuters.com/article/uk-astrazeneca-china/astrazeneca-links-with-alibaba-and-tencent-in-china-push-idUKKBN1FM1FS

⁵⁵ www.tskf.com.cn

⁵⁶ www.gsk-china.com/en-gb/about-us/gsk-in-china/

⁵⁷ www.gsk-china.com/en-gb/media/press-releases/2017/gsk-china-partners-with-ali-health-to-launch-innovative-online-service-platform-to-improve-adult-vaccination-consultation-experience/

⁵⁸ www.congenica.com/2018/09/17/congenica-announces-partnership-digital-china-health

⁵⁹ Note that although Congenica and Oncimmune already have a foothold in China, the goal of the mission was to help Innovate UK to understand the precision medicine landscape in China. Therefore, delegates were purposely selected to represent businesses with and without foothold in China in order to balance the views.

⁶⁰ nanoporetech.com/services

⁶¹ The nanopore technology seems to have gained a lot of traction in China, with a number of companies that were met by the delegation either using or distributing their products for various applications.

2.1.9 UK Government Presence in China

2.1.9.1 UKRI China

UKRI's office in the British Embassy in Beijing facilitates the development of UK-China joint research and innovation programmes⁶². It provides on-the-ground insight and experience working in China's rapidly-changing research and innovation landscape and boosts the visibility of UK excellence in science and innovation in a highly competitive market through coordinated outreach and stakeholder engagement.

Since 2007 the office has brokered a total of £270 million in Research Council and Innovate UK funding across 60 joint programmes. In the same period, an additional £150 million in UK research council funding has been awarded to independently coordinated bottom-up, curiosity-driven research and innovation activities with China.

2.1.9.2 Public Health England

Digital China Health⁶³ (a subsidiary of the Lenovo spin-off Digital China) is working with Public Health England to develop a national oncology database similar to the UK Cancer registry. This has been commissioned by the National Health Committee and will be used to help clinicians with diagnostics as well as general R&D.

2.2 Opportunities

2.2.1 Precision Medicine in China: A Continent of Opportunities

China is investing heavily in precision medicine as it sees it as a core pillar for the development of its healthcare system. Policymakers, clinicians, and entrepreneurs alike recognise the potential benefits for both targeting new therapies and for efficiently improving health outcomes through preventative measures and targeted diagnostics.

Figure 5: Number and size of hospitals in China⁶⁶
Most have scale similar to Class I or II hospitals.

	Number	Beds	Bed utilisation (%)	Average number of out-patients per year (thousands)
Class II hospitals	~1,230	>500	~100	~520
Class II hospitals	~6,520	100-499	~80	~120
Class I hospitals	~5,110	20-99	~55	~30
Unclassified hospitals ¹	~7,430			

¹Including both public and private/joint-venture hospitals

Through the Healthy China 2030 and PMI, new infrastructures are being built (e.g. including research parks, institutes, hospitals etc.), and new healthcare services and innovative technology are currently being explored.

The Chinese healthcare sector, and the precision medicine one, in particular, will continue to rapidly grow and invest in new technologies over the next decade providing a wealth of trade and R&D collaboration opportunities for UK companies.

Given that the UK and China are long-term trade partners, exploiting trading opportunities in the precision medicine sector might be easier and the mission has perceived this as the preferred approach by the Chinese organisations (companies, hospitals, and healthcare providers). Nonetheless, opportunities to run joint clinical trials or cohort studies were discussed during meetings held with the Wuxi Health Bureau, the Shanghai Health Bureau and Zhongshan Hospital, given the size of their patients' populations and available samples. Immediate opportunities for mission companies were also identified in this space.

The hospitals in China are much larger than in the UK (Figure 5), e.g. Zhongshan Hospital has 1,700 beds serving 84,000 inpatients and 3,111,000 outpatients and emergency in 2013.

China also has a very active venture capital market that is targeting healthcare and precision medicine. A number of these funders are seeking western companies with established products ready to launch into the Chinese market, e.g. Cocoon Networks⁶⁴ and Dynasty Biotechnology⁶⁵. Alongside the investment, these investors provide contacts and customers to facilitate access to the market.

⁶² www.ukri.org/research/international/ukri-international-offices/ukri-china/

⁶³ <http://www.dchealth.com/dch-en/>

⁶⁴ www.cocoonglobal.com

⁶⁵ www.dynastybio.com/

⁶⁶ China Healthcare reforms, McKinsey, www.mckinsey.com/~/media/mckinsey/dotcom/client_service/healthcare%20systems%20and%20services/health%20international/hi10_china_healthcare_reform.ashx

2.2.2 Skills, Expertise in Precision Medicine

During the mission, an issue was raised regarding the availability of skills and expertise in precision medicine. For example, at Cloud Health the mission delegates were impressed by the amount of sequencing capacity, but this did not appear to be matched by a sufficient number of experienced investigative scientists. Thus, the sequencing equipment was not being utilised to maximum impact. This provides an opportunity for UK companies to provide the skills and expertise to Chinese organisations and to train staff. The 1000 Talents programme is one intervention that is specifically targeting this issue (see 1.3).

2.2.3 Cancer Diagnostics and Therapies

China has high rates of cancer, in particular, liver and lung cancer. These diseases are a focus for healthcare initiatives to improve diagnosis, provide new treatments and continue to attract large investments in facilities and services. The country has around 22% of the world's cancer cases and approximately half of the world's liver and oesophageal cancer cases. This provides opportunities for UK companies and organisations to partner and/or trade.

2.2.4 Clinical Interpretation and Reporting

During the mission, it became apparent that although China is leading the way in data collection and analysis, there is a huge gap in interpreting and reporting.

There is an incredible appetite for ground-breaking technologies that can support clinicians in decision-making. By providing clinical and pharmacogenomics reports and decision support tools, the clinicians will be able to identify the clinical findings and the right clinical pathway for each patient.

2.2.5 UK Brand

The UK is currently viewed positively in China, and the UK and China have a long history of trade and collaboration (see section 2.1.1). The UK is recognised as a leader in research and development and in particular in genome sequencing and precision medicine. The UK's 100,000 Genome Project⁶⁷ is widely seen as one of the most advanced in the world and has recently been expanded to target one million whole genomes sequenced by the NHS and UK Biobank in five years⁶⁸. In 2019, the NHS will offer whole genome analysis for all seriously ill children with a suspected genetic disorder, including those with cancer. The NHS will also offer the same for all adults suffering from certain rare diseases or hard-to-treat cancers.

2.2.6 Genetic Counselling and Clinical Genetics

During the mission, it became clear that genetic counselling and clinical genetics expertise is very limited or completely

absent in the Chinese healthcare system. The implementation of genomic-based diagnostics and therapies means that both clinicians and patients are faced with new data and decision matrices. Genetic counsellors and clinical geneticists are viewed as critical in ensuring that patients and clinicians understand the data being presented and the pros and cons of the treatment options. The UK is viewed as a leader in these fields, and this provides an opportunity for the UK to leverage its expertise in training and utilisation of genetic counsellors to develop these services in China.

2.2.7 Routes to China

China is actively seeking to attract foreign companies and researchers to both collaborate and to locate in China.

China has a stratified government and decision-making structure headed by the central government in Beijing. Under this, there are provinces and city regions with their own government structures and policies, and this leads to competition between cities/regions for resources and investments, e.g. both Beijing and Shanghai have significant life sciences sectors and investments in precision medicine. The mission visited Shanghai and the neighbouring city of Wuxi (population 6.4 million) to help understand how central government policies are translated at the city level.

At the World Precision Medicine (China) Summit 2018 there was a presentation from the Deputy Mayor of Jiading District of Shanghai. The economy of Jiading is dominated by the automotive industry but in 2018, it was announced that a precision medicine cluster would be created by 2019. Jiading district has been chosen as one of the five districts in Shanghai to develop medical industrial clusters, which will accelerate the development of Jiading's precision medicine and health service⁶⁹. The cluster will be formed of three science park facilities:

1. Park 1. Anchor project: National liver cancer centre. Undertaking research for the prevention, diagnosis and treatment of liver cancer.
2. Park 2. Shanghai cell therapy group.
3. Park 3. Office and research incubator: Focus on medical equipment, cell therapy, data and collaboration platforms.

The other four districts in Shanghai earmarked to develop the medical-industrial clusters are Pudong New Area, Hongqiao district, Taopu town of Putuo district, and Fenglin Street of Xuhui district.

This competition between regions keen to attract foreign companies is an opportunity for businesses interested in entering the Chinese market as attractive benefits and

⁶⁷ www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/

⁶⁸ www.genomicsengland.co.uk/the-uk-has-sequenced-100000-whole-genomes-in-the-nhs/

⁶⁹ www.chinadaily.com.cn/m/shanghai/jiading/2018-08/21/content_36796813.htm

incentive packages are offered. One example is h12323⁷⁰, a government-funded networking space that helps tech companies to access resources and commercialise products and is actively scouting for promising companies that want to have a presence in the country.

In addition, there are a range of UK and Chinese organisations that offer to facilitate accessing markets in China, e.g. DIT, CBBC and Cocoon Networks. China also hosts a range of business and research conferences which often offer free or subsidised rates to attract UK attendees, e.g. WuXi Healthcare Forum 2019 – Solving Tomorrow’s Health Challenges, 5-6 March 2019 in Shanghai⁷¹.

2.3 Barriers

2.3.1 Cross Border Data Sharing and Clinical Samples

The China Data Protection Regulations (CDPR) is viewed as an important barrier and risk factor for a UK company seeking to collaborate and/or market products in China.⁷² China’s first comprehensive law of data protection, the Cybersecurity Law of the People’s Republic of China (CSL), took effect on 1 June 2017.⁷² The CDPR states that a company that collects personal information within China must store that information within China. CSL also limits the cross-border transfer of “important data”, which is defined as data closely related to national security, economic development and societal and public interests. During the mission, it became clear that both clinical and genomic data were included in “important data” and would be covered by restrictions on transferring data out of China.

The fines imposed by the CSL for breaching cross-border data transfer requirements are relatively small, but enforcement relies on severe penalties such as suspension of related business and revocation of business licenses.

Although, the issue of data transfer was raised throughout the mission meetings the scope and application of the regulations were not completely clear and there did not appear to be a consensus on how a UK business could obtain clarity on the legality of its proposed operations. How they applied to different types of data was a particular issue that remained unresolved, e.g. genomics data, clinical data and clinical images. There is concern that these laws will inhibit collaboration with foreign pharma and biotech companies in China.⁷³

2.3.2 IP Issues, Technology and Knowledge Transfer

Concerns regarding Intellectual property (IP) are widely acknowledged as a significant risk for foreign businesses working in China. IP rights have been protected since 1979 but

the lack of a clear way to enforce IP rights and the potential theft inhibits many businesses from operating in China. China has been a World Trade Organisation (WTO) member since 2001 and thus, IP regulations are part of national laws and must be in line with minimum standards. As a result, there should be few major differences between China’s laws and those of other developed countries in IP protection.⁷⁴

China’s Patent Law deals with the protection of rights over technological inventions, as in the UK, but it also covers utility models and designs (also known as “design patents”). Invention patents give protection for a maximum of twenty years, utility models for ten, and each is subject to the payment of annual fees. Chinese patent law operates under the “first to file” principle - that is, if two people apply for a patent on an identical invention, the first one to file the application will be awarded the patent. China is not a signatory to the Hague Agreement, which allows the protection of designs in multiple countries through a single filing. Therefore, separate IP rights must be applied in China.

Although China’s enforcement of IP rights is viewed as continuing to improve there are still cases of concern. Specialist IP courts have been established but enforcement can still be difficult.

2.3.3 Need for a Chinese Partner Company

For a UK SME to successfully access the market, a Chinese partner company is required to facilitate regulations, market access and logistics. Identifying an appropriate partner is far from trivial and can take more than a year. Although China presents many opportunities, evaluating potential partners and customers is difficult, time-consuming and presents significant risks.

2.3.4 Need to Establish a WOFE

A foreign-based company is not able to trade in China and has to establish a China-based wholly-owned foreign entity (WOFE). This involves a bureaucratic process that requires investment in resources. The process of establishing a subsidiary company that is able to operate in China may take more than one year. An additional factor is that foreign companies are not able to transfer funds out of China and that a subsidiary based in Hong Kong is required to transfer funds back to the UK.

2.3.5 Language and Cultural Barriers

China may be viewed as a relatively hard place to do business. Although English is widely understood it is still spoken only by a minority of the business community. Formal meetings require translators (even when English is spoken by all

⁷⁰ Website online available in Chinese

⁷¹ wxpress.wxiaaptec.com/wuxi-healthcare-forum-2019-solving-tomorrows-health-challenges/

⁷² www.china-briefing.com/news/chinas-cybersecurity-law-an-introduction-for-foreign-businesspeople/

⁷³ www.ft.com/content/69a44c36-689a-11e8-8cf3-0c230fa67aec

⁷⁴ assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/456352/IP_rights_in_China.pdf

participants), and this can add a layer of complication and lead to delay, in particular during highly technical meetings. In an attempt to promote the smooth running of meetings they are often chaired by English-speaking employees, although they may not be the most appropriate and experienced company representatives.

The business and government cultures in China operate differently than the UK. There is a high level of state control and information, and regulations are not always readily accessible and understandable to forging entities.

The Chinese healthcare system is undergoing rapid change, and the application of policies and regulations can change with little or no notice, e.g. drug prices can be reduced by the government overnight. This presents a significant risk to foreign-based companies investing in China.

2.3.6 Chinese Genome Database

China does not yet have a genome database, but the genomics characteristics of the populations are different from European and North American ones. This raises potential issues for any genomic-based diagnostic or service developed outside of China as the effect of the different genomes will not be completely quantifiable. Thus, the absence of a Chinese genome database currently presents a potential barrier to a number of companies.

2.3.7 Lack of Genetic Counselling and Clinical Genetics

Genetic counselling and clinical genetics expertise is very limited or completely absent in the Chinese healthcare system. This presents a risk for precision medicine companies looking to develop and launch products in China. Without the counselling and clinical genetics expertise, the potential impact of any product will be limited and could be counter-productive, i.e. the risk of failure for the product is increased. Also, the healthcare system may not have the staff resources and expertise (doctors and nurses) to commit sufficient time to successfully implement new precision medicine-based diagnostics and treatments.

3. China - Vaccines

A second objective of the mission to Shanghai was to understand priority areas in China's emerging vaccine market, its manufacturing capabilities and infrastructure. The UK-based vaccine company, DIOSynVax, participated in the mission. The mission met with GSK in Shanghai to discuss vaccines in China, and vaccines were also included in the other meetings during the mission.

3.1 Vaccine Market Overview

China represents one of the world's largest markets for vaccines, for example in 2018, there were an estimated 16.7 million newborns in China, and the Chinese childhood vaccination market is about four times the size of the USA. The vaccine market is estimated to be worth RMB 35.2 billion by 2022. China has been actively developing its own vaccine R&D and manufacturing capability for a number of years and also has been restricting foreign-produced vaccines.

Vaccines in China are grouped into two categories. Category 1 vaccines, such as measles and hepatitis vaccines, are mandatory and administered free of charge. The majority of category 1 vaccines are made by Chinese domestic companies. Category 2 vaccines are voluntary, for-profit vaccines, including varicella, pneumonia, and human papillomavirus (HPV) vaccines. Most foreign-made vaccines are in category 2. The uptake of paediatric vaccines is nearly universal (they are free) but adults have to pay for vaccines and have very low usage rates (<2% of the population). Vaccines are normally administered at Tier 3 hospitals rather than primary care facilities, and this may be another factor limiting uptake in adults.

The vaccine industry in China is undergoing a period of change which has been partially driven by a number of recent scandals involving the manufacture and use of vaccines. For example, Changchun Changsheng was fined \$1.3 billion in 2018 for manufacturing and distributing faulty vaccines for rabies, diphtheria, tetanus and whooping cough⁷⁵. This is not an isolated case, and a number of the 46 Chinese-based vaccine manufacturers have faced quality issues. China now appears to be making it easier for vaccines to be imported, and companies such as GSK are cautiously increasing their activities. However, this is focussed on sites of high market demand.

The government is expected to update the regulations relating to vaccines in 2019 and to impose new manufacturing standards. Recently, regulatory approval times have decreased dramatically from more than five years to five months. For clinical trials, it is now possible to submit non-China based studies so long as they have an Asian-based population arm.

China recognises that vaccines are a key part of the future healthcare system. Both HIV and oncology vaccines were identified as areas of interest.

⁷⁵ www.nytimes.com/2018/10/17/business/china-vaccine-fine.html

APPENDIX 1

Healthcare System in China

Healthcare reforms in China in 2016 highlighted the need to strengthen the primary care system as a priority to improve health equality and to mitigate against increasing healthcare costs. Healthy China 2030 and the 13th Five-Year Plan set out plans to rebalance service delivery away from hospitals and into the community and focus on the following clinical areas:

- Elderly care: there is a strong focus on improving the health literacy of elderly people, promoting integrated care, preventing common diseases and chronic diseases of the elderly and developing community-based elderly care health services, as well as the prevention and treatment of dementia and making the best use of traditional Chinese medicine (TCM).
- Paediatrics: with the ending of the one-child policy, China expected a significant increase in demand for these services. China's initial focus since 2016 has been increasing the number of maternity beds, but this is under review because the anticipated increase in birth rates has not occurred. However, paediatric services remain strained in hospitals and there has been a push to move services into the community.
- Non-communicable diseases (NCD): there has been recognition of improved outcomes from NCDs with better community care along with significant cost savings. There has been a significant domestic shift towards care associated with NCDs which is aligned with global trends.

Hospitals in China are organised according to a three-tier system that recognises a hospital's ability to provide medical care, medical education, and conduct medical research. Based on this, hospitals are designated as Tier 1, 2 or 3 institutions.

A Tier 1 hospital is typically a township hospital that contains less than 100 beds. They are tasked with providing

preventive care, minimal healthcare and rehabilitation services. Tier 2 hospitals tend to be affiliated with a medium-size city, county or district and contain more than 100 beds, but less than 500. They are responsible for providing comprehensive health services, as well as medical education and conducting research on a regional basis. Tier 3 hospitals are comprehensive or general hospitals at the city, provincial or national level with a bed capacity exceeding 500. They are responsible for providing specialist health services, perform a bigger role with regard to medical education and scientific research, and they serve as medical hubs providing care to multiple regions.

There is no control of where patients seek healthcare from the different tiers of provision. Patients have the option to attend a tier 3 hospital for routine medical care but will often pay more in out-of-pocket expenses to do so. If they attend a tier 1 or 2 centre, there is a huge variation in quality of service and availability of diagnostics and medicines. Most tier 1 and 2 centres do have referral pathways to tier 3 hospitals and telemedicine is a growing area nationwide. However, only 55% of patient consultations are in primary care settings. Health policy over the last two years has prioritised the creation of a tiered and integrated health system, where primary care takes the bulk of patient consultations as in the UK. This is well-received and pursued on the ground, and the UK is well-placed to be the partner of choice in this respect.

Medical Insurance

Although China's medical insurance coverage rates have increased to over 95% of the population, there remains significant variability in the extent of coverage. There are three types of health insurance:

1. Urban employee basic medical insurance: mandatory for urban employees of state-owned or private companies. Employers are required to contribute at least 6% of an employee's salary to this insurance and in wealthier cities like Shanghai this could be as high as 12%.
2. Urban resident basic medical insurance: voluntary for all other urban residents.
3. New rural cooperative medical system: voluntary for rural residents.

The range of coverage varies between the insurance schemes and healthcare remains a major expense for most Chinese citizens. On average, the Chinese pay 40% of all healthcare costs themselves as either premiums or out-of-pocket payments. As a result, 44% of China's rural poor are impoverished due to catastrophic healthcare costs.

Primary care institutions provided 55% of outpatient care in 2016 (often referred to as tier 1 and tier 2 centres). Typically, they offer both outpatient and inpatient care and are linked to larger hospitals for referrals, although their IT systems are often not linked. There is a wide variety of care provided by primary care institutions and staffing levels are often strained. There is no gatekeeper system and patients will often bypass the primary care system and seek medical help from large city hospitals (tier 3 centres) directly. There are no restrictions on access but typically services in the community are better remunerated by insurance schemes than are hospital services.

In China's primary healthcare system there are consistent national policies emphasising the advantages of traditional Chinese medicine (TCM). TCM is widely provided either alone or in conjunction with western medicine in the vast majority of primary care institutions.

Annex 1

List of UK Participants

AstraZeneca

Congenica

Department for International Trade (DIT)

DIOSynVax

Genomic England

Innovate UK

Knowledge Transfer Network (KTN)

Oncimmune

Perspectrum

List of China Participants

AstraZeneca Innovation Centre (Wuxi)

Cloud Health Genomics

Dian Diagnostics

GeneTech

GSK

Polaris Bio

Shanghai Health Bureau

Simcere

Wuxi Health Bureau

Yourgene

Zhongshan Hospital



