



Department for
Business, Energy
& Industrial Strategy

UK Vaccine Taskforce 2020 Achievements and Future Strategy

End of year report



December 2020



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Introduction

By Sir Richard Sykes, Chair of Royal Institution

As a microbiologist, the fact that infectious diseases have and continue to be one of the major killers of mankind is not surprising. What I do find surprising is that as a Nation we are ill prepared to deal with pandemics when they arrive.

In 1998 as CEO of GlaxoWellcome, I was instrumental in establishing and funding a three-way collaboration between Government, Industry and Academia designed to carry out the basic research necessary to develop and produce new vaccines. At the centre of the collaboration was a new research institute¹ named after the British vaccine pioneer, Edward Jenner and officially opened by Peter Mandelson the Secretary of State for Industry.

GlaxoWellcome made a commitment to fund the Institute for 10 years following which it struggled to obtain Government support and eventually ended up at Oxford University. So I am extremely supportive of renewed approaches to grow and strengthen the UK vaccine industry.

When I was approached by Kate Bingham in June of this year to review the strategy and goals of the UK Government Vaccine Taskforce (VTF), I was very pleased to do so.

The UK Government VTF was established in April 2020 by the Government's Chief Scientific Advisor, Sir Patrick Vallance, to drive forward, expedite and co-ordinate efforts to ensure that the UK population would have access to a clinically safe and effective vaccine against COVID-19. Kate Bingham was appointed in May 2020 as chair of the VTF reporting directly to the Prime Minister and working within the Department for Business, Energy and Industrial Strategy (BEIS).

The VTF was given three objectives:

1. Secure access to the most promising vaccine/s for the UK population as quickly as possible;
2. Make provision for international distribution of vaccines so that the benefits of UK leadership and investment in this area could be widely shared; and
3. Support the UK's Industrial Strategy by establishing a long-term vaccine strategy to prepare the UK for future pandemics.



¹ https://www.nature.com/articles/nm1298_1349a

The Prime Minister specifically emphasised his desire that the VTF consolidate the UK's position at the forefront of global vaccine research and development.

The UK was at this point in the early stages of the COVID-19 pandemic. Given the need to work at extreme speed, it was quickly agreed that the VTF would have most success in meeting its goals if it had a ring-fenced budget and a clear and dedicated ministerial approval process to govern spending commitments. Without these measures it is inconceivable that the VTF would have been able to secure the desired vaccine portfolio and lay the foundations for the UK's improved pandemic preparedness.

As I commented to Government in July, "the team leading the VTF highlights the depth of talent and expertise we have in the UK. They are in my opinion perfectly suited for the complex task ahead, being a team of highly experienced individuals, smart and pragmatic. If anyone can do it, they can."

Just six months on under Kate Bingham's leadership, the VTF has made enormous progress. The UK had already ordered 40 million doses of the first vaccine to show highly encouraging clinical results, which was the Pfizer/BioNTech vaccine. Phase 3 efficacy data showed this vaccine will be 94% effective in the elderly which is a key population for protection. This was the first vaccine supply agreement the VTF announced in July 2020, and the first deal signed by Pfizer/BioNTech. Through the decisive and rapid work of the VTF, the UK was the first country to pre-order the vaccine from Pfizer/BioNTech, and is expected to receive a total of 40 million doses, enough to vaccinate up to a third of the population, with the majority of doses anticipated in the first half of next year. Deployment of this vaccine will now start first in the UK in early December, following recent approval by the UK Medicines and Health products Regulatory Agency (MHRA).

My own assessment of the VTF's progress against the three goals is as follows:

1. VTF has built an attractive portfolio of the most promising vaccines for the UK population

The VTF's strategy to build a diverse portfolio of vaccines across different formats gives the UK the greatest chance of providing a safe and effective vaccine, recognising that many of these vaccines in development may fail. The VTF focused on vaccines that could be in the clinic in 2020, which could be manufactured at scale preferably in the UK, which had the potential to secure rapid regulatory approval and be delivered ready for deployment as rapidly as possible.

It was sensible to prioritise those vaccines with the earliest delivery schedules, for example to prioritise Pfizer/BioNTech over Moderna given that Moderna was likely to deliver vaccines to the UK up to four months later than Pfizer/BioNTech. VTF's strategy of striking early deals at risk has offered several advantages to the UK, including securing early dose volumes and giving plenty of time to the NHS teams to prepare for deployment. Oxford/AstraZeneca's vaccine also has the potential for early approval and delivery and the UK's 100m doses could be used to protect 50m people.

However, this is only part of the picture. The VTF has balanced innovative, more clinically advanced but less well-known vaccine platforms (adeno and mRNA vaccines) with established platforms with proven safety profiles (protein subunit vaccines and whole inactivated virus vaccines) that will take longer to secure possible regulatory approval but should provide future contingency options and flexibility of response to a virus we are still learning about.

The rapid pace of scale up of the vaccine manufacturing processes has been remarkable given the complexity and challenges of the biological systems. Delivering any doses at all in 2020 is a great achievement.

Having access to a range of safe and effective vaccines in the UK portfolio provides the opportunity to mix and match different combinations of vaccines in the two-dose regime, to identify the optimum combination for durable and robust immunity.

2. VTF has shaped new collaborative arrangements to ensure that successful vaccines will be distributed internationally

The COVID-19 Vaccines Global Access facility (COVAX), to which the UK has made up to £548 million available, will provide access to vaccines for lower income countries including one billion doses for developing countries worldwide. The UK through the VTF has helped to develop the COVAX facility and has shared its expertise and people with COVAX to support their global efforts.

The VTF has also suggested that such an initiative should become a permanent global facility that can respond to future pandemics with a trusted and effective governance structure.² They believe, and I would concur, that a trusted leading organisation is needed to create a permanent funding platform for pandemic vaccines, so that the international community can respond much more rapidly for the next potential pandemic and deliver vaccines to rich and poor countries in parallel.

3. VTF has supported the UK's industrial strategy by reinforcing long-term vaccine capability to prepare the UK for future pandemics, helping to place the UK at the forefront of vaccine R&D, manufacturing and distribution, but more is needed

One of the most interesting and imaginative aspects of the VTF's work lies in the plans it has laid for future resilience and industrial leadership in this vital area. The VTF has provided targeted funding and focus across three broad areas that support the UK's long-term pandemic preparedness.

First, the VTF has provided funding to accelerate and expand the UK's ability to manufacture a range of vaccines at three sites

- VMIC (Harwell);
- CGTC Braintree; and

² Plan now to speed vaccine supply for future pandemics: <https://www.nature.com/articles/d41586-020-02798-0>

- Valneva (Livingston).

These sites will now form the core UK vaccine manufacturing capability for the future.

Funding was also provided to the Centre of Process Innovation (CPI) to develop a good manufacturing practice (GMP)-ready mRNA manufacturing capability and support mRNA process development. It was sensible for the VTF to also provide funding for critical skills training, both online (including virtual reality) as well as physical training to bring people into advanced manufacturing in the UK.

Consideration should be given to secure bulk antibody manufacturing capability and nimble plant antigen manufacture – both critical parts of the UK’s pandemic armoury to support a rapid response to future pandemics. The UK also needs to develop a strategy to access mRNA vaccines in the future since none of the most advanced mRNA vaccines are currently manufactured in the UK. The UK also needs to attract the best future cutting-edge vaccine platforms for development in the UK.

Secondly, the VTF has created several world class clinical assets which support the development of COVID-19 vaccines but will prove invaluable for future pandemics, namely

- the NHS Citizen Registry;
- standardised assays offering rich immunological profiling of immune responses provoked by different vaccines; and
- supporting the development of the UK’s capacity to run Human Challenge studies for testing vaccines earlier in development and for future vaccines.

And thirdly, the VTF delivered a comprehensive strategic communications campaign

- to launch successfully the National NHS Citizen Registry for rapid trial enrolment;
- for public education to communicate simply the complexities of vaccine approach, progress and strategy; and
- to establish the UK as a global leader in vaccine R&D by encouraging international cooperation and to drive future economic growth.

These communications appear professional, widespread and have given appropriate messages about vaccine expectation and the UK capability. At the time of writing, the Citizen Registry had over 360,000 registrants.

It will be important to ensure that these VTF initiatives are permanently established, nurtured and governed appropriately including with industrial and technical experts so that the UK maintains the momentum and opportunities that the VTF has created.

The number one priority for any vaccine remains its safety. In the normal course of events developing a new and novel vaccine from research to market would take a minimum of 10 years. In the present climate the combination of VTF leadership and private sector research and development has reduced this timescale dramatically.

We are at the early stages of managing the pandemic and while the scientific and governmental response to this pandemic is far from over, I would pay tribute to Kate Bingham and the Vaccine Taskforce for the drive, focus and creativity they have shown in getting the UK so far forward in such a short time.

Richard Sykes, 2 December 2020

Reflections from the Chair



Unsustainable agricultural practices and the climate crisis alter the way that animals and humans interact with one another, which intensifies existing zoonotic diseases and enables the emergence and spread of new ones. In the last century we have seen the outbreak of many zoonotic infections including AIDS and Ebola and at least six major outbreaks of novel coronaviruses and so it is highly likely we will face new pandemics in the near term. Even now mink farms for fur production and trading in Europe may become long term reservoirs of SARS-CoV-2, and subsequent viral mutations could generate new viral strains unrecognised by the current vaccines which could spill over into humans. It is therefore critical that the UK learns from this COVID-19 pandemic and puts in place infrastructure, capabilities and governance to ensure the UK is better placed to respond rapidly to future threats.

It is important to be clear about the risks and uncertainties of this undertaking. Vaccines typically take up to ten years to deliver to market. There are many diseases, notably AIDS, for which no vaccine has ever been developed despite years of effort. In May, it was far from clear that any vaccine could be obtained rapidly, which among several different technologies would be effective, and if so, how effective, for whom and for how long. And we still don't have many of the answers.

There are three key features of the VTF which should be noted. First, which is unusual in government, was the bringing in of private sector technical and manufacturing expertise into a government body partnering with the civil service to support informed decision making and optimal investment of public funds at a really critical time. The VTF developed an effective, timely and cost-effective operating model whereby the VTF made recommendations to a cross Department Ministerial panel³ which then took decisions on spending and funding allocation. BEIS officials managed the procurement processes for day-to-day operating matters. We should recognise the flexibility and nimbleness of the civil service and the Ministers who balanced appropriate oversight and governance measures with respect to spending taxpayer money, with the making of big, difficult decisions at pace. Without this streamlining of decision making, it is unlikely that the VTF could have delivered this successful range of outcomes in such a short time.

Secondly, was the speed at which the VTF operated. The team defined strategy, assessed the global vaccine landscape quickly, performed detailed due diligence work and developed plans to prioritise, secure supply and develop optimally the most promising portfolio of vaccines for the UK. The results over six months speak for themselves, including the fact that the UK was the first country to secure access to and start deploying the Pfizer/BioNTech vaccine.

Thirdly, as can be seen from this report, the VTF has progressed a range of initiatives to improve the UK's pandemic preparedness relating to both manufacturing and clinical

³ Annex A lists Ministerial Panel members

infrastructure, to respond quickly to potential pandemic threats as well as build long term sustainable prosperity.

We have an opportunity to make the UK a global centre of excellence for the next generation of vaccines, and to lead the world in vaccine preparedness for future endemic or pandemic threats. The UK's vaccine industry can maintain its sovereign security and deliver long term prosperity for the UK, underpinned by a skilled advanced manufacturing workforce to drive economic growth.

The UK benefits from a fast-moving innovative life science industry, well connected to world-leading academic and clinical centres as well as biotech industry clusters around the world. Through this ecosystem, the UK can drive highly responsive, globally relevant pandemic vaccine development, supported by the MHRA, a widely respected, flexible regulator who can oversee real-time, widespread and long-term pharmacovigilance. State-of-the-art digital and analytics tools⁴ will be critical for ongoing real-time pharmacovigilance to support the role of the MHRA and vaccine developers and secure the trust of the public.

