



UK-China Roundtable on research and development (R&D) for Future Pandemic Prevention: Testing, Vaccines and Therapeutics

Summary report and key messages from the academic and scientific research communities of the UK and China

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Virtual roundtable, hosted on Zoom by the British Embassy in Beijing and the National Innovation Centre par Excellence (NICE China)

## **Roundtable participants**

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**Dr. Jonathan Sheffield,** Board member of the Northern Health Science Alliance (NHSA) and Government Advisor to the Vaccine and Therapeutics Task Force, UK

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**Prof. Andrew Ustianowski,** Clinical Lead for the NIHR COVID Vaccine Research Programme / Joint National Speciality Lead for Infection for the National Institute for Health Research (NIHR), UK

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## Aims of the roundtable

International co-operation and cutting-edge research and development (R&D) based on lessons learned, will be essential to mitigate future outbreaks of novel diseases and prevent them turning into future pandemics.

This bilateral roundtable event brought together leading academics and research institutes from the UK and China to:

 discuss each country's cutting-edge research and development (R&D) in novel technologies, platforms and pipelines for future pandemics;

 identify research needs and areas where a change in approach would be beneficial to future pandemic preparedness;

create a short report, including key messages to share with the governments of both countries.

The roundtable format comprised opening remarks and plenary presentations from each nation, followed by an expert speaker session on 'New Horizons in Testing', then a second session on 'New Horizons in Vaccines and Therapeutics', each of which concluded with a moderated question and answer (Q&A) session with the online audience.

#### Executive summary

The COVID-19 pandemic has focussed the attention of the world on the adverse human and economic impacts of the SARS-CoV-2 coronavirus. Future pandemics could have an even greater global impact. The opportunity is here and now to learn the lessons of COVID-19 and prepare to protect the long-term future of global society.

This roundtable highlighted key successes from the UK and China in academic and clinical research and development (R&D) which delivered safe and effective COVID-19 diagnostics, vaccines, and therapeutics to the world. Millions of lives have been saved and the impact of the pandemic on healthcare systems across the globe is being significantly reduced through investment in cutting-edge R&D. International co-operation in the pursuit of continuing R&D will further reduce the burden of infectious diseases and prevent future pandemics.

Both the UK and China have developed vaccine candidates at pace and scale, with the Oxford-Astra Zeneca COVID-19 vaccine now being the most widely distributed, with over 180 countries administering doses currently. China's Sinopharm and Sinovac vaccines comprise 45% of all those administered globally.

In June 2021, the UK government's pandemic preparedness partnership prepared a report for the <u>G7</u> advocating for a <u>100 Days Mission</u> to reduce the impact of future pandemics by making diagnostics, therapeutics and vaccines available within 100 days of a pandemic threat being declared by the World Health Organisation (WHO) as a Public Health Emergency of International Concern (PHEIC). This ambitious target is based on the work of a global partnership, the <u>Coalition for Epidemic Preparedness</u> Innovations (CEPI), launched in 2017 to develop vaccines against future pandemics within 100 days of sequencing a novel pathogen.

In therapeutics, the international <u>Randomised Evaluation of COVID-19</u> <u>Therapy (RECOVERY) trial</u> continues to deliver new data on a range of potential treatments. The RECOVERY trial recruited its first patient within seven days of securing ethical approval. By June 2020, RECOVERY had successfully demonstrated the effect of low-cost dexamethasone to reduce the risk of death by up to one third in hospitalised patients with severe respiratory complications, saving an estimated 1 million lives worldwide.

In this report, experts from China highlight how human organ-on-a chip technologies are being used to evaluate novel coronavirus infection and treatment, and the ongoing potential of mRNA technologies to develop vaccines and more. International collaboration in the Sino-European R&D Centre illustrates the mutual advantage gained when each nation pools its resources and expertise, for the common good.

The opening keynote session asked how we can harness our host immunity against future pandemics like COVID-19? The answers come from the lessons of other pandemics in recent human history, like those caused by the Spanish, Hong Kong and Russian flu viruses. Immunologically why do some people fight off an initial infection, but go on to suffer repeat infections of the same, or different strains of virus? Severity of illness varies widely from person to person, not only for obvious reasons, such as immunodeficiencies, but also less understood risk factors, requiring research to understand the impact of age, nutritional status, and comorbidities such as diabetes. An inability in the individual to produce broad neutralising antibodies gives rise to repeat infections, and genetic factors may be at play here. Researchers in China are exploring the impact of all these variables on viral infection and vaccine response, using mouse models. Further investment in such R&D will lead to a greater understanding of host innate and adaptive immunity, leaving humanity in a stronger position to combat future pandemics.

Experts from the UK shared details of the national effort that continues to deliver research excellence at pace and scale in the global fight against COVID-19. In England, the National Institute for Health Research (NIHR) has a well-established Clinical Research Network (CRN), which delivers clinical trials through the National Health Service (NHS). The NHS is a single-payer, publicly funded healthcare system, which is free of charge at the point of care to all citizens. During the COVID-19 pandemic, the NIHR CRN had to ensure that the NHS could continue to deliver high-quality research as part of good clinical care, even during this time of unprecedented pressure on staff and resources in the healthcare system. Fundamental to this was collaborative R&D.

Doctors and healthcare professionals in the UK, from general practice and community care through to secondary and tertiary care, from non-academic centres to leading teaching hospitals, all pulled together to recruit patients and public to well-designed, statistically powered, randomised clinical trials. Their efforts continue to deliver a gold-standard evidence base for safe and effective COVID-19 diagnostics, therapeutics, and vaccines. Key to the success of these national and international clinical trials is ensuring that studies are accessible to the whole population at risk. Furthermore, agreeing common study endpoints and data standards ensures that researchers can compare trial findings in healthcare systems across the world.

## Key messages on investing in R&D for future pandemic prevention:

There is a real opportunity to harness the academic and scientific learning from the COVID-19 pandemic, by further investing in the research platforms and pipelines that delivered the gold-standard evidence to satisfy regulators and bring novel diagnostics, vaccines, and therapeutics to the global market.

Fostering scientific discussions between the UK and China in the development of organ-ona-chip technologies for novel viral infection and treatment

may promote mutually advantageous collaborations over the next decade.



Maintaining and funding these R&D ecosystems for non-pandemic research means that the academic and scientific communities are armed and ready to pivot and study new preventative

technologies at future times of threat from infectious disease.



A joint venture, or consortium approach can play to the strengths and resources across nations, by linking industry, academic communities, and healthcare systems in collaborative R&D that drives proven diagnostic, vaccine and therapeutic technologies to mass manufacture and market adoption worldwide. During a pandemic, there needs to be prompt international agreement on data standards



and study endpoints that enable scientists to compare trial findings in healthcare systems across the world.



# Current state of play Session 1: New Horizons in Testing

The current situation in the UK sees regional, mobile and community units for PCR testing, and a national provision of rapid antigen (or 'lateral flow') tests that enable healthcare workers and the mass population to self-test in the community. However, the range of point-of-care test (POCT) technologies on offer from industry for COVID-19 is vast, including molecular, microfluidic PCR antigen, LAMP assays and lateral flow devices. A need for a national framework to evaluate the multitude of new tests was recognised, in the context of the clinical and community settings intended for use. The <u>COVID-19 National DiagnOstic Research and Evaluation</u> <u>Platform (CONDOR)</u> was publicly funded by the NIHR and UK Research and Innovation (UKRI), in partnership with Asthma UK and the British Lung Foundation charities.

The CONDOR evaluation methodology is based on a 'target product profile', established in conjunction with the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). It determined the minimum required accuracy of a POCT technology, and a national procurement system was instigated for those that met this standard. From amongst the first technology referrals to the CONDOR platform, the LumiraDx SARS-CoV2 Ag solution was chosen for procurement, for the hospital setting.

In August 2020, the UK government launched 'Operation Moonshot', a programme of research into testing for COVID-19. The Facilitating AcceLerated Clinical validation Of novel diagnostics for COVID-19 (FALCON) study, which is part of the CONDOR research and evaluation platform, was used to deliver part of that new programme of diagnostic test evaluation. FALCON had been set up to evaluate multiple rapid tests for COVID-19 in hospital settings, but was amended to include a workstream in which COVID positive patients were identified at government-funded 'Lighthouse laboratories', which processed PCR tests. Telephone consent was obtained from these patients, and they were released from selfisolation to attend drive-through testing centres for additional swabs. These swabs were used to assess the sensitivity of four rapid antigen, 'lateral flow' tests (i.e., the ability of each test to correctly identify patients with COVID-19). Specificity of these four tests (i.e., the ability to correctly identify healthy people without COVID-19) was evaluated separately, using PCR-negative samples. Over 800 participants were recruited to this workstream of the FALCON study and results demonstrated that sensitivity increased with increasing viral load, although the absolute figure was confounded by the skills set and experience of the staff administering the test (lab scientists versus healthcare workers).

The UK is now preparing to end all restrictions, including self-isolation of people who test positive for COVID-19. Home testing with lateral flow devices plays an increasingly prominent role in this strategy.

As an alternative to these pathology-based IVD testing technologies, ongoing research in China is investigating the potential for organ-on-a-chip technology to be applied to infectious disease modelling, drug discovery and evaluation. Organ-on-a-chip is an innovative micro-physiological system in vitro, which emerged in 2010, adopting the technique of microfluidics and tissue engineering.

Organs such as the brain, heart and liver are constructed on a chip that is a comparable in size to a USB memory stick, to mimic the physiological function of the body. The technology offers the potential to help eliminate animal testing in the coming decades. R&D into organ-on-a-chip technology in China is keeping pace with the USA. By 2020, a lung-on-achip for the evaluation of novel coronavirus infection and treatment had been developed and applied in clinical trials in Jiangsu, with the approval of the China Food and Drug Administration (FDA). The lung-on-a-chip is constructed to mimic bronchial and alveolar function, using a culture of lung epithelial and endothelial cells between air-liquid interfaces, with macrophages added. According to the trial application, either the virus or the drug is introduced to the chip, around 7 days after its construction, with results available on day 10.

In the next section of this roundtable report, we summarise the findings and lessons learned from these new horizons in testing R&D, and consider the future need for diagnostics in pandemic preparedness.



Harvard University Organs-on-Chips (OOC)

The goal of OOC : simulation of different organs/ tissues

# Current state of play Session 2: New Horizons in Vaccines and Therapeutics



The second session of the roundtable began with our first presentation from industry. <u>Suzhou Abogen Biosciences</u> was established in 2019, backed by venture capital investors, and is a platform company advancing mRNA-based therapies for cancer and infectious diseases.

Abogen Biosciences has developed and manufactured ARCoV, which is an innovative lipid nanoparticle-encapsulated mRNA (mRNA-LNP) vaccine candidate, encoding the receptor binding domain (RBD) of SARS-CoV-2. This differs from comparator mRNA technologies Moderna, Pfizer-BioNTech, CureVac and Novovax, which use the S-Protein as the antigen. The company claims that their formulation can mimic many aspects of natural viral infections, to activate the immune system.

In pre-clinical studies, intramuscular immunisation of ARCoV elicited robust neutralising antibodies against SARS-CoV-2, as well as a Th1biased cellular response in mice and non-human primates. Two doses of ARCoV immunisation in mice conferred complete protection against the challenge of a SARS-CoV-2 mouse-adapted strain. Additionally, ARCoV is manufactured as a liquid formulation and can be stored at room temperature for at least 1 week and is stable when refrigerated at 2 to 8°C for at least 6 months. ARCoV was the first mRNA vaccine to be approved for clinical trials in China, with the first dose administered at Shulan (Hangzhou) Hospital in June 2020 and safety and immunogenicity results from Phase 1 published in February 2022. All dose levels demonstrated a strong humoral and cellular response and the vaccine was generally well tolerated, with all adverse effects being transient - most participants recovered within 48 hours post vaccination. ARCoV has received regulatory approvals from Mexico, Indonesia, Nepal, Malaysia and the Philippines and over 20,000 participants have been enrolled in the ARCoV Phase 3 clinical trial.

More broadly, we heard in greater detail how the UK undertook research quickly and effectively during the COVID-19 pandemic. Huge progress was made in clinical trials of novel technologies, platforms and pipelines, by using the national research infrastructure to adopt an agile, efficient and effective way of conducting studies, which provided the evidence for use and deployment of novel vaccines and therapeutics. The Clinical Research Network (CRN) is the delivery arm of the National Institute for Health Research (NIHR) and it provides services from early contact, engagement and feedback, through site identification and optimising delivery, to effective study set up and performance monitoring of clinical trials on its portfolio.

At the start of the pandemic, many organisations and individuals in the UK pivoted to concentrate on COVID-19 research. Studies were selected for CRN support based on 'Urgent Public Health' (UPH) prioritisation and a nationwide COVID-19 vaccine research programme was established. UPH designation of a study led to it having expedited set-up and ethical and regulatory reviews, with prioritisation of resources. Designation was based upon an assessment of the scientific rationale in the study protocol, confidence in its deliverability during the pandemic, ensuring minimal overlap with any similar studies on the CRN portfolio and the likelihood of results impacting population health within 12 months. Of >1,600 applications, only 101 studies were designated as UPH and these recruited over 1.2 million participants.

The UK adopted a national approach to setting up vaccine studies, but with local and regional delivery plans. Many recruitment sites were non-hospital locations, utilising a conveyor approach, which enabled high throughput recruitment of 20 to 60 participants per day. A national COVID vaccines registry enabled citizen consent to contact, plus pre-screening and booking

systems to reduce the manual workload of recruitment on research staff. Targeted social media and advertising maximised representation from the whole population, across all ethnic groups.

The third presentation in this second session of the roundtable on vaccines and therapeutics introduced an international joint venture, founded in China in June 2019, between JLP Health GmbH in Austria, Suzhou Baimajian Life Health Town, and Jiangsu Industrial Technology Research Institute (JITRI). This <u>Sino-European venture</u>, <u>Angal Biotechnology Co., Ltd</u>. (Angalbio), has secured a funding plan for three-and-a-half years, focusing on groundbreaking discoveries of novel drug targets and first-in-class drugs for global unmet medical needs. As an exemplar of international collaboration in R&D, Angalbio has a goal to bring European-initiated innovative medical research projects into China, for development and industrialisation. Their early drug discovery and R&D platforms include all the research tools required for novel drug discovery, and their business models include project licensing in, intellectual property (IP) licensing out and spin-offs.

One Angalbio project is their natural compound screening of an anti-obesity drug (AK201), in which the technology is validated first in cell-lines, and then in animal models, where variables such as body weight, lipolysis, metabolic profiling and health profiling are investigated. A similar methodological approach for anti-viral applications is planned.

The final presentation of the roundtable returned to the UK and summarised how the <u>infection innovation consortium (iiCON)</u>, led by the Liverpool School of Tropical Medicine (LSTM), is delivering integrated solutions for human infections. In a similar pathway to the Angalbio joint venture, iiCON was a multi-partner consortium, established before the COVID-19 pandemic, which brought together small- and large-scale industry partners with research institutions, to co-develop and de-risk new infectious disease formulations for vaccines, drugs and diagnostics. The market for infection therapeutics has largely been commoditised reducing industry engagement, in a broad unmet need to work with academia, industry, health systems and government to get these preventative technologies to market, and adopted for patient and public benefit more quickly. iiCON supports this pathway to market by co-developing, validating and positioning technologies to facilitate global access to cheaper, quicker and smarter anti-infectives through an open access approach, which pushes proven products from discovery to the clinic and beyond. The goal of iiCON is to make a significant, measurable, impact on reducing infectious disease transmission.

The iiCON offering to industry comprises a number of research platforms, including: natural product libraries and high throughput screening; hits to leads for antibiotics and antivirals (this platform was pivoted to address COVID-19 during the pandemic); human organoid screening and drug optimisation (where iiCON has a liver and lung organ-on-a-chip that can be immunologically connected and operated with live pathogens in Cat 3 facilities); in vivo models for antimicrobial resistance (AMR) drug development; human challenge models for vaccines (originally for large scale pneumococcus trials, and latterly applied to human respiratory syncytial virus (RSV) and influenza applications, with multi-resistant tuberculosis (TB) and SARS-CoV-2 at an early stage of development); amongst others.

In the next section of this roundtable report, we summarise the findings and lessons learned from these new horizons in vaccines and therapeutics R&D and consider the future need for these in pandemic preparedness.



# Future need

## **Diagnostics**

In the UK, the development and evaluation of rapid in vitro diagnostic (IVD) tests was crucial to the nation's recovery from the COVID-19 pandemic. Case numbers appeared low early in 2020, before mass testing protocols were implemented. As a result, transmission rates at the start of the pandemic were high, particularly from asymptomatic spread. As the volume of severe cases grew exponentially and began to overwhelm the capacity of the NHS to provide good clinical care, including demand on intensive care units, it became necessary to mandate lockdowns at local, regional, and national scale. Testing became a key pillar of the UK government's strategy to protect the NHS and save lives. Later, testing offered a route out of lockdown, began opening the economy, and saw a return to normal daily activities.

A question from the audience at the roundtable picked up on the fact that at the start of the pandemic, there was supposed to be an incubation period of "up to 14 days" for the novel SARS-CoV-2 coronavirus, which seemed to have dramatically reduced now, in most cases. The UK expert was asked whether this was a real effect, or a function of improved testing? Data do suggest that the incubation period for the omicron variant is 2 to 3 days, i.e., much shorter than the preceding delta and earlier variants. This new knowledge highlights the importance of regular testing of healthcare workers and others in close contact with vulnerable people. Rapid testing each morning, when viral load is at its highest, offers the opportunity to limit spread by identifying an infection at its pre-incubation phase.

Results from the innovative R&D in progress on lung-on-a-chip technology

in Jiangsu demonstrated that three inflammatory cytokines (i.e., small proteins which mount and co-ordinate an immune response in the body) were secreted in significantly greater quantities in a chip with two types of immune cell, compared with only one. Further R&D is developing a deep learning-based algorithm to predict the number of stimulated bronchial and alveolar tissues. The lung-on-a-chip is being applied in a biosafety level-3 lab in Jiangsu province as part of vaccine development and the research team are keen to inspire scientific discussions and collaborations.

One roundtable audience member observed that in the human body, organs don't exist in isolation, rather they all interact as a system. "On a chip" testing would have limitations in drawing conclusions about the working of the entire system. Whilst agreeing that this was the case at present, the expert from China hoped that future developments would enable the technology to mimic whole body systems. Even for the single organ, sequential progress is being made with the model in Jiangsu, warranting further R&D to continue.

In 2021, Angalbio licensed <u>SARSeq</u> from IMBA in Vienna, Austria, which is a Next Generation Sequencing (NGS) method to monitor for the presence of SARS-CoV-2 and other respiratory viruses in tens of thousands of samples, in parallel. The advantage of this sequential approach is to detect multiple pathogens which can help clinicians to make a diagnosis, whilst at the same time, distinguishing which pathogen or variant is the cause of the disease. The next stage of this research project will see Angalbio marketing their first respiratory (COVID-19) infection kit for investigational / research use only.



Source: Official data collated by Our World in Data

## Vaccines

Building on the evidence base of ARCoV, Abogen Biosciences has rapidly developed an omicron-specific vaccine, based on its proprietary mRNA platform. The company has also started building a full ecosystem of partners for mRNA vaccine R&D, for a range of infectious diseases and therapeutic applications, covering all manufacturing, transcription and purification, and formulation stages of development.

In the UK, successful recruitment through the national approach to setting up vaccine trials saw 514,000 volunteers sign up to the vaccine registry, contributing 47,500 participants to 37 vaccine trials. Legacies from COVID-19 trials that will contribute to the future need for R&D include mobile units (buses) with research facilities onboard. These will enable greater numbers of decentralised and digitised trials in future, with buses driving to non-hospital sites like leisure centres and schools in the community, to drive high throughput, diverse and representative recruitment, applicable to many studies.

One such multi-centre trial ensured that the Oxford COVID-19 vaccine safety and efficacy data were reported at the earliest opportunity. Liverpool, home of the iiCON research platform, was the top recruiting site for this trial, vaccinating 1000 participants. The scale and pace of their contribution was achieved through the expansion of the iiCON human challenge model platform and associated clinical facilities to commercial scale. Their Accelerator Research Clinic was expanded from 5 to 18 beds (with plans to extend to 21 beds for overnight human challenge activities), with a dedicated pharmacy for dispensing drugs on site. These facilities

are set up on hospital premises, but not embedded in routine clinical service, rather the unit is completely dedicated to clinical trial delivery. The team in Liverpool are open to international collaborations and keen to ensure that, post-pandemic, the R&D momentum is maintained and their ecosystem flourishes, to make a future impact on the multitude of global problems in infectious disease.



NIHR National Institute for Health Research National Patient Recruitment Centre

## **Therapeutics**

The RECOVERY trial of many COVID-19 therapeutics continues to recruit at 178 sites in the UK and has informed international guidance more than any other study, demonstrating the power of a co-ordinated response with regulatory agencies. Through the Sino-European Angalbio joint venture, in future pandemic preparedness, as soon as a novel viral infection target is identified in Europe, the natural and financial resource in China can be employed to discover the candidate lead compound for therapeutic purposes.



## Lessons learned in the UK regarding testing, vaccines and therapeutics for future pandemics include:

Mass population testing asymptomatic population testing with mandated selfisolation periods, to reduce virus transmission in the community,

whilst minimising disruption to daily life and the economy.



Life Sciences, industry and others would benefit by engaging with the NIHR CRN early in their technology and evidence development, to benefit from

Rapid testing in hospitals - was less well established during the COVID-19 pandemic in the UK but offers excellent potential to reduce nosocomial infection (also called health-care-associated or hospital-acquired infections).



Not only the UK, but other

locations worldwide have

Pandemic preparedness – setting up a diagnostic test validation programme during a pandemic is sub-optimal; the nation needs to have such R&D platforms in place, ready to start recruiting as soon as possible, in preparedness for the next pandemic.



These lessons should be of significant benefit to research, development and innovation for all, for both the next pandemic, and also non-pandemic research.



the multiple support structures available in the UK. Study protocols could be adapted at an early stage, e.g., to build in high throughput or decentralised components.

## become more efficient, agile and responsive, as a result of the pandemic.

improved their

healthcare

systems and

pathways to

The roundtable concluded with a moderated panel discussion that summarised the key messages heard from leading academic and scientific researchers in both China and the UK. We learned how mRNA can be adapted for vaccines and beyond; heard success stories of embedding an R&D culture into healthcare systems; and how developing gold-standard evidence on the safety, efficacy and scalability of diagnostics, vaccines and therapeutics for infectious disease can accelerate the licensing of these technologies into market.

The experts were asked their thoughts about the future direction of infectious disease R&D over the next few years.

Given the number of viruses of global concern, there is real opportunity for further research into the efficacy of mRNA vaccines to combat multiple variants in future pandemic preparedness. Not only in infectious disease, but also cancer therapy, such as human papillomavirus (HPV), that can otherwise overcome the immune system.

More generally, during a time of global crisis with COVID-19, there has been a huge opportunity to learn how to undertake high quality research during a pandemic. Collaborations between industry and the UK R&D infrastructure have designed the pathways to do research at scale, delivering results in a short period of time.

The legacy of the COVID-19 pandemic is the potential to apply this learning to both future pandemic preparedness and delivering non-pandemic clinical research at pace and scale, to address unmet global needs.

A further benefit is the proven ability of well-designed and statistically powered randomised clinical trials, conducted in the population at risk, to get proven products through to market and adopted into new pathways and ways of working. The next decade offers an exciting opportunity for increasing global collaboration and developing the ecosystem for infectious disease R&D more broadly, to mass population and economic benefit.

#### **Closing remarks**

The UK and China have made significant public health changes to keep pace with COVID-19 infection during the global pandemic and these changes have become the new normal. There is hope in the academic and scientific research communities that the world will unite against the likelihood of future pandemics. International collaboration is key and both nations have highlighted why ongoing investment in R&D of diagnostics, vaccines and therapeutics are crucial tools to be ready for the next novel disease of global threat.

