

Building a sustainable UK diagnostics sector

**Summary report of a FORUM workshop
held on Friday 19 March 2021**

The Academy of Medical Sciences

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Executive summary

During the COVID-19 pandemic, the diagnostic testing, microbiology surveillance and manufacturing capabilities of the UK have expanded at an unprecedented speed. By applying the lessons learned from this response, as well as harnessing the investment in people, infrastructure, collaborations and innovative regulation, there is the opportunity to build a sustainable ecosystem that supports diagnostics across therapy areas and helps address unmet health needs and public health challenges.

To discuss these issues, the Academy of Medical Sciences convened a FORUM workshop on 19 March 2021, bringing together experts from a wide range of disciplines across the NHS, academia, industry and wider life sciences sector. The challenge for the UK's diagnostic sector, emphasised by participants, is to maintain momentum going forward and to ensure that the progress made throughout the pandemic is not lost. Finding improved ways for academia and industry to access and work with the NHS, through samples, data and patients, can help drive the development of new, innovative tests that benefit patients in the future. In part this can be achieved by ensuring that current investments in the sector form the building blocks of an enduring legacy – by making sure that the best use is made of The Rosalind Franklin Laboratory and Lighthouse laboratories, for example, and by providing training opportunities to the COVID-19 workforce so they can build careers in diagnostics.

Among the key issues raised by participants were:

Leadership and collaboration

- **Clinicians and the diagnostics industry need to work more closely together** to define unmet need and where the use of new diagnostics will improve care, and thereby develop the most useful innovation for use in the clinic.
- **There is an opportunity to maintain and capitalise on the relationships that have been built** over the last year. Relationships flourished between academia and industry during the swine flu epidemic in 2009, for example; however these were not maintained, undermining the resilience of the system to future pandemics.
- **Enhancing links between industry, academia and the NHS**, and raising the visibility amongst researchers of the work performed in other sectors, is integral to supporting effective collaboration.

Nurturing innovation

- **The long-term sustainability of the diagnostics sector in the UK will require a mix of manufacturing capabilities and an environment that supports companies of all sizes.** The critical hurdle is the speed of uptake of innovation from both SMEs and global companies by the NHS.

- **Greater access to clinical samples and data for academic and industrial partners** would enable the NHS to be a powerful research and innovation platform for generating high-quality evidence for diagnostic development.
- **The development of new diagnostic technologies by industry can be incentivised by setting clear goals** for what tests need to achieve in order to be approved and adopted (e.g. target product profiles), and **by developing a health economic model that places an appropriate value on diagnostics**. Once target product profiles are developed, industry, academia and the NHS should come together to define how these needs might be met through collaboration and mutual knowledge exchange. A system for expedited approval, and processes for provisional rapid uptake, would incentivise the development of products that match the agreed target product profile.
- **Making the case for the value of diagnostics across all modalities and therapy areas** is an important step to gaining the support needed to prioritise diagnostics from funding bodies and policymakers. Currently, perceived value-for-money can take precedence in procurement.
- **The pandemic has created a new impetus behind point-of-care and home testing**, which could help the healthcare system to clear a backlog of tests and increase capacity in the long-term.

Maximising resources

- **Investment in new facilities, such as the network of Lighthouse Labs and the new Rosalind Franklin 'mega lab' opening in Leamington Spa, creates the potential for these facilities to be repurposed** for regular clinical diagnostics in the future, while retaining capacity for future pandemics.
- **Large, highly centralised laboratories can provide scale, reproducibility and quality control, with tests carried out at low marginal costs**. There are also opportunities for large-scale facilities to be used for innovation.
- Several thousand scientists and support staff have been employed and trained in COVID-19 testing facilities over the last year, with many developing molecular diagnostic skills. **The challenge now is to find ways to ensure that these new skills are not lost**. Enhanced training opportunities would help the COVID-19 testing staff build their skills in diagnostics or more broadly in multidisciplinary sciences.

Engaging the public

- Over the course of the COVID-19 pandemic, millions of people in the UK have taken a PCR COVID-19 test and several million people have consented to and carried out home testing. **There is a new awareness and willingness among the public to be more involved in public health surveillance and biomedical and health research**.

Introduction

During the COVID-19 pandemic, the diagnostic testing, microbiology surveillance and manufacturing capabilities of the UK have expanded at an unprecedented speed. With rapid validation, uptake and delivery of diagnostic tests required for the pandemic response, there has been unprecedented collaboration across sectors, investment in people and physical infrastructure, and accelerated regulatory assessment.

This growth has been driven by urgency, however, and it is not clear which elements are sustainable for the long term and can continue beyond the pandemic, and which are temporary products of the pandemic response. In addition, there are ongoing challenges for the diagnostics sector that pre-date the pandemic. Compared to pharmacological therapies, diagnostics suffer from more complicated evidence generation for efficacy, from uncertainty in their value proposition, and from a lack of a well-established and robust clinical trial infrastructure. The system in which diagnostics operates is complicated and disjointed, with decision-making in the UK markedly slower and more disparate than in other countries. The route to adoption into the NHS, reimbursement models and long-term returns on investment can also be unclear, so diagnostics typically attract less private investment than pharmacological therapies.

These challenges have been identified in work by a number of stakeholders, including the Academy's 2018 FORUM workshop report, 'Accelerating the translation of early detection and diagnosis research in cancer', and the Association of British HealthTech Industries in its August 2020 report, 'Diagnostics: a future roadmap'.^{1,2} Following this, the Academy's November 2020 roundtable report 'Lessons learnt: the role of academia and industry in the UK's diagnostic testing response to COVID-19', explored the experience of the COVID-19 diagnostic response in more detail, and highlighted several areas, including the need to:³

- Enhance collaboration across, and capitalise on, the combined strengths of the NHS, academia and industry in the development of testing strategies.
- Rapidly adopt proven innovative diagnostics and better define the use cases in which novel diagnostics could be used to address unmet diagnostic needs.
- Leverage local and community-based diagnostics.
- Maintain the regulatory agility catalysed by the COVID-19 pandemic.
- Create a sustainable workforce strategy.
- Provide certainty to laboratories by agreeing sufficient, timely and longer-term funding and contracts.

The COVID-19 pandemic has re-emphasised the importance of overcoming the challenges faced by the diagnostics sector. By applying the lessons learned from the diagnostic testing response to COVID-19, as well as harnessing the investment in people, infrastructure, collaborations and innovative regulation, there is the opportunity to build a sustainable ecosystem that supports diagnostics across therapy areas and helps address unmet health needs and public health challenges. This is an opportunity that spans the whole diagnostics sector, across different modalities, technologies and therapy areas, and building on the

¹ Academy of Medical Sciences (2018). *Accelerating the translation of early detection and diagnosis research in cancer*. <https://acmedsci.ac.uk/file-download/87699839>

² Association of British HealthTech Industries (2020). *Diagnostics: a future roadmap*. <https://www.abhi.org.uk/media/2768/diagnostics-a-future-roadmap.pdf>

³ Academy of Medical Sciences (2020). *Lessons learnt: the role of academia and industry in the UK's diagnostic testing response to COVID-19*. <https://acmedsci.ac.uk/file-download/23230740>

COVID-19 response needs to go further than just scaling up our ability to mitigate potential future pandemics.

To discuss these issues, the Academy convened a FORUM workshop on 19 March 2021, co-chaired by Professor Sharon Peacock CBE FMedSci, Director of the COVID-19 Genomics UK Consortium and Dr Nitzan Rosenfeld FMedSci, Senior Group Leader at the Cancer Research UK Cambridge Institute, University of Cambridge. The meeting convened experts from a wide range of disciplines across the NHS, academia and industry (see Annex II for a full list of participants) to explore how the recent investment and growth of the UK diagnostics system as part of the response to the COVID-19 pandemic can be harnessed to create a long-term, sustainable system that can not only respond to public health crises, but also grow and support the wider diagnostics sector.

This report summarises the key points from the discussion. Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows.

Leadership and collaboration

Effective leadership and collaboration has been central to the COVID-19 diagnostics testing response. Participants discussed some examples of these and explored how they could provide learnings that could be applied for the benefit of the wider diagnostics sector.

Leadership

Each year, the NHS undertakes more than one billion diagnostic tests – imaging, endoscopy, physiology, pathology and genomics – which amounts to about 6% of the NHS budget.⁴ These tests include everything from routine physiological tests and blood testing, which may only cost a few pounds per patient, up to more resource intensive and specialist tests such as advanced genomic and molecular tests, endoscopies and radiological imaging, which may cost hundreds or thousands of pounds per patient. Despite this scale, participants described how the diagnostics sector is often seen as a ‘service industry’ for healthcare, with pressures to produce better tests at reduced turnaround times and for lower costs. However, the COVID-19 pandemic has generated increased awareness of the vital role that diagnostics play. Over the last year, there has been significant infrastructure investment in the sector – notably the network of Lighthouse Labs and a new ‘mega lab’ opening in Leamington Spa (see below) – and a wider understanding from clinicians, politicians, the media and the public of the importance of diagnostics.

Alongside this, there have been a number of developments looking to transform the role of diagnostics in the NHS (see Box 1). These include the 2020 Richards Review, which recommended significant reform and investment in diagnostic services to meet the objectives of the NHS Long Term Plan.⁵ These developments support the overarching goal of moving from a health the complex diagnostics system requires leadership, and participants noted how recent impetus at the national level has led to some transformations of the sector for *in vitro* diagnostics.⁶ For example, the introduction of liquid-based histology required workforce retraining, and the scale-up of COVID-19 testing has used factory-line principles in some facilities. These are innovations in operational efficiency. A wider challenge raised by participants is to understand how a ‘mixed economy’ of large-scale industrial laboratories, smaller laboratories, point-of-care and home testing can be integrated cohesively.

Participants also called for stronger leadership from clinicians. If the clinical requirements and the problems to be solved are not clear, it is difficult for target product profiles to be developed. Clinicians and the diagnostics industry therefore need to work more closely

⁴ NHS England and NHS Improvement (2020). *NHS England and NHS Improvement Board meetings held in common: Diagnostics: recovery and renewal*. <https://www.england.nhs.uk/wp-content/uploads/2020/10/BM2025Pu-item-5-diagnostics-capacity.pdf>

⁵ NHS England and NHS Improvement (2020). *Diagnostics: recovery and renewal*. <https://www.england.nhs.uk/wp-content/uploads/2020/10/BM2025Pu-item-5-diagnostics-recovery-and-renewal.pdf>

⁶ *Ibid.*

together to define unmet need and use cases, and thereby develop the most beneficial innovation for use in the clinic. Clinicians and clinician scientists need to feel empowered to move into industry where their insights could be invaluable and support closer working between industry, academia and the NHS. Similarly, industry scientists could benefit from time spent in academia and the NHS, which could provide new insights into the opportunities offered by academic research, and the drivers and influencers of NHS adoption of innovations.

Box 1: The future of diagnostics in the NHS

Diagnostic activity forms part of over 85% of clinical pathways. The NHS spends over £6bn a year on over 100 diagnostic services and with this carries out an estimated 1.5 billion diagnostic tests.⁷ These services include imaging, endoscopy, physiology, pathology and genomics.

The Richards Review (2020) – published as ‘Diagnostics: Recovery and Renewal – Report of the Independent Review of Diagnostic Services for NHS England’ in November 2020 – recommended significant reform and investment in these critical diagnostic services, as well as the creation of community diagnostic hubs away from main hospital sites.⁸ These recommendations were approved by the NHS Improvement Board in October 2020.

The National Diagnostics Implementation Plan sets out the NHS’s strategic ambitions for diagnostics. These include:

New service delivery model

- Establishing community diagnostic hubs and establishing new pathways to minimise visits to acute hospitals.
- Continuing the implementation of diagnostic networks, including imaging, pathology, endoscopy and cardio-respiratory services.

Equipment

- Expanding diagnostics capacity to meet increasing demand.
- Replacing and upgrading equipment and facilities.

Workforce

- Expanding the workforce.

⁷ NHS England and NHS Improvement (2020). *NHS England and NHS Improvement Board meetings held in common: Diagnostics: recovery and renewal*. <https://www.england.nhs.uk/wp-content/uploads/2020/10/BM2025Pu-item-5-diagnostics-capacity.pdf>

⁸ NHS England and NHS Improvement (2020). *Diagnostics: recovery and renewal*. <https://www.england.nhs.uk/wp-content/uploads/2020/10/BM2025Pu-item-5-diagnostics-recovery-and-renewal.pdf>

- Establishing training schools and academies.

Digitisation and connectivity

- Improving IT connectivity and digitisation.
- Developing a standardised universal test list across all diagnostic disciplines.

Delivering the enablers of change

- Providing and developing managerial and clinical leadership at national, regional and local/network level.
- Reviewing data requirements, and commissioning, tariffs and contracting arrangements.

Collaboration

Collaborations and relationships between academia, the NHS and industry have been crucial to the diagnostics sector's response to COVID-19.

The ReACT (Real-time assessment of Community Transmission) collaboration, for example, has developed home antibody testing using lateral flow assays (see Box 2).⁹ Funded by the Department of Health and Social Care, the collaboration between Imperial College London and Ipsos MORI (the industry partner) enabled more than 900,000 people to carry out self-testing at home by the end of May 2021.

The ReACT team's experience of collaboration had many positive learnings, and extended across industry, the NHS, regulators and the public. Aspects that worked well included:

- Good public engagement, which helped ensure that participants felt confident about what they were participating in.
- Collaboration with NHS teams that enabled the rapid evaluation of tests.
- Multidisciplinary working; bringing together epidemiologists, virologists, clinicians, behavioural scientists and modellers.
- Implementation support from the industry partner.
- Engagement with the Medicines and Healthcare products Regulatory Agency (MHRA), who were flexible in their process but robust on key issues, such as how members of the public might interpret their results.

However, when choosing a test that could be deployed at scale, the team found that the domestic supply chain was limited, despite the fact that there were many companies looking to get their products into the market. For future sustainability, the UK may need greater domestic supply chains, especially in situations where demand could increase at short notice, such as in the case of a new infectious disease.

⁹ Imperial College London (n.d.). *Real-time Assessment of Community Transmission (REACT) Study*. <https://www.imperial.ac.uk/medicine/research-and-impact/groups/react-study/>

Box 2: Real-time assessment of Community Transmission (ReACT)

The ReACT programme is a series of studies seeking to improve understanding of the prevalence of COVID-19 across England.¹⁰ A collaboration between Imperial College London and Ipsos MORI – the industrial partner – the ReACT-2 component of the programme has developed and implemented home antibody testing using lateral flow assays.

The development process began with small clinical validation studies in close collaboration with NHS partners, followed by usability studies that increased in scale. Large national studies then involved multiple rounds, each of more than 100,000 people using the kit. By the end of the sixth national round, in May 2021, more than 900,000 people had carried out self-testing at home.

Another collaboration, between Imperial College London and the company DnaNudge, developed the COVID Nudge point-of-care PCR test (see Box 3). This project also benefited from collaboration with the NHS, which enabled the team to test patients when evaluating the product's specificity and sensitivity.

Again, the success of this programme was largely down to its collaborative nature, which included:

- Working with existing infrastructure and collaborations focussed on other diagnostic indications.
- Co-location of laboratory research with acute clinical sites.
- Collaborative approach with regulators.
- Active engagement with procurement ahead of more formal evaluation structures being established.

Relationships between the diagnostics industry, academia and the NHS were not always present before the COVID-19 pandemic. Relationships flourished between academia and industry during the swine flu epidemic in 2009, for example; however these were not maintained. The opportunity, recognised by participants, is to maintain and capitalise on the relationships that have been built over the last year to both bolster the diagnostics sector and maintain the resiliency of the system to future pandemics.

Participants recommended improving visibility of activities in other sectors, and enhancing links between industry, academia and the NHS. The COVID-19 Genomics UK Consortium

¹⁰ Imperial College London (n.d.). *Real-time Assessment of Community Transmission (REACT) Study*. <https://www.imperial.ac.uk/medicine/research-and-impact/groups/react-study/>

(COG-UK) – was highlighted as an example that can be learned from.¹¹ This group has brought together NHS organisations, Public Health Agencies, academic partners providing sequencing and analysis capacity, Lighthouse labs, and the central sequencing hub of the Wellcome Sanger Institute. Established in April 2020, by mid-January 2021 the group had sequenced more than 200,000 SARS-CoV-2 genomes, provided data on viral transmission and introduction into care homes, universities, hospitals and through international travel, which in turn has enabled the tracking and analysis of viral variants, and developed freely available bioinformatics and data sharing tools.

The NHS's Genomic Medicines Service (GMS) was discussed as another example of collaboration.¹² The Service has seven genomic laboratory hubs working as a national network, delivering a mandated national genomic test directory. Clinicians, academics, industry and others can suggest changes to the test directory, with a fast-track process that enables the GMS to work with industry to make immediate changes when, for example, there are changes in NICE guidance, or new licence changes for medicines.

Box 3: COVID Nudge

The COVID Nudge point-of-care test was developed through a collaboration between Imperial College London and the company DnaNudge, whose platform for rapid DNA SNP genotyping was repurposed for SARS-CoV-2.^{13,14} The collaboration benefited from strong pre-existing relationships between the partners.

A fully automated platform where a dry swab is inserted into a fully sealed cartridge, the portable multiplexed PCR test allows safe testing outside of the laboratory with results delivered in 90 minutes.

Development began in March 2020, with evaluation using commercial RNA and viral samples. Patient testing was then carried out to understand sensitivity and specificity, with CE marking and MHRA approval in July 2020. By the end of 2020, COVID Nudge had been deployed in 87 NHS sites with 320 machines.

¹¹ COVID-19 UK Genomics Consortium (n.d.). <https://www.cogconsortium.uk/>

¹² NHS England (n.d.). *NHS Genomic Medicine Service*. <https://www.england.nhs.uk/genomics/nhs-genomic-med-service/>

¹³ Gibani MM, et al. (2020). *Assessing a novel, lab-free, point-of-care test for SARS-CoV-2 (CovidNudge): a diagnostic accuracy study*. *Lancet Microbe* **1(7)**, E300-E307

¹⁴ SNP – single nucleotide polymorphism, genetic variations within a gene where a single nucleotide is different.

Nurturing innovation

The COVID-19 pandemic has brought important lessons for *in vitro* diagnostics. Yet diagnostics encompasses imaging, endoscopy, physiology, pathology, digital health and genomics, and participants noted that lessons from the pandemic can be applied to make improvements across the diagnostics sector.

The role of industry

The UK's diagnostics industry is smaller than some other life sciences sectors, such as the pharmaceutical industry. It consists of a range of start-ups, SMEs and multinationals working across many different modalities and therapy areas. Examples cited at the meeting include Binding Site in Birmingham, Randox in Northern Ireland, Abbott in Berkshire and LifeScan in Scotland.

A lot of the UK manufacturing base has been focused on exports, however, either because the companies have been focused on infectious diseases of the developing world, or because it can be slow for innovative diagnostics to be taken up in the UK. For example, only about 8% of Binding Site's products for blood cancers and immune system disorders are used by the UK.

Through the manufacturing coalition, and with significant government investment, UK companies in the field have focused their work on COVID-19. For example, Omega Diagnostics, based in Alva in Scotland, specialises in infectious disease tests for the developing world. However, they now have a contract, along with Global Access Diagnostics (based in Thurleigh), to supply COVID-19 antigen lateral flow tests to the Government.

The long-term sustainability of the diagnostics sector in the UK will require a mix of manufacturing capabilities to both meet export demand, and to react quickly to UK demand, not only for future pandemics but to support the rapid adoption of innovative diagnostics into the NHS. Enabling the sector to flourish will require an environment that supports companies of all sizes. The critical hurdle, cited by multiple participants, is the speed of uptake of innovation from both SMEs and global companies by the NHS.

The development pathway

The UK has an excellent track record in the invention of diagnostic technology. Participants noted, however, that the UK is traditionally less successful at the commercialisation of technology, and that often UK developed innovations are initially marketed outside of the UK, and only later, if at all, adopted in the UK. Challenges discussed at the meeting included a lack of clearly defined gaps in clinical pathways, and target product profiles to help pull innovations along the translational pathway. When developing COVID Nudge, for example, the team encountered issues with a lack of a target product profile to guide approval (see Box 3). Conversely, whereas other tests face uncertainty in whether they will be adopted or commercially viable, for COVID Nudge the requirement for NHS sites to test all admissions created the demand, while central procurement to supply NHS sites provided the funding.

However, as this case was unique to the urgency of the COVID-19 pandemic, this cannot be relied on as a sustainable model for demand signalling and procurement.

Participants discussed how the development of new diagnostic technologies by industry can be incentivised by setting clear goals for what tests need to achieve in order to be implemented (e.g. target product profiles), and by developing a health economic model that places an appropriate value on diagnostics. Demand signalling from the healthcare system is a powerful stimulus for innovation and translation of new diagnostics, and so a greater use of target product profiles would be one mechanism by which the needs of the healthcare system could be better articulated. Once target product profiles are developed, industry, academia and the NHS should come together to define how these needs might be met through collaboration and mutual knowledge exchange. Strong direction from clinical leaders will be vital to the success of this.

In addition to being a source of demand signalling, clinicians and clinical scientists in the NHS are themselves a potential source of innovation, and where possible NHS staff should be supported in conceiving and developing ideas that could improve health and care. Dedicated time for NHS staff to conduct or take part in research could provide wider benefits to both patient outcomes and service delivery by allowing staff to develop or capitalise on new innovations.¹⁵

The COVID-19 pandemic has brought opportunities for innovation into view. Participants noted that there is a new impetus behind point-of-care testing, and discussed how home testing could help the healthcare system to clear a backlog of tests.

Clinical samples and data

Despite the need to develop and validate COVID-19 tests rapidly, issues with sample access were noted by attendees. For example, problems with access to well-characterised clinical samples were encountered during the development of the ReACT (see Box 2) and COVID Nudge (see Box 3) tests. Participants – both from industry and from academia – discussed how difficulties obtaining samples were a long-standing problem across the sector, and recommended that improving access to samples would assist the development and validation of tests. It was noted that in many cases samples are not used before their expiry date and end up being destroyed rather than used for research, which is a great waste.

Similarly, participants discussed how improved access to NHS data, such as electronic health records and medical images, would benefit their work. As well as helping industry and academia in their development of new diagnostics, there are opportunities for innovation that could be driven by data. Examples cited by participants included: integrating data from multiple tests – such as from pathogens, resistance factors, host factors and clinical drug factors – to produce a more holistic diagnosis; and developing machine learning artificial intelligence to assist in clinical decision-making.

Overall, if access to clinical samples and data were available to academic and industrial partners, the potential of the NHS as a research and innovation platform to generate high-quality evidence for diagnostic development could be realised.

¹⁵ Academy of Medical Sciences (2020). *Transforming health through innovation: Integrating the NHS and academia* <https://acmedsci.ac.uk/file-download/23932583>

Regulation

While robust accreditation and quality assurance structures are required to ensure the quality of testing across all laboratories, frustration was expressed by participants that it can take a long time for a test or technology to be approved. If there are regulatory barriers to innovation, this can prevent patients from accessing beneficial technology.

The COVID-19 pandemic has seen innovators and regulators working in partnership to progress innovations through to clinicians and patients. For example, regulatory flexibility by the MHRA was highlighted as being particularly important for the rapid development of the ReACT diagnostic test (see Box 2). Participants discussed how this agility might be applied more broadly, for example using post-marketing evidence generation where it is appropriate and safe to do so.

The new structures set up for COVID-19 tests were also noted – such as the COVID-19 Technical Validation Group (see Box 4) – and it was recommended that such approaches are applied more widely across the diagnostic sector.

Box 4: The COVID-19 Technical Validation Group

The Technical Validation Group was established to review SARS-CoV-2 viral detection and antigen tests after technical validation and in-service evaluation.¹⁶

The Group includes a range of experts in technologies, viral testing and infectious disease, including representatives from:

- Central validation labs (including Public Health England, Frimley, Cumbria)
- CONDOR (COVID-19 National Diagnostic Research and Evaluation Platform)
- Innovate UK
- Academia professional body (Royal College of Pathology)
- MHRA

The Group reviews the outcome of all validation and evaluations and makes recommendations to the wider COVID-19 Test, Trace, Contain and Enable (TTCE) programme on the suitability of the solutions/technologies.

¹⁶ Department of Health and Social Care (n.d.). *National technical validation process for manufacturers of SARS-CoV-2 (COVID-19) tests*. <https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview>

On the other side, participants recognised that developers of tests could make improvements to help accreditors in their assessment of new diagnostics. In particular, identifying the data that needed to be generated for accreditation at an early stage, and working with defined target product profiles. In addition, the need for transparency of rules and understanding with whom responsibility lies at the different stages of accreditation were raised by participants. Examples were cited of commercial providers who developed oncology diagnostics that would not be used – either because they were too expensive or because they did not solve a relevant clinical problem.

For products developed to an agreed target product profile, participants recommended a system for expedited approval, and processes for provisional rapid uptake. This may help to strike a balance between the gathering of pre-market evidence, post-market surveillance and clinical performance evidence, enabling a few more calculated risks to be taken in a pre-market context.

Funding

The value proposition for diagnostics has, historically, been difficult to determine. Participants recognised that this is a global problem, with diagnostics – and *in vitro* diagnostics in particular – being undervalued and expected to be low cost. The overall value of diagnostics to healthcare is seldom examined. This can be especially true for diagnostics focused on early detection or prevention, where the cost-savings may be accrued over many years. This can make it difficult for new diagnostic tests developed in academia to be taken forward by engaging with private equity. However, the COVID-19 pandemic has helped demonstrate in clear terms the potential value that diagnostics can have, in a way that might not previously have been predicted. Seizing this opportunity to make the case for the value of diagnostics across all modalities and therapy areas will be an important step in gaining the support needed from funding bodies and policymakers to make diagnostics a priority.

Participants also discussed the impact of value-for-money taking precedence in procurement. This can create problems with secure supply chains in difficult circumstances, as seen during the initial response to the COVID-19 pandemic, where key diagnostic components manufactured abroad were in short supply. They recommended a balance of domestic and international suppliers, which would ensure both security and value.

Integrating new innovations into healthcare

Once evaluated, adoption across the NHS can be slow and heterogeneous. Participants noted that the adoption rate of innovation in the UK's pathology sector is slow when compared to the UK's diagnostic imaging sector, and that this lag is even more pronounced when compared to the adoption of innovation in the UK's surgical sector.

Participants discussed the difficulties caused for small companies by the length of time between the marketing of a new product and it being adopted into the NHS. This process requires approval from NHS commissioners, followed by adoption and procurement throughout the NHS, which takes time and can be heterogeneous. During this period, the small company may not be receiving any income, which constitutes a large risk that can inhibit investment in these companies. Government support of smaller companies was considered crucial, as without it many innovations will not progress further than a proof-of-concept.

Diagnostics in primary care was described as an area of huge future potential, especially for areas such as supporting prescribing to prevent antimicrobial resistance. However, it was acknowledged that the adoption of diagnostics into primary care would need to accommodate existing time and cost pressures, and seek to reduce the burden on staff and budgets rather

than increase it.

The involvement of clinicians in the development process was seen as important for the adoption of an innovation. True clinical leadership in this way can lead to transformations in the sector. However, involvement of particular clinicians may mean that innovations are adopted in certain geographical areas, and are not universally adopted at the same speed. It is important to ensure that patchy adoption of innovative diagnostics does not exacerbate health inequalities – a ‘joined-up’ approach to introducing new technologies is essential.

The issue of scalability was also raised – both as a current gap when trying to bring new innovations into diagnostic laboratories, and as a requirement for business cases for implementation. The experience gained through the scale-up of COVID-19 testing was seen as invaluable for the sector.

Other participants noted that the NHS is not the only route to commercialisation for the UK diagnostics industry. While the UK healthcare system was seen as the priority, the market is global. The regulatory and business environment in the UK needs to be attractive for both UK and non-UK businesses to translate and deploy their technologies.

Maximising resources

The last year has seen unprecedented investment in diagnostics by the UK Government, for new or improved infrastructure, and for an enlarged workforce. Participants discussed how these changes could benefit the sector as a whole as we emerge from the COVID-19 pandemic.

Infrastructure

With a network of Lighthouse Labs, each carrying out thousands of COVID-19 tests each day, a new 'mega lab' opening in Leamington Spa (see Box 5), and investments in partner labs, the UK's testing capabilities have scaled-up remarkably over a period of 12 months.

Box 5: The Rosalind Franklin Laboratory

A new 'mega-lab', the Rosalind Franklin Laboratory (formerly known as Project Jupiter), has been established in Leamington Spa.¹⁷ Its primary role is to be a high-throughput COVID-19 testing laboratory as part of the Pillar 2 network. Over time, as the demand for COVID-19 testing decreases, its operations are expected to diversify so that it becomes an enduring legacy.

The site is owned by the Department of Health and Social Care; after the merger of Test & Trace and Public Health England, it will be part of the new UK Health Security Agency (UKHSA).

Situated in a repurposed distribution centre, with 220,000 square feet of space, the site includes laboratories, conference and welfare areas, and warehousing facilities. The layout was designed with help from industry experts using factory-line principles that take into account not just the molecular testing, but also how samples are delivered, packed and processed in large numbers. The Category 2 laboratories (with the possibility of introducing Category 3 if required) are therefore constructed as 13 independent, linear, workflow-centric lanes.

¹⁷ Department of Health and Social Care & UK Health Security Agency (2021). *New megalab opens to bolster fight against COVID-19*. <https://www.gov.uk/government/news/new-megalab-opens-to-bolster-fight-against-covid-19>

In the short term, the 13 laboratories will be focused on COVID-19 testing and sequencing. Longer-term, their usage could be adjusted, for example:

- 30% ongoing COVID-19 surveillance (depending on factors such as new variants of concern, vaccine uptake and efficacy, and supporting policy)
- 10% COVID-19 sequencing
- 60% repurposed for applications such as biosecurity, diagnostic testing, research and development, or commercial propositions.

These facilities have the potential to be repurposed for normal clinical diagnostics in the future, while retaining capacity for future pandemics. Participants felt it is imperative that the opportunity afforded by the investment in these facilities is not squandered and that the sector agree how they might be used in a sustainable way. Large, highly centralised laboratories can provide scale, reproducibility and quality control, with tests carried out at low marginal costs. Tests such as molecular screening for cancer, or genetic screening studies for inherited disorders of metabolism were suggested. However, participants also noted that while large facilities can provide high-throughput testing, with sample handling, analysis and storage, they are expensive to run and need a guaranteed throughput of samples to remain economical.

Alternative models were also discussed, from large scale facilities with a large capacity, some of which may need to be 'mothballed', ready to respond to a pandemic crisis, through to a more regionalised and distributed approach with capacity built into the networks. Ultimately, participants felt that a mixed economy that combines large, centralised facilities for non-urgent tests, distributed facilities (likely within NHS hospitals) for urgent tests, and point of care testing taking place in primary care or in the home may be required.

Participants also raised possibilities for innovation in large-scale facilities. For example, unlike clinical biochemistry, the use of automation and robotics in the molecular space is still relatively limited, with a reliance on manual sample handling. This provides an opportunity for robotics SMEs, potentially reducing the UK's current reliance on imports. Challenges were also identified – in particular, the potential for point-of-care testing in acute sites, GP sites or hubs to reduce the need for factory-style laboratories in the future. This would be a marked change from the current model of diagnostics delivery.

If the large facilities are used for normal clinical diagnostics, participants raised the importance of the integration of the data with other systems. While COVID-19 testing is a simple result and reporting pipeline, tests for biochemistry, haematology and genetics, for example, often need to be integrated with other data to form a full clinical picture.

Workforce

To staff the new COVID-19 testing facilities, several thousand scientists and support staff have been employed and trained over the last year, with many developing high quality molecular diagnostic skills. The challenge now is to find ways to ensure that these new skills are not lost when the pandemic recedes and less COVID-19 testing is required, so that there are opportunities in clinical diagnostics or research.

Enhanced training opportunities were proposed by participants, helping the COVID-19 testing staff to build their skills in diagnostics or more broadly in multidisciplinary sciences. The programme could have an NHS training component, with staff then transferring into industry or academic research teams. This would not only help provide the diagnostic sector with a skilled, adaptable workforce, but would also help build engagement between the NHS, industry and academia. In the long-term, automation may be beneficial, or even essential, to some diagnostics, but such a shift should be anticipated and prepared for to avoid detrimental impacts on the diagnostics workforce.

Engaging the public

Before the COVID-19 pandemic, diagnostic testing was seldom discussed by the public or media; other than screening programmes, it was a largely invisible part of healthcare. Over the course of the COVID-19 pandemic, however, tests have been headline news, millions of people in the UK have taken a PCR COVID-19 test and several million people have consented to and carried out home testing. This has created a potential for change in the culture of diagnostic testing going forward.

Participants discussed how public acceptance and understanding of testing has evolved through the pandemic. The number of tests available, with a range of sensitivities, specificities, turnaround times, and where they can be delivered, can be quite bewildering to many, even those who work in the field. Despite this, the high profile of COVID-19 testing – with extensive discussion in the media and on social media – has, in some ways, upskilled the public in the uncertainty of diagnostics and science more generally. In addition, the removal of journal paywalls for COVID-19 research has allowed papers to be shared widely by the public.

The COVID-19 pandemic has therefore brought an opportunity for improving this scientific literacy further, and to broaden understanding of diagnostics. Mathematical literacy was seen as essential too – in particular, helping to explain how some tests relate to probabilities in diagnosis, while others provide a yes or no answer. Such health-related education will become increasingly important if, through more prevalent point-of-care testing and home testing, the public becomes more engaged in their healthcare.

The use of home testing has also changed people's expectations of what healthcare testing involves. This has been taken even further with the launch of self-testing for secondary school children in March 2021 – a whole generation is now familiar with testing at home.

For the diagnostics community, the experience gained from COVID-19 home testing will be invaluable when developing new home tests for other conditions. Participants described how it is essential to engage with the public in the development of new diagnostic tests to ensure they are acceptable, as well as ensuring that the tests themselves are as easy to use as possible for patients.

An additional outcome of COVID-19 testing is the embracing of technology that reports results directly to patients. Enabling patients to access their healthcare data more generally and to receive all their test results – often difficult at present – could help them to engage with their diagnostics and to become more informed about their health. Participants raised concerns over public expectations and the requirement for support, however. While COVID-19 tests are binary – positive or negative – other types of tests, such as those related to cancer, often require clinical interpretation and should be delivered through a healthcare professional.

Looking ahead

The UK's diagnostic field has delivered some remarkable achievements during the COVID-19 pandemic. The challenge, emphasised by participants, is to maintain this momentum going forward and to ensure that progress is not lost. In part this can be by ensuring that the investment in the sector becomes an enduring legacy – by making sure that best use is made of the Rosalind Franklin Laboratory and Lighthouse laboratories, for example, and by providing training opportunities to the COVID-19 workforce so they can build careers in diagnostics.

The pandemic has provided wider lessons for the diagnostics community, notably the changing nature of testing. Community testing and home testing, centralised and distributed testing, large-scale and small-scale laboratories – all need to be considered strategically for new models of where and how testing is carried out. Making better use of the UK's greatest healthcare resource – the NHS – was also considered important by participants. Finding improved ways for academia and industry to access and work with the NHS, including by access to samples, data and patients and by collaboration with clinicians, can help drive the development of new, innovative tests that benefit patients in the future. Other key issues included developing the workforce so that it is ready for the future diagnostics landscape, and the importance of validation, quality control, and regulation.

Long-term, the most significant outcome of the COVID-19 pandemic for diagnostics may be the public's exposure to and interest in testing. This presents an opportunity to build scientific literacy and trust, which is particularly important in this era where information is widely accessible, and opinions shift.

Annex I - Agenda

Friday 19 March 2021, 13.30-17.00

13.30 – 13.40	<p>Introduction from the co-chairs Professor Sharon Peacock CBE FMedSci, Director, COVID-19 Genomics UK Consortium and Professor of Public Health and Microbiology, Department of Medicine, University of Cambridge & Dr Nitzan Rosenfeld FMedSci, Group Leader, Cancer Research UK Cambridge Institute, University of Cambridge</p>
Session 1: Views on the current UK landscape for diagnostics	
13.40 – 13.55	<p>The current state of play: what does the UK diagnostics sector look like? Doris-Ann Williams MBE, Chief Executive, British In Vitro Diagnostics Association</p>
13.55 – 14.10	<p>The future of diagnostics in the NHS Professor Dame Sue Hill OBE DBE FMedSci, Chief Scientific Officer, NHS England</p>
14.10 – 14.25	<p>Building for the future: Project Jupiter Professor Dame Anna Dominiczak DBE FRSE FMedSci, Director of Laboratories, COVID-19 National Testing Programme, Department of Health and Social Care and Regius Professor of Medicine, University of Glasgow</p>
14.25 – 14.40	<p>Case study: the rapid development, evaluation and adoption of a diagnostic test Professor Graham Cooke, NIHR Research Professor of Infectious Diseases, Imperial College London</p>
14.40 – 14.50	Break
Session 2: Laying the foundations for growth and sustainability	
14.50 – 15.40	<p>Breakout session Delegates will split into breakout groups of 8-10 people, and discuss the following two topics in a facilitated discussion.</p> <ul style="list-style-type: none"> • What opportunities has the COVID-19 testing response realised that could be harnessed for the benefit of the wider diagnostics sector? Eg. <ul style="list-style-type: none"> o New collaborations and ways of working o Streamlined processes and regulation o Investment in infrastructure and people • How might we address • other outstanding issues to support the growth and sustainability of the UK diagnostics sector? Eg. <ul style="list-style-type: none"> o Encouraging innovation in academia, industry and the NHS. o Growing a sustainable workforce. o Promoting uptake and adoption of innovations.
15.40 – 15.55	Break

15.55 – 16.45	Reporting back and plenary discussion Breakout group facilitators will report back their key points, followed by a plenary discussion with the whole delegation, led by the workshop co-chairs.
16.50 – 17.00	Closing remarks from the co-chairs Professor Sharon Peacock CBE FMedSci , Director, COVID-19 Genomics UK Consortium and Professor of Public Health and Microbiology, Department of Medicine, University of Cambridge & Dr Nitzan Rosenfeld FMedSci , Group Leader, Cancer Research UK Cambridge Institute, University of Cambridge

Annex II - Participants

Co-chairs

Professor Sharon Peacock CBE FMedSci, Director of COVID-19 Genomics UK Consortium, University of Cambridge

Dr Nitzan Rosenfeld FMedSci, Senior Group Leader, Cancer Research UK Cambridge Institute, University of Cambridge

Speakers

Ms Doris-Ann Williams MBE, Chief Executive Officer, British In Vitro Diagnostics Association

Professor Dame Sue Hill DBE FMedSci, Chief Scientific Officer, for England

Professor Dame Anna Dominiczak DBE FRSE FMedSci, Director of Laboratories, COVID-19 National Testing Programme, Department of Health and Social Care

Professor Graham Cooke, NIHR Research Professor of Infectious Diseases, Imperial College London

Attendees

Professor Eric Aboagye FMedSci, Director, Comprehensive Cancer Imaging Centre, Imperial College London

Dr Wendy Alderton, Early Detection Programme Manager, Department of Oncology, University of Cambridge

Dr Lyndsy Ambler, Strategic Evidence Manager, Cancer Research UK

Professor Andrew Beggs, Professor in Surgery & Cancer Genetics, University of Birmingham

Dr Neil Bentley OBE, Head of Specialist Microbiology Technical Services, Public Health England

Dr Matt Burney, Business Development Executive, Cancer Research UK

Mr Bruce Caldwell, Country Business Leader, Integrated Diagnostic Solutions, UK & Ireland, Becton Dickinson

Dr Alex Cole, Head of Strategic Marketing, CPI

Dr David Crosby, Head of Prevention and Early Detection Research, Cancer Research UK

Professor Jack Cuzick CBE FRS FMedSci, Director, Wolfson Institute of Preventative Medicine, Queen Mary University of London

Professor David Denning FMedSci, Professor of Infectious Diseases in Global Health, University of Manchester

Dr Laurent Dupays, TIN Coordinator (Biologics, Devices, Diagnostics), University College London

Dr Helen Firth FMedSci, Consultant clinical geneticist, Addenbrooke's Hospital

Dr Ciaran Fulton, Head of Diagnostics, LifeArc

Professor Sonia Gandhi, Group leader, Neurodegeneration Biology Laboratory, The Francis Crick Institute

Professor Keith Godfrey FMedSci, Professor of Epidemiology and Human Development, University of Southampton

Dr Charlotte Harden, Deputy Director and Chief Operating Officer, Leeds NIHR In Vitro Diagnostic Co-operative, University of Leeds

Mr Peter Harrison, Managing Director, Siemens Healthineers

Professor Gail Hayward, Deputy Director, NIHR Community Healthcare MedTech and In vitro Diagnostic Co-operative, University of Oxford

Ms Suzanne Holden, Vice President, Corporate Accounts & Country Leader, ThermoFisher Scientific

Mr Stewart Hutton, Business Lead Diagnostics, Siemens Healthineers

Mr Pierre Hazlewood, Director of Marketing, Roche

Professor Alison Holmes FMedSci, Professor of Infectious Diseases, Imperial College London

Ms Basma Jeelani, Head of Business and Innovation Group, School of Life and Medical Sciences, University College London

Professor Peter Johnson CBE FMedSci, Professor of Medical Oncology, University of Southampton

Dr Rachael Liebmann OBE, Group Medical Director, The Doctors Laboratory and Health Services Laboratories

Dr Elizabeth Loney, Associate Medical Director and Consultant Radiologist, Calderdale and Huddersfield NHS Foundation

Dr Leila Luheshi, Associate Director of Clinical and Translational Research, Oxford Nanopore

Dr Ruth March FMedSci, Senior Vice-President of Precision Medicine, AstraZeneca

Professor Joanne Martin, Director of Academic Health Sciences and Professor of Pathology, Queen Mary University

Dr Mike Messenger, Principal Science Adviser for IVDs, Medicines and Healthcare Products Regulatory Agency

Dr Massimo Micocci, Research Associate, NIHR London In Vitro Diagnostics Co-operative

Dr Johan Ordish, Group Manager (Medical Device Software and Digital Health), Medicines and Healthcare Products Regulatory Agency

Dr Mike Osborn, President, The Royal College of Pathologists

Dr Tim Peakman, Chief Operating Officer, University of Leeds

Dr Marcia Philbin, Chief Executive, Faculty of Pharmaceutical Medicine

Professor Alex Richter, Professor and Honorary Consultant in Clinical Immunology, University of Birmingham

Professor John Simpson, Director, NIHR Newcastle In Vitro Co-operative

Mr Adrian Smith, General Manager, HOLOGIC

Dr Alexandra Smyth, Senior Program Manager, Royal Academy of Engineering

Mr Nishan Sunthares, Chief Operating Officer, Association of British HealthTech Industries

Ms Helen Tucker, Chair Elect, British In Vitro Diagnostics Association

Dr Philip Turner, Manager & Senior Researcher, NIHR Community Healthcare MedTech and In Vitro Diagnostic Co-operative

Ms Claire Wallace, Vice President, Life Sciences Group, Thermo Fisher Scientific

Professor Mark Wilcox, Professor of Medical Microbiology, University of Leeds

Mr Allan Wilson, President, Institute of Biomedical Science

Professor Lawrence Young FMedSci, Professor of Molecular Oncology, University of Warwick.

Staff and secretariat

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Dr Anna Hands, Policy Officer, Academy of Medical Sciences

Dr Claire Cope, Head of Policy, Academy of Medical Sciences

Mr George Phillips, Policy Officer, Academy of Medical Sciences

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Ms Alex Straw, Programme Officer, Academy of Medical Sciences

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