This report assesses the long-term trajectory of HMG investments made before and throughout the span of the VTF. Recommendations have been made separately for ongoing discussion and development with Government to secure the viability of domestic vaccine development and production to maintain government readiness and resilience in the event of future pandemics and to drive international engagement on vaccination, putting the UK at the forefront of global vaccine research, development, manufacturing and distribution. We must ensure that UK manufacturing facilities are commercially viable with sustainable private sector demand for them, ready for such time as the government steps in for pandemic manufacture.

I would like to say a personal thank you to all members of the Vaccine Taskforce; external secondees from industry and contractors, civil servants, military as well as individuals from across BEIS, the Department of Health and Social Care, the Foreign, Commonwealth and Development Office, HM Treasury and key parts of the Cabinet Office who have been working tirelessly to support the VTF. Together, we have built a comprehensive COVID-19 vaccine portfolio for the UK which in December 2020 - against the odds - has now started deployment. We have also strongly supported the COVAX initiative to ensure that the most promising vaccines are available internationally, built UK vaccine infrastructure and made recommendations to ensure the UK is better prepared for the next pandemic threat.

The enthusiasm, skill and productivity I have seen in the VTF have been astonishing - not to mention the evenings, weekends and excessive hours worked - and as a nation we owe each and every one of them a debt of gratitude. In particular, I would like to thank Sir Patrick Vallance for identifying the urgent need to focus on vaccines and for creating the VTF so early in the pandemic; to the Prime Minister for appointing me and giving me the scope to act swiftly and decisively; to the BIA for kick-starting the manufacturing consortium and scale up activities in February before the VTF even existed; to all the vaccine developers and all those supporting vaccine development and delivery; to SV and my investors who graciously allowed me to take

⁴ Examples of digital tools include OpenSAFELY: [Factors associated with COVID-19-related death using OpenSAFELY | Nature](#)

on this temporary role and to my outstanding VTF Steering Group team without whom none of this would have been possible.

This report marks the end of my six-month term as Chair of the VTF and there remains a lot left to do! I wish the ongoing VTF team luck, wisdom and energy as under their expert guidance our plans, contracts and vision turn into safe and effective vaccines both for this COVID-19 pandemic and pandemics of the future.

2020 VTF Goals and Achievements

The Prime Minister asked the Vaccine Taskforce to deliver three objectives: first to secure access to promising COVID-19 vaccine/s for the UK population as quickly as possible, secondly, to make provision for international distribution of vaccines and thirdly, to support the UK's industrial strategy by establishing a long-term vaccine strategy and to prepare the UK for future pandemics.

The VTF has sought to protect the UK population from the health, social and economic impact of COVID-19 as quickly as possible since the Office for Business Responsibility's central forecast⁵ shows a drop in UK GDP of 12.4% in 2020, compared to 2019 – equating to a £250bn cost of the COVID-19 pandemic in 2020 and a monthly cost of £20.8bn. So the sooner we can ease restrictions by widespread vaccination, the sooner we will return to a normal level of productivity.

The achievements of the VTF against the three goals defined by the Prime Minister in May are described below.

Goal 1: Secure access to promising COVID-19 vaccine/s for the UK population as quickly as possible

In six months, the VTF has built a portfolio that includes established vaccine platforms with proven safety profiles (including those able to elicit immune responses in the elderly) namely GSK/Sanofi, Novavax and Valneva and newer but clinically advanced platforms, including Oxford/AstraZeneca, Pfizer/BioNTech, Janssen and Moderna. VTF's strategy to build a balanced portfolio with different proven and unproven vaccine types allowed the VTF to engage broadly with the industry and academic community, generating new opportunities and maximising the chances of success.

The UK has struck agreements to access seven different vaccines across four different formats, with a total of 357 million doses of different vaccines. In addition, the VTF has entered into a provisional agreement for doses of the engineered antibody cocktail developed by AstraZeneca for the short-term passive protection of immunosuppressed patients and those who need immediate protection. The VTF's focus has been to secure access to the most promising vaccines likely to be safe and effective with the highest confidence of early approval and delivery to the UK to help protect the population as soon as practicable.

The speed with which the VTF has acted has benefited the UK positively by giving the greatest possible time for the NHS and other teams responsible for deployment to plan and secure the necessary equipment to manage the cold chains and complex vaccination programme.

⁵ <https://obr.uk/coronavirus-analysis/>

Following constructive discussions, HMG ultimately chose not to participate in the EU joint procurement on vaccines, as it would not have been possible for the UK to have a say in decisions such as vaccine choice or key contract terms. It would also not have been possible for us to participate whilst also pursuing negotiations with individual vaccine suppliers. However, we continue to work with the EU on our shared international goal of accelerating global vaccine access to end the pandemic, for example the EU and UK co-hosted the launch of the ACT-Accelerator and we are both supporting the COVAX initiative as participants and donors.

Table 1: Portfolio of COVID-19 vaccines secured by the UK

Vaccine	Format	Other vaccines approved of this format	Stage of development	# doses per regime	# doses
Oxford/Astra Zeneca	Adeno (chadox)	No	Initial P3 data	2	100m
Pfizer/BioNtech	mRNA	No	Temporary authorisation granted by MHRA	2	40m
Janssen	Adenovirus vector (ad26)	Yes (Ebola)	In Phase 3	1 (tbc)	30m with an option for further 22m
Novavax	Protein + adjuvant (VLP)	Yes	In Phase 3	2	60m
Moderna	mRNA	No	Filed for conditional approval	2	7m
GSK/Sanofi	Protein + adjuvant	Yes	In Phase 1/2	2	60m

Valneva	Whole inactivated viral vaccine	Yes	Preclinical	2	60m + 40m option; plus options for a further 4 years
AstraZeneca antibodies	Antibody cocktail	Yes	In Phase 3	2	TBC

Vaccine companies range from small biotechs to big pharma, each with different commercial objectives and differing in terms of financial support needed for manufacturing scale up and/or clinical trials. Some vaccine companies are selling their vaccine on a non-profit basis, at least for the pandemic period, such as AstraZeneca, GSK/Sanofi and Janssen; others view the resources and risk they are assuming as justification for seeking a profit.

In the pandemic, the VTF was not able to adopt typical outsourcing practices of competing supply contracts since we were purchasing vaccines that were unproven clinically with unproven manufacturing processes, from suppliers each in a monopoly position in a very competitive market, with strictly limited near term supply. The UK was typically placing considerably smaller orders than other larger countries and consortiums such as the US or the EU which meant the UK had to explore creative deal structures and approaches to ensure early supply.

Goal 2: Make provision for international distribution of vaccines

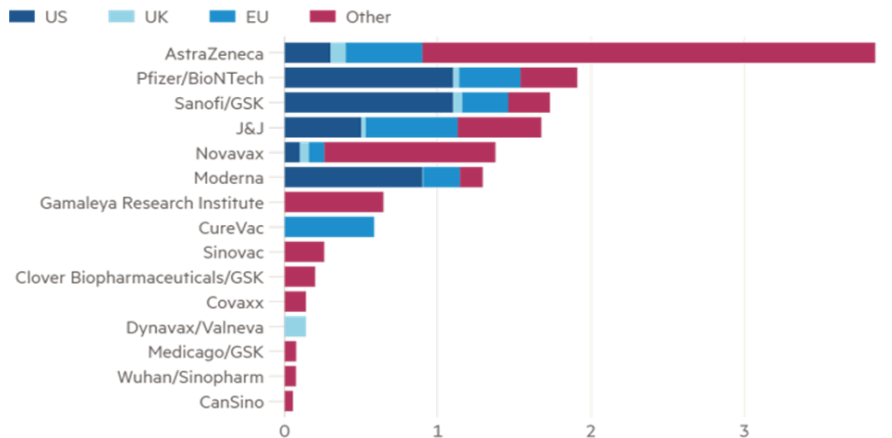
The UK Government is leading global efforts to ensure that everyone at risk, anywhere in the world, has access to a safe and effective vaccine, irrespective of their ability to pay. The COVID-19 Vaccines Global Access facility (COVAX), to which the UK has committed up to £548 million, will provide access to vaccines for low, middle and high income countries – initially two billion doses for one billion people worldwide. As well as helping to shape the COVAX facility, the VTF has shared its expertise and people with COVAX to support their global efforts.

The biggest challenge facing the world is to establish a fair global pooling facility for buying, manufacturing, and distributing pandemic vaccines to all those people at risk around the world, since national solutions will not control the pandemic alone. COVAX’s global access vaccine facility, led by GAVI, the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organisation (WHO) is making progress, but it may still take 18- 24 months from the initial identification of the SARS-CoV-2 virus before safe, effective vaccines are available to most countries, whether high, middle or low income.

The VTF has also supported the international distribution of vaccines by:

- Working closely with AstraZeneca to agree distribution of its vaccines internationally; to date AstraZeneca have signed supply contracts for three billion doses worldwide in 2021, which is more than twice as much as any other vaccine developer globally;

Figure 1: Global supply agreements of COVID-19 vaccines (doses/billions)



Source: Airfinity ©FT

- Offering to potentially co-fund the Janssen two-dose vaccine protocol to generate data showing whether a more durable immunity could be generated by two doses versus one dose, as well as long term safety. This data can be used to support regulatory approvals worldwide; and
- Funding the expansion of UK based manufacturing facilities which have capacities greater than that needed by the UK alone, which enables high quality vaccines to be exported internationally.

Goal 3: Support industrial strategy by establishing a long-term vaccine strategy to prepare the UK for future pandemics

The Prime Minister asked the VTF to help position the UK at the forefront of global vaccine research, development, manufacturing and distribution as part of the UK's long-term industrial strategy.

The VTF has led important activities in three key areas which will provide lasting benefits to the UK's pandemic preparedness:

- Expanding and reinforcing the supply chain for the manufacture of vaccines;
- Improving the scope of the UK's clinical development of vaccines; and
- Communicating the breadth of the UK's vaccine capability to all stakeholders to position the UK at the forefront of vaccine R&D.

a) Expanding and reinforcing the supply chain and manufacturing of pandemic vaccines

Starting in February 2020, the BIA's Bioprocessing community brought academic and industrial partners together and provided practical, industrially experienced management, as the Oxford vaccine candidate snowballed at incredible pace from an academic idea into a world leading COVID-19 vaccine candidate.

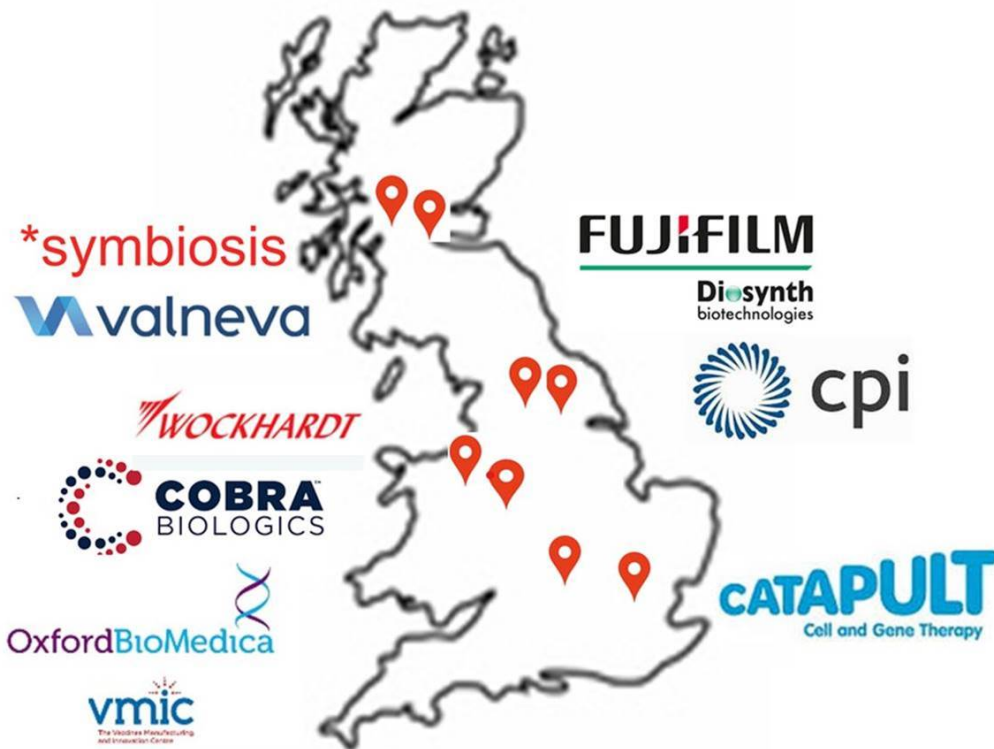
Since then, on the VTF's advice, the government has provided funding in several UK sites to secure rapid manufacturing capability of millions of doses of vaccine for the UK population, with the flexibility to manufacture different platforms namely viral vectored vaccines, recombinant protein-based adjuvanted vaccines, whole inactivated viral vaccines as well as mRNA vaccines. We do not yet know which vaccine format, or combination of formats in heterologous prime boost regimes generate the longest and strongest immunity, or what frequency of re-vaccination is required and consequently how many annual doses will be required in the future. We also do not yet know which if any of these formats can be optimised into an oral, buccal, transdermal or other format which would be suitable for rapid scale-up and simple mass deployment, so it is important to maintain optionality in manufacturing capability.

Three of the seven most advanced COVID-19 vaccines are being manufactured in the UK: AstraZeneca's adeno vaccine (Oxford Biomedica, Cobra, Wockhardt, Symbiosis), Valneva's whole virus vaccine (Livingston, Wockhardt), and Novavax VLP protein adjuvant vaccine (Fujifilm plus fill finish and adjuvant manufacture in Sweden).

We are building the capability to manufacture mRNA vaccines (CPI, VMIC) for future mRNA projects. There are several UK companies with state-of-the art DNA production which could provide important technologies for future mRNA vaccines and opportunities to collaborate are being explored. Market engagement with the private sector is underway to explore collaborative options for building a bulk antibody manufacturing capability in the UK.

Funding for skills training has been provided to ensure we have the specialist workforce necessary for advanced medical manufacturing.

Figure 2: Map of current sites engaged with manufacturing COVID-19 vaccines in UK



Source: VTF

Accelerating and expanding the Vaccines Manufacturing and Innovation Centre (VMIC)

By the end of 2021, the Vaccines Manufacturing and Innovation Centre in Harwell will have expanded its capability for process development, bulk manufacture of a broad range of vaccine formats plus high throughput fill and finish, a year earlier than originally planned, thanks to investment recommended by the VTF. We have worked with VMIC to increase VMIC's delivery capability from the 3m dose capacity originally planned for, to 70m doses of pandemic vaccine, deliverable within a six-month response time. This is a permanent facility, with government step-in rights during a crisis. VMIC's flexible cleanrooms and single use bioreactors could be used to manufacture mRNA, protein, or viral vectored vaccines.

In the interim, VTF worked with VMIC to establish a temporary rapid response unit (virtual VMIC) by providing equipment to Oxford Biomedica to manufacture a potential vaccine. Oxford Biomedica will be providing training and technical assistance to VMIC staff. This skilled team will move to VMIC when the site is ready. This demonstrates the value of government collaboration with VMIC and industry to bring online capacity rapidly.

Acquisition of a site in Braintree as a Cell and Gene manufacturing and innovation centre (CGTC Braintree)

In July 2020 the VTF supported the acquisition of and investment into Benchmark's veterinary plant by the Cell and Gene Therapy catapult to provide additional manufacturing flexible capacity. By the end of 2021, this facility will be able to manufacture up to 70m doses within six

months of a broad range of vaccines formats. This is a permanent facility, and the government has a right to 'step-in' during crisis periods and direct production towards vaccines.

Potentially this facility could be focused on antibody scale up and clinical scale production of neutralising antibodies for prophylactic and therapeutic treatment as well as the manufacture of viral vectors.

Investment in Valneva's site in Livingston, Scotland – a unique facility that establishes permanent UK capability to manufacture inactivated viral vaccines

As part of a broad supply agreement, the VTF recommended the government provide funding for the upgrade and expansion of Valneva's inactivated whole viral vaccine manufacturing capability to Biosafety Level 3 (BSL3), to produce up to 200m doses annually of COVID-19 viral vaccines in 2021. The UK has secured supply for 2021, in addition to options over further supply for four subsequent years thereafter.

Valneva's new plant, one of the few BSL3 containment facilities in Europe, is a key part of the UK's long term pandemic preparedness as it will have the capability to grow rapidly new pandemic viruses which can be inactivated and combined with an adjuvant to create future vaccines. This capability could shorten the time dramatically to developing whole inactivated vaccines against future pandemic viruses.

Agreement with Wockhardt for bulk fill finish of vaccines

Wockhardt has reserved capacity to fill finish millions of vaccine doses for the UK Government's exclusive use for the next 18 months to allow for the supply of multiple vaccines in its fight against COVID-19. This includes AZD1222, the vaccine co-developed by the University of Oxford and AstraZeneca. This ensures that there is sufficient capacity of fill finish of drug substance to get the vaccine in a form to be given to patients.

Strengthening the UK vaccine supply chain

The UK's pandemic response has drawn upon specialist UK suppliers and contract development organisations. These companies provide critical supplies for the manufacturing of different vaccines, including bioreactors, reagents and raw materials, for product analysis and testing as well as contract manufacturing services. This sector has expanded its capacity in response to the new demand and created future capability to support the bioscience industry, which underpins the UK's vaccine and pharmaceutical development activities. They remain central and vital to the UK's future preparedness.

Investment to develop advanced manufacturing skills

We not only need the right infrastructure, but it is important that we have the advanced vaccine manufacturing skills base and other capabilities to match it. Investment in upskilling our workforce, technology transfer capability and innovation will boost the UK's attractiveness for vaccine developers to choose the UK as a manufacturing centre for their vaccines and related advanced therapies which will help to mitigate future risks around the UK's current reliance on international supply chains. This investment also helps support workforce relocating from declining industries into the high growth advanced medical manufacturing industry.

As a result, the VTF supported the £4.7m grant to the Cell & Gene Therapy Catapult⁶ to start an Advanced Therapy Skills and Training Network programme to boost cell and gene therapy as well as vaccine skills in advanced manufacturing. The initial focus will be on physical training for vaccine manufacturing and advanced therapies including GMP, process development and bioprocessing using a National Training Centre (NTC) launching in Q1 of 2021. The NTC will involve the rapid deployment of 2-4 centres by expanding existing training infrastructure and creating dedicated training programmes, developing a classroom-based model to complement the virtual offer.

Physical training will be complemented by the Online Training Portal - a one-stop virtual training portal to address immediate skills needs which includes industry developed training content and as well as new online specialist content. The specific training and educational programmes include virtual reality simulation to support new people entering the advanced manufacturing industry from other sectors, and upskilling existing staff within organisations across the UK.

The online platform also highlights pathways available to enable people to build new career routes by identifying potential roles for those with transferrable skills from non-manufacturing related jobs, by assessing how their experience maps across to five key manufacturing roles. This is particularly crucial for cross-industry recruitment, and offers an opportunity to those in declining sectors, as well as building the UK's skills base for an increasingly critical part of our future preparedness.

In 2018, the Cell and Gene Therapy Catapult, in partnership with the Medicine Manufacturing Industry Partnership (MMIP), launched the first Advanced Therapy Medicinal Products (ATMP) focused apprenticeship programme, aimed at building the skills base to enable industry growth. The early investment and focus on ATMP skills through the Cell and Gene Therapy Catapult meant the UK already had a strong foundation to build on. Upskilling someone with ATMP skills through our new training programmes would take approximately one to two months, which is a rapid pace for this activity, and essential to securing our readiness as well as energising an emergent part of our economy as a result of the pandemic.

New GMP mRNA supply capability at CPI

On VTF advice, the government provided £8.6m of funding for the CPI in Darlington based on its expertise in biotherapeutic and nucleic acid manufacturing processes, nano particle encapsulation and formulation. This has supported the creation of a new Centre of Excellence in mRNA vaccine manufacture with equipment that can synthesise the mRNA, purify it and then stabilise it using lipid nanoparticle technology. In addition to creating a UK facility with significant expertise in developing commercially viable and scalable manufacturing processes, the funding has also upgraded the CPI's National Biologics Manufacturing Centre at Darlington to GMP standard, meaning they can manufacture batches of a range of therapeutics and

⁶ <https://ct.catapult.org.uk/news-media/general-news/cgt-catapult-launches-national-training-centres-industrial-skills>

vaccines, including mRNA and self-amplifying RNA vaccines for use in clinical trials and for supply to patients.

In the current global pandemic RNA vaccines have been prominent front runners; the RNA is formulated in lipid nano particles. This technology is a way of enabling intracellular delivery of vaccines and medicines of different types. CPI's expertise in lipid nanoparticles based in the UK will advance not just the vaccines sector but also the future waves of other advanced therapies in which the UK already has strong discovery capability.

The VTF funding creates a UK centred GMP supply chain for the manufacture of mRNA vaccines and an anchor for research and innovation which will accelerate improvements of this novel technology, such as improved stability at room and refrigerated temperatures and reduced cost of goods.

Options for Long-Term Antibody Manufacturing Capacity

Currently the UK does not have the capability or scale to manufacture bulk levels of antibodies and the VTF identified this as a potential weakness in the UK's future pandemic response, as well as a surprising gap for a country as focused on the life sciences industry as the UK.

Encouraging clinical data has led to the FDA issuing emergency authorisations^{7 8} for two COVID-19 antibodies use in people who have tested positive for the virus and are at risk of severe illness. Antibodies can also potentially be used for prophylactic treatment to prevent infection.

There are over 500,000 'at risk' people in the UK who are heavily immunosuppressed and are unlikely to benefit from a vaccine. There may also be future requirements to provide immediate protection, for example for front line workers or military who are not able to wait the ~six weeks usually needed to build up immunity through vaccination.

One way to protect these individuals is by using passive antibody prophylaxis, which is likely to require dosing every ~6 months depending on the length of protection afforded by the antibodies.

The VTF estimates that the UK may need up to 1.5 million doses of antibodies per annum under GMP for therapeutic and/or prophylactic use. The VTF estimates that this could require up to twelve 2,000 litre production bioreactors.

As a result, the government has issued a Prior Information Notice in October⁹ to engage with the market to explore how UK antibody manufacturing capability can be developed to secure permanent UK access and build resilience. This process will evaluate different possible

⁷Lilly [Coronavirus \(COVID-19\) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19 | FDA](#)

⁸Regeneron [Coronavirus \(COVID-19\) Update: FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19 | FDA](#)

⁹UK Antibody Supply Prior Information Notice <https://www.delta-sourcing.com/delta/respondToList.html?sessionId=D8A301A57346833023CF0A58BE2944A1?noticeId=535012293>

commercial mechanisms to secure long-term, guaranteed supply contracts with 'step-in' rights in the event of future pandemics.

b) Clinical development of pandemic vaccines

In 2020, the UK faced an enormous challenge in delivering a large number of vaccine trials concurrently and with compressed timelines to determine their safety and efficacy. The NIHR Clinical Research Network rapidly set up a UK-wide Vaccine Research Delivery Programme to coordinate efforts across 18 regions in the UK (15 in England plus devolved administrations). Over 50 regional research delivery sites have been established and are delivering vaccine trials and remain ready to further deliver swift recruitment into studies throughout 2021.

To support the NIHR in delivering clinical trials, the VTF launched several critical clinical initiatives which have helped to accelerate and optimise the clinical development of COVID-19 vaccines which will have a lasting benefit for the UK:

Creation of the world's first National Citizen Registry on the NHS website: WWW.NHS.UK/CORONAVIRUS

In July 2020, the VTF collaborated with NIHR Clinical Research Network, the devolved nations and NHS Digital to create the world's first national citizen registry to accelerate the enrolment of clinical trials and so generate the safety and efficacy data as rapidly as possible. Now any member of the UK public interested in taking part in clinical trials for vaccines can sign up, giving permission to be contacted about upcoming trials. Over **360,000** people have already signed up.

Thousands have been recruited into Phase 3 vaccine trials including Oxford/AstraZeneca, Novavax, Janssen and AstraZeneca antibodies to date, and more are expected to be approached for all phases of vaccine trials starting in 2021. Without this NHS registry the UK would not have been able to enrol its trials so quickly¹⁰ and generate the necessary safety and clinical efficacy data rapidly.

To encourage the UK public to sign up to this citizen registry, the VTF funded a targeted strategic communications campaign to launch this ambitious initiative and to attract those most at risk to sign up, including the elderly, those with severe underlying diseases, ethnic minorities and front-line workers.

It is important that all vaccines being developed work successfully for everyone, especially those at high risk from COVID-19 infection. The age demographic of the registrants is encouraging with ~33% over the age of 60. A further ~33% of registrants are in front line and public facing occupations. However, only ~8% of registrants are from black, Asian and minority ethnic backgrounds which does not reflect the UK demographics.

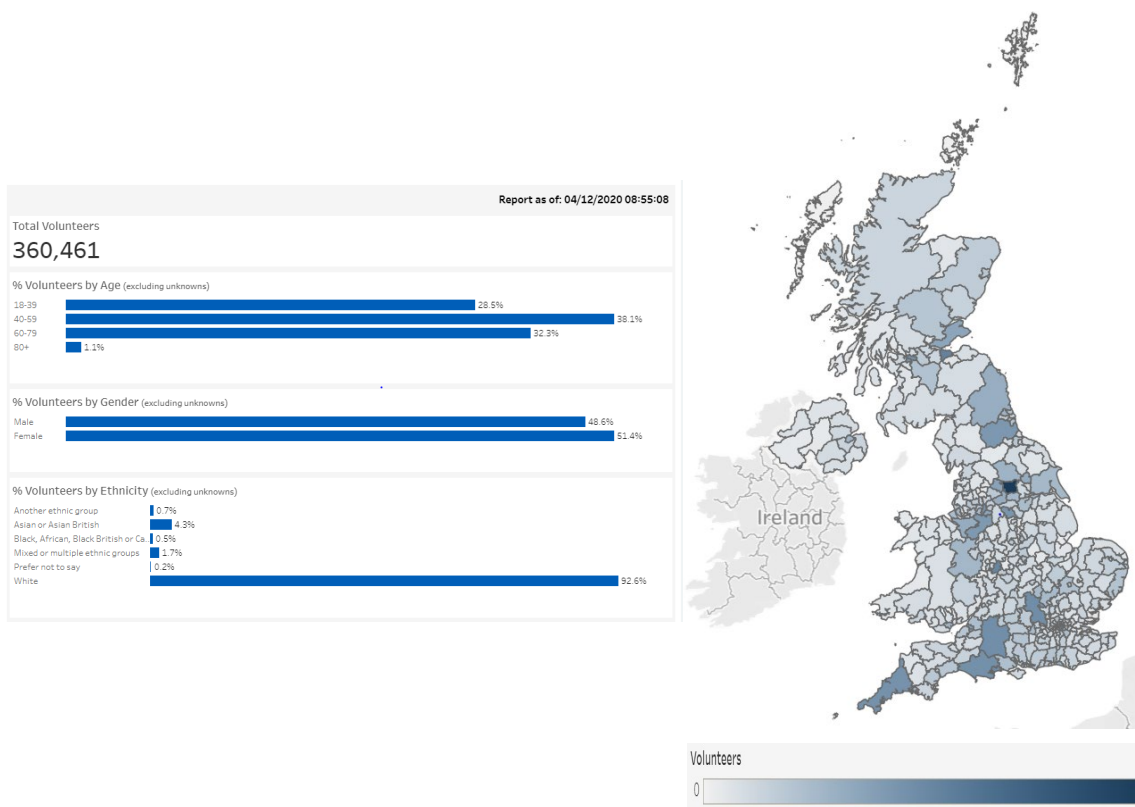
¹⁰ [Novavax Phase 3 COVID-19 vaccine trial completes enrollment in two months \(nihr.ac.uk\)](https://www.nihr.ac.uk/news/novavax-phase-3-covid-19-vaccine-trial-completes-enrollment-in-two-months/)

Specific communications campaigns have been run to attract more people from black, Asian and minority ethnic backgrounds who remain underrepresented in the registry, yet disproportionately affected by COVID-19.

94% of those who have signed up to date have indicated willingness to be approached for trials other than COVID-19 vaccine trials and communications with those that have signed up indicate that levels of engagement are very high. Currently “open rates” for a regular newsletter to volunteers on the registry are 80 per cent. It is inevitable that engagement levels will decrease once vaccine deployment begins and therefore continued communications and engagement with these volunteers become even more important.

This digital approach to building the NHS citizen registry provides an enduring legacy for future vaccine development and highlights again the value that the UK can bring to both global pandemic vaccine development as well as more broadly

Figure 3: Profile of volunteers signed up on the NHS citizen registry



Source: NIHR - NHS Digital

Establishment of the world’s first Human Challenge Model for SARS-CoV-2

Just as the government has invested in flexible manufacturing capability to increase capacity, it has also invested in developing new clinical trial capability to accelerate vaccine development and advance mechanistic understanding of viral controlled infection through the Human Challenge Programme. The VTF has made it a key priority to get human challenge studies up and running for the controlled testing of new vaccines, where young healthy subjects receive the vaccine prior to being infected by the virus.

In October, the VTF created and recommended funding of the first phase of a Human Challenge Programme¹¹ as a partnership between Imperial College London (trial sponsor), the Department for Business, Energy and Industrial Strategy (BEIS), hVIVO, a leading clinical company with expertise in viral human challenge models, and the Royal Free London NHS Foundation Trust. This complex £33m programme required multiple arrangements to ensure the integration of the required technical expertise under the leadership of the VTF, working with other government departments such as DHSC and organisations such as the Wellcome Trust, Medical Research Council, Health Research Agency (HRA), Health and Safety Executive and MHRA.

In addition to running large placebo-controlled efficacy studies it is important to gain information about the coronavirus as we go forward. We do not yet know enough about the behaviour of the virus and the impact it has in different populations. Human challenge studies in flu revealed critical information and data about the infectivity of subjects prior to their showing symptoms and this was only discovered through the tightly controlled human challenge studies. Such studies could help define the immunopathogenesis of COVID-19, duration of vaccine-induced immunity and correlates of protection in healthy populations.

Once the SARS-CoV-2 Human Challenge model has been established in early 2021, the VTF has secured the first three slots to run clinical trials on the most promising new vaccines ahead of everyone else. Critically this provides optionality for the UK. The model can be used as a 'fast to fail' approach to select the most promising vaccines faster and optimising investment. Regardless of whether the first wave of vaccines are successfully licensed, follow on vaccines are likely to be needed (whether for heterologous boosting or to address supply challenges, cost of goods, mutations, sub populations, duration, reinfection etc.) If disease transmission rates are low, the only way that next the wave of vaccines could be 'immuno-bridged' to first generation licensed vaccines quickly will be through human challenge studies. The option for large-scale field efficacy studies simply may not exist. Building this world leading, ambitious capability now will enable the UK to optimise and prioritise future pandemic vaccines, generating long term value and pandemic preparedness for the UK for SARS-CoV-2 and beyond - a valuable legacy for the UK.

Launch of industrialised, standardised assays to assess the performance of different vaccines head-to-head

To harmonise results from the various clinical trials and to help define immune correlates of protection, we have developed standardised, accredited assays including quantitative high-throughput Spike [S] protein ELISAs [enzyme-linked immunosorbent assays], live viral neutralization assays and antigen-specific functional T-cell assays which will be available to all vaccine developers.

The assays are delivered by experienced contract research organisations and Government labs; S-ELISA by Nexelis (US/Canada), live viral neutralization assays by PHE Porton Down and the functional T cell assays by Oxford Immunotec. The assays measure the antibody and

¹¹ <https://www.gov.uk/government/news/expert-partnership-to-explore-and-establish-human-challenge-studies-of-covid-19-in-the-uk>

T cell responses triggered by the vaccine and will enable comparison across vaccine modalities, delivery methods, dosing regimes etc and will also enable a comparison to the natural immune response to infection e.g. by their use in the human challenge study. Without these standardised assays it would not be possible to directly compare the immune responses triggered by different vaccine trials because different assay procedures and lack of assay quantification standards mean data cannot be compared.

We do not yet know about the durability of any of the vaccines or the role of cellular immunity in providing infection¹². These standardised assays will help us start to understand this better.

c) Championing the UK capability to be at the forefront of global vaccine R&D, manufacturing and distribution

As the VTF strategy developed it became clear that in order to deliver the PM's mandate to place the UK at the forefront of vaccine research, development, manufacturing and distribution, we needed to develop a strategic, transparent and non-political communications strategy to explain and highlight the UK's capabilities and commitment to become a global leader in the vaccine field.

The VTF has engaged in numerous scientific, industry, non-profit, government and public events to articulate the UK's strategy regarding COVID-19 vaccines and share opinion and views about UK capability plus broader vaccine development and expectations. VTF outputs include several articles including in Nature¹³ ¹⁴ and Lancet¹⁵, a podcast series with experts discussing all aspects of vaccine discovery, development, supply, clinical testing, international distribution etc widely available¹⁶ ¹⁷, as well as a large number of "explainer" interviews and media articles.

The Lancet article - *The UK Government's Vaccine Taskforce: strategy for protecting the UK and the world* - was widely read internationally. In the first 24 hours, 384 articles citing the Lancet article were published in 38 countries, with a combined total reach of 7,301,469,000. The majority of coverage was found in the UK, where 103 articles were published. Other countries with a significant amount of coverage include the United States (59 articles), India (45 articles), Russia (22 articles), Canada (16 articles), Germany (10 articles), South Africa (6 articles), and Japan (5 articles). This international recognition of the ambition, success and breath of the UK's response to COVID-19 vaccine development is important in the task to place the UK at the forefront of global vaccine R&D.

¹² <https://immunology.sciencemag.org/content/5/53/eabe8063>

¹³ Whither COVID-19 vaccines? <https://www.nature.com/articles/s41587-020-0697-7>

¹⁴ Plan now to speed vaccine supply for future pandemics; <https://www.nature.com/articles/d41586-020-02798-0>

¹⁵ The UK Government's Vaccine Taskforce: strategy for protecting the UK and the world [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32175-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32175-9/fulltext)

¹⁶ The Vaccine Taskforce – Search for a Vaccine: (Spotify)

<https://open.spotify.com/episode/7qTKDP9cncTHU5WWCNXH73>

¹⁷ The Vaccine Taskforce – Search for a Vaccine: (Amazon podcasts)

<https://podcasts.apple.com/gb/podcast/ep1-the-uk-vaccine-taskforce-portfolio-strategy/id1527299221?i=1000487808208>

Most of the most promising innovative COVID-19 vaccines have originated from biotech companies or academia even if they are ultimately manufactured and sold by major pharmaceutical companies. For example, AstraZeneca's vaccine was developed by Oxford academics at the Jenner Institute together with private biotech company, Vaccitech; Janssen's ad26 technology was originally developed by Crucell; Pfizer and the German biotech, BioNTech, co-developed their vaccine based on BioNTech's mRNA technology platform. And in some cases biotech companies have sought funding directly from the public markets and NGOs such as CEPI and Gates Foundation to progress their vaccine such as Novavax (NVAX) who do not have financial support from strategic partners underpinning their vaccine development activities and commercial supply.

So if the UK is to be a global centre of excellence for the next generation of vaccines, then the UK needs to champion its capabilities. Innovators, investors, funders, biotechs, NGOs and the strategic partners need to know what the UK can offer and why they should consider developing their vaccines in the UK, and ongoing strategic communications are essential to support this.

Way Ahead

It is clear from the COVID-19 pandemic that the UK needs to be part of a rapid response system to discover and develop vaccines for novel threats and ensure it has a resilient supply of vaccines and antibodies for infectious threats new and old.

We need to act quickly to prevent pandemics occurring, so the UK needs a permanent ecosystem for rapidly developing, manufacturing and supplying vaccines for future pandemics, ensuring domestic resilience and security, while also creating long term economic prosperity.

To cement the UK's role as a global leader for pandemic response, we need a diverse, informed infrastructure for surveillance of adverse events, flexible capacity for manufacturing and testing vaccines and a global funding facility for purchasing and distributing vaccines internationally.

For vaccines to play an effective part of pandemