Moving from ‘made in China’ to ‘discovered in China’ – opportunities and challenges

May 2011

Lecture by Dr Jingwu Zang, Senior Vice President and Head of R&D China, GlaxoSmithKline
The Academy of Medical Sciences

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Introductory note

In May 2011, Dr Jingwu Zang, Senior Vice President and Head of R&D China for GlaxoSmithKline, gave a talk entitled ‘Moving from ‘made in China’ to ‘discovered in China’ – opportunities and challenges’.

This report summarises key insights and issues presented by the recent expansion of medical research in China that were explored during the event. Information from Dr Zang’s lecture is combined with points raised by the diverse audience of 70 Academy Fellows, representatives from across industry and policy making and other invited guests during the extensive and vibrant discussion. The event was chaired by Academy Treasurer Professor Sue Iversen CBE FMedSci.

The event concluded with comments from the Academy President Professor Sir John Bell FRS HonFREng PMedSci and The Rt Hon David Willetts MP, Minister of State for Universities and Science, who joined at the end of the meeting.
Summary

China’s emergence as a research powerhouse has produced increasingly attractive and important prospects for foreign investment and collaboration in the field of medical science. This emergence is driven by China’s rising Gross Domestic Product coupled with a focus on science and technology R&D investment by the Chinese Government. An increasingly skilled workforce, many of whom are Western-educated students who have returned to China, is turning this investment into large rises in scientific outputs such as numbers of research publications and patent applications.

Collaboration and investment prospects lie in two main areas, and developing either type of prospect requires a balanced view of the opportunities and challenges that lie in the Chinese healthcare system and that underpin the fast-changing and dynamic landscape of Chinese R&D. This report provides background analysis of Chinese R&D before focusing specifically on these two prospective areas.

The first set of prospects lie in capitalising on China’s benefits as a healthcare market. The manifold opportunities include: high purchasing power; an increasingly Westernised disease burden; unmet vaccine and regional disease needs; and recent changes in the approach to Traditional Chinese Medicine. Running clinical trials in China is attractive due to low cost, large patient pools and extensive medical records. However, there are challenges in delivering on these opportunities. Though attractive for clinical trials, some aspects of the supporting infrastructure are still developing, and the regulatory burden can be significant. Delays commonly arise from performing bridging studies, increasingly necessary for Chinese licensing, which assess whether a medical product has an ethnicity-dependent response. These delays can be greatly relieved by incorporating Chinese participation at early stages of development. Additionally, enforcement of Intellectual Property, though developing, is still inconsistent.

The second set of prospects lie in collaborating to grow further and embed Chinese medical research capacities, important to China’s own medical future and to further increasing its attractiveness as a location for investment and R&D. China’s cutting-edge basic research infrastructure has led to particularly strong centres of excellence in stem cells, structural biology and infectious diseases. Key UK collaboration opportunities lie in training, translation and clinical research. These can be achieved partly by ensuring high quality UK-based training and increasing UK-China training links. Also important is engaging with the large Chinese pharmaceutical sector as it seeks international partnership for innovation and early stage co-development projects. The UK can also provide guidance based on our established models of academic teaching hospitals and early clinical development. Building on existing partnerships and ensuring greater UK-China collaboration provides important opportunities to: help China bridge the gap between basic and clinical research; integrate research activity firmly into clinical practice; and build cadres of clinical academics.
The emergence of a biomedical research powerhouse

China represents an increasingly attractive and important prospect for investment and collaboration in the field of medical science, currently ranking second in the world for patent applications filed and predicted to lead the world in the number of scientific publications by 2013.\(^1\),\(^2\) Collaboration and investment prospects lie in two main areas. The first is capitalising on China’s benefits as a healthcare market and R&D location. The second is collaborating to further develop and embed Chinese medical research capacities, important to China’s own medical future and to further increasing its attractiveness as a location for investment and R&D.

Developing either type of prospect requires a balanced view of the opportunities and challenges that lie in the Chinese healthcare system and that underpin the fast-changing and dynamic landscape of Chinese R&D. Dr Zang’s uniquely balanced view, arising from his 20 years in the US and 9 years back in China - 4 of which he has spent heading GSK China’s R&D activities, positions him well for surveying these prospects.

Economy

The key drivers of China’s rapid development in biomedical science and technology are summarised below in Box 1. Underlying this development has been, and still is, China’s rising national Gross Domestic Product (GDP), currently the second largest in the world and expected to be the largest by 2040.\(^3\)

Box 1 Key drivers for China’s rapid development in biomedical science and technology.

- Biomedical science research receives priority support from the Chinese Government.
- Increasing R&D funding through Chinese Government investment.
- Government support for R&D clusters (e.g. science parks).
- An increase in the skill base: more graduates from both home institutions and returning from abroad.
- A focus on innovation that is leading to increasing patent applications.
- Healthcare reforms that aim to establish a bigger and better-structured healthcare market. See Box 3.
- Increased international partnerships.
- Low wage costs.

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Government spend on R&D, encapsulated by the centrally formulated Five Year Plans (FYPs), increases steadily each year. The twelfth FYP, 2011 to 2016, explicitly identifies healthcare as a strategically important sector, and promises continued increases in R&D spending whilst introducing a focus on social benefit e.g. translational research.4

**Workforce**

Chinese students who train abroad and return home highly skilled (termed ‘Sea Turtles’), are providing the required skill base to translate this investment into scientific outputs. They are also occupying key positions in Government: the current Chinese Health and Science & Technology Ministers are both returnees. It was noted that Chinese students returning from the UK and the rest of Europe mostly go into academic research, whereas many of those returning from the US go into industrial research.

Regarding home grown talent, the Chinese university sector and the quality of its graduates is developing. However, despite the fact that Chinese university sector produces ten times the amount of US science graduates, current Chinese R&D recruitment relies greatly on the few top Chinese institutions and Hong Kong’s two prominent research-intensive universities. A drive to close gaps in university quality within China should change this. As the quality of the skill base increases over time, the normalised impact factor of Chinese publications is expected to increase and either meet or surpass the global average. The recently published ‘Nature Publishing Index China 2010’, covering 2000 to 2010, reveals an 8.3-fold increase in share of Nature Publishing Group articles by basic researchers from China, compared to a 1.2-fold increase from Japan in the same period.5,6

Based on experiences at GSK China facilities, Western researchers who have moved to China do well, with many wanting to stay. The transition to a new culture is a unique personal experience, well suited to those who can adapt quickly in line with the speed at which research opportunities arise.

**The second largest healthcare market in the world**

**A fusion market**

China currently has the third largest pharmaceutical market in the world, which is a unique fusion of Western medicine and traditional Chinese medicine (TCM).7 This arises from the routine prescribing of TCM in both ‘Western’ and ‘Traditional’ hospitals, constituting approximately 20% and 80% of all prescriptions respectively. In 2007, TCM represented about 40% of the Chinese pharmaceutical market with annual sales of US$21 billion, and has been growing since.8

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4 Gov.cn (2011). *Key targets of China’s 12th five-year plan.*
http://www.gov.cn/english/2011-03/05/content_1816822.htm
7 Campbell D & Chui M (2010). *Pharmerging shake-up: new imperatives in a redefined world.*
http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Pharma_Shake-up_Imperatives_3_10.pdf
A change in approach to TCM has resulted in the discovery of single compounds responsible for pharmaceutical activity, and the development of novel formulations wherein the active components of the original preparations are concentrated. This interesting evolution of TCM from experience to evidence based represents significant pharmaceutical opportunities: Tebonin®, a novel formulation of ginkgo biloba produced by Schwabe, now enjoys extensive sales. Ongoing drivers for growth of the healthcare market are listed in Box 2.

**Box 2 Drivers for growth of the Chinese healthcare market**

**Macro-environmental factors**
- Change of demographics: an aging and increasingly urbanised population.
- Change of disease patterns: ‘Westernisation’ of the disease burden.
- Increased spending power: Chinese middle class larger than US population.
- Healthcare system reform: see Box 3.

**Industry-driven factors**
- Growth in capacity and expertise of local companies.
- Increased investment by multinational companies: see Box 4.
- Expansion of contract research organisations: both local and global, e.g. WuXi AppTec Pharma and Quintiles respectively.9

**A Western shift**
Demographic changes and associated social and healthcare improvements have impacted considerably upon disease burden. The two key demographic changes are a rapidly aging population - the number of persons over 65 is expected to triple in the next 40 years, and increasing urbanisation - rising from 36% to 50% in the last ten years.10 Since the mid-90s respiratory diseases and infections have decreased, and a disease profile very similar to many Western countries has emerged, characterised by cancer, hypertension and metabolic disease. Like the West, the incidence of stress-related conditions is also likely to increase. However, depression and dementia are underdiagnosed relative to the West, due to a significant cultural component which renders their classification as diseases a controversial issue. Nonetheless, other Central Nervous System diseases are an established burden, and the strong neuroscience R&D sector in China is working hard in this growing space.

China additionally suffers from high incidence of diseases such as tuberculosis and hepatic cirrhosis, as well as liver, lung and stomach cancers. Investment in innovative healthcare solutions for these diseases to raise both the coverage and standard of treatment is a key government priority.

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**Who’s paying?**
Total Chinese healthcare expenditure has grown rapidly over the last 20 years, and though it is currently low per-capita considering China’s national GDP, a growing per-capita GDP and an increasing precedence of ‘out-of-pocket’ expenditure means healthcare product consumption will continue to rise.\(^{11,12}\)

New healthcare reforms, detailed in Box 3, are underway. The full impact of increasingly controlled access to and delivery of healthcare remains to be seen, but it already appears that a two-tier market will emerge. A low cost ‘mass’ market covering basic healthcare need with costs mostly met by insurance plans, and a premium market accommodating to innovative drugs, paid for by insurance contributions supplemented by ‘out-of-pocket’ expenditure. Insurance coverage is not currently extensive, but the Government is aiming for 90% by the end of 2011.\(^{13}\) The Chinese urban middle class, already greater than the whole population of the USA, is getting larger, and represents significant purchasing power for novel expensive medicines.\(^{14}\)

**Box 3 Healthcare reforms in China**

- **Basic Medical Insurance System.** Reforms aim to increase: basic medical insurance coverage to over 90% of China’s population by 2011; government subsidies per person; premium individual contributions; and reimbursement ratios.
- **National Essential Drugs System.** Establish a list, managed through rational mechanisms, that defines which drugs will have their supply secured and whose cost is reimbursed via basic medical insurance.
- **Primary Healthcare System.** Implement a drive in construction of county hospitals, and urban and rural clinics.
- **Public Health.** Establish a standardised health records system for gradual national rollout, increase public health service programs, promote fair access to all services and promote the role of TCM.
- **Public Hospital Reform.** In preparation for a 2011 rollout, 2009 saw the start of experiments in: reforming operation, regulation, management and funding of public hospitals; raising service standards; and accelerating private involvement in healthcare provision.

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\(^{13}\) WICON Pharma China (2009). *The State Council approves healthcare reform plan with CNY 850 billion government investment by 2011.*
[http://www.pharmachinaonline.com/Archives/index_1_news.asp?id=350&sortid=26](http://www.pharmachinaonline.com/Archives/index_1_news.asp?id=350&sortid=26)

Clinical trials and product licensing in China

**Regulation**
As with other locations around the world, the time taken to acquire regulatory approval of novel drugs or global R&D clinical trials can be significant, with approval of generic drug trials often taking longer still. The same criteria, e.g. pre-licensing clinical trials, also apply to TCM. The Chinese regulatory framework is unlikely to change soon and therefore such timescales must be factored into plans for Chinese clinical trials. Based on recommendations from the Academy, the UK Government recently introduced measures to streamline regulation in the UK, and the possibility of similar success in China was considered.\(^\text{15}\)

**Capacity**
Though early stage capacities such as biomarker identification and imaging are still developing, performing late-stage clinical trials in China is very attractive: such trials can cost less; the infrastructure is present and developing; the workforce skill base is expanding and a large patient pool exists. An extensive system of medical records means that cohort studies are particularly attractive.

**Bridging the ethno-genetic gap**
Ethno-genetic factors can cause disparity in drug responses that necessitate careful consideration. Though the vast majority of interventions affect a similar response in both Chinese and Caucasian individuals, perhaps with a variation in timing or magnitude of effect, examples exist of significant disparities.\(^\text{16}\) To extrapolate clinical data from one ethnicity to another, a ‘bridging’ study must be performed on a Chinese cohort. The Chinese regulatory authorities now increasingly ask for such studies. Significant delays to Chinese licensing can be avoided by incorporating Chinese participation into early global pivotal studies at Phases 1 and 2, which is becoming more common.

Industry in China

**Local and global**
The Chinese biomedical sector has been dominated by domestic companies in the recent past, and it is becoming increasingly likely that some Chinese companies may become global entities. Though the gap in quarterly sales growth between multinational and domestic companies has closed in the last two years, it has been accompanied by intensification in competition. Nonetheless, there remains significant room for expansion of multinational companies in China. It was noted that the greatest scope for UK-China collaboration, due to the strength of Chinese manufacturing and basic science, is in translational and clinical research.


‘China fast’

In Dr Zang’s experience at GSK China, the development of their operations since the start in 2007 has been incredibly fast – ‘China fast’. In Shanghai they employ more than 400 people, having successfully recruited much home-grown talent as well as a large number of returnees, and operational capacity now stretches from initial chemistry to late stage development. They are also building collaborative networks of disease specialist clinicians and clinical academics.

Multinational companies with established operations in China include Wyeth, AstraZeneca, Novartis, Roche and Pfizer. Box 4 details the opportunities and challenges for industry aiming to capitalise on China’s benefits as a healthcare market.

Box 4 Opportunities and challenges for multinational companies in China

Opportunities

• Vaccines: there is room for expansion in a market currently dominated by multinational companies. However, domestic companies are receiving increased government funding for vaccine development to establish basic coverage.
• TCM: mining for active compounds and novel therapeutics present significant opportunities. The recent construction of a single compound library derived from Chinese herb extracts has resulted in the discovery of novel chemical scaffolds, which are being screened against known disease targets.
• ‘Western’ disease burden: a big market for the extension of global product lines.
• Regional diseases: China-specific burdens such as tuberculosis and hepatic cirrhosis are largely unmet needs for healthcare solutions.

Challenges

• Preferential treatment of domestic companies.
• Intellectual Property enforcement: still a critical issue, with enforcement success inconsistent.
• Ethno-genetic differences: require bridging studies and add an extra dimension to stratified medicine research.

Collaboration with China

Co-authors: academics working together

The UK ranks third in the world, after the US and Japan, for the number of co-author papers with Chinese researchers.\(^{17}\) Publication in English language journals is a common aim of Chinese researchers, perhaps due to the widespread use of impact-factor based bibliometrics in career assessment, and many Western publishing organisations are actively seeking increased Chinese submissions to their journals. China-based English language journals are increasing, such as ‘Cell Research’ by the Chinese Academy of

Sciences, which experienced a huge increase in impact factor in a short period of time. Chinese funds for collaborations are available as merit-based and peer-reviewed grants from the Chinese National Science Foundations.\textsuperscript{18}

Professor Zhengming Chen’s Kadoorie Biobank study, detailed in Box 5, was referenced specifically as an example of a large, impressive and successful UK-China clinical research collaboration.

**Drug development partnerships: building a value chain**

The large domestic pharma sector, established with government support in the last 20 years, seeks international partnerships for innovation and early stage co-development projects. Government funding ensures that these companies maintain good cash flow, and their better understanding of the regulatory system may help ease regulatory burdens.

A strong foundation of collaborative drug development will be critical to develop products for both global and domestic Chinese markets. It will require the building and establishing of ‘value chain’ models i.e. processes of cumulative production involving multiple specialised entities. This could involve bringing UK technology into one of China’s 30 national science parks, securing funding, employing contract research organisations, and using the talent and clinical resources within academia in conjunction with the development expertise of multinational company R&D. Intellectual Property enforcement, though developing, remains a barrier to the export of UK technology to Chinese science parks and it is unknown whether joint ventures generally increase chances of such enforcement.

**Box 5 The Kadoorie Biobank Study in China (KBSC)\textsuperscript{19,20}**

Professor Zhengming Chen, at the University of Oxford’s Clinical Trial and Epidemiological Studies Unit, manages this large-scale collaboration with the Chinese Center for Disease Control and Prevention. Operational since 2004, and previously known as the Kadoorie Study of Chronic Disease in China (KSCDC), the project has many key elements:

- **Broad remit:** ‘a prospective health study investigating the causes of major chronic diseases, such as stroke, heart disease, cancer, diabetes and chronic respiratory disease’. Current projects are investigating lung function, under and over nutrition and the relationship between reproductive history and other conditions in females.

- **Extensive sampling:** involving ‘512,000 people aged 30–79 ... from 10 areas across China’, there are five urban and five rural study centres.

- **Multiple data types:** initial blood samples, physical examinations and questionnaires are being followed by additional questionnaires and decades-long monitoring of health records.

- **Open to the community:** further collaboration is actively sought. Collaborating scientists are able to submit proposals to the study’s Data Access Committee.

\textsuperscript{18} For further information see http://www.nsfc.gov.cn/e_nsfcdesktop/zn/0110.htm

\textsuperscript{19} For further information see http://www.ctsu.ox.ac.uk/static/silverstripe/ss/index.php/

Box 6: Two initiatives fostering UK-China collaboration

- **Innovation China UK (ICUK)** was set-up in 2007 to support staff exchange, feasibility studies, proof-of-concept research and joint commercial R&D projects using a £3 million collaboration fund from HEFCE matched by Chinese funds. A total of £2.79 million has since been awarded, including 39 partnership grants and 33 proof-of-concept projects. ICUK currently focuses mostly on case-by-case tech transfer projects.²¹
- **Science Bridges China** is a £1.3m programme set up by Research Councils UK in 2008. Based at the University of Bradford and involving the China-Britain Business Council and UK Trade and Investment, it develops collaborative schemes for ‘research, open innovation and teaching provision’.²²

**The main areas for collaboration**

There are multiple prospects for collaborating to further grow and embed Chinese medical research capacities, important to China’s own medical future and to further increasing its attractiveness as a location for investment and R&D.

Due to strong centres of excellence with good publication records clustered in Shanghai and Beijing, China’s core strength lies in the basic research of stem cells, structural biology and infectious diseases. The key opportunity for growth lies in translational and clinical research. The Chinese government is accordingly focusing on innovation and translation, and is notably targeting high quality returnees to set up Chinese activities to fill this gap.

Key UK collaboration opportunities lie in training, translation and clinical research. It was suggested the UK, as a key destination for returnees, should ensure high quality training provision and increasing training links with China, through establishing centres of training excellence that attract R&D involvement. It was stated that Chinese government funding exists for such initiatives, and that their success would depend upon not only ideas and initiative, but good managers. Strengthening pre-existing UK-China links is the aim of initiatives such as those detailed in Box 6. Also important is engaging with the large Chinese pharmaceutical sector as it seeks international partnership for innovation and early stage co-development projects. The UK can also collaborate to provide guidance based on our established models of academic teaching hospitals and early clinical development. Building on existing partnerships and ensuring greater UK-China collaboration provides important opportunities to: help China bridge basic and clinical research; integrate research activity firmly into clinical practice; and build cadres of clinical academics.

²¹ For further information see [http://www.icukonline.org/index.shtml](http://www.icukonline.org/index.shtml)
²² For further information see [http://www.brad.ac.uk/science-bridges-china/](http://www.brad.ac.uk/science-bridges-china/)
Post-discussion comments

Left to right: Minister of State for Universities and Science, the Rt Hon David Willetts MP; Academy President, Professor Sir John Bell FRS HonFREng PMedSci; and Senior Vice President and Head of R&D China GlaxoSmithKline, Dr Jingwu Zang.

Comments from the Academy President, Professor Sir John Bell FRS HonFREng PMedSci

Professor Sir John Bell reflected on a recent ten day visit to China and the huge progress being made there to expand biomedical research, for example through significant infrastructure developments. The large scale and momentum of growth were demonstrated to him during visits to the impressive Xinhua University and Beijing Genomics Institute.

Chinese enthusiasm for further UK-China collaboration was evident in the time spent with the Chinese Health Minister Professor Chen Zhu FMedSci. Sir John highlighted how the UK is well positioned to strengthen existing links. Elements that underpin UK strengths, for example academic teaching hospitals and early clinical development, are not yet present in China and may serve as a basis for future partnership activity. China may also benefit from considering ongoing UK attempts to streamline clinical trials regulation.

Considering the momentum in China, it is easy to question the UK’s role in future growth. However, the President reflected on how healthcare and innovation is not a football match, with one winner and one loser: there are multiple winners. Engaging fully with China will be an exciting and mutually beneficial enterprise, with benefits for all of medical research.

Comments from the Minister of State for Universities and Science, The Rt Hon David Willetts MP

The Minister highlighted how the UK Government recognises the importance of medical science research as an engine for future growth. Even during these financially constrained times, medical research was prioritised in this year’s Budget and accompanying Plan for
Growth, as demonstrated by the protection of Medical Research Council funding in real terms. The Government has also taken steps to improve the wider environment for medical research. Following recommendations in the Academy’s report ‘A new pathway for the regulation and governance of health research’ the Government recently announced its intention to create a new Health Research Regulatory Agency to streamline clinical trials regulation.

Steps have also been taken to encourage and facilitate collaborations in this area, with Global Medical Excellence Cluster (GMEC) driving forward collaborations between a number of pharmaceutical and healthcare companies, leading Universities and NHS Trusts.23 A second example is the research collaboration between the University of Manchester and AstraZeneca.24 Reflecting on opportunities for international collaboration in China, Mr Willetts highlighted his own forthcoming visit to China to explore the opportunities for fostering further important and beneficial partnerships in medical science research.

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23 For further information see http://www.gmecuk.com/who-are-we
24 For further information see http://www.manchester.ac.uk/business/working/astrazeneca/
Biography Dr Jingwu Zang

Jingwu Zang received his medical degree in Shanghai JiaoTong University School of Medicine (formerly Shanghai Second Medical University) before earning his PhD in Immunology in Belgium, where he started his illustrious pursuit of a cure for multiple sclerosis through basic and clinical research. He later received an advanced research fellowship award from the US National Multiple Sclerosis Society, and conducted his postdoctoral research on multiple sclerosis at Harvard Medical School.

Dr. Zang subsequently joined the Faculty of Neurology and Immunology at Baylor College of Medicine in Texas and obtained a US medical licensure through a clinical residency program. Whilst there he was Professor of Neurology and Immunology and Research Director of the Multiple Sclerosis Center, and also the scientific founder of spin-off biotech company Opexa Pharmaceuticals. Dr. Zang has published more than 140 scientific articles in prestigious journals, chapters and books and received many international science awards. He is well known for his pioneering work in T cell vaccination as a treatment for multiple sclerosis, which led to landmark publications in Science.

In his recent career in China, Dr. Zang established both the Institute of Health Sciences (Chinese Academy of Sciences) as the founding director, and also the Institut Pasteur Shanghai (Chinese Academy of Sciences and Institut Pasteur Paris) as the Chinese founding director. Among other academic positions he held in China are Dean of the School of Medical Sciences at Shanghai JiaoTong University and Director of the Shanghai Institute of Immunology. In June 2007, Dr. Zang joined GlaxoSmithKline as Senior Vice President to head their R&D Center in China.
## Annex I Lecture delegates

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<tr>
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<td><strong>Professor William Doe FMedSci</strong></td>
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Professor Susan Iversen CBE FMedSci  Emeritus Professor of Psychology ad PVC Special Projects  University of Oxford
Imran Khan  Director  Campaign for Science and Engineering
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MOVING FROM ‘MADE IN CHINA’ TO ‘DISCOVERED IN CHINA’

Professor Sir Keith Peters FRS FMedSci
Past President

Dr Lara Phillips MRC and Health Research Team, Research Councils Unit

Professor Rodney Phillips FMedSci
Professor of Clinical Medicine and Chairman

Dr Alastair Reith Director, External Alliances & Development, R&D China

Professor William Richardson FMedSci
Professor of Biology

Dr Jill Richardson Director, External Alliance and Development, R&D China and Visiting Professor, Imperial College London

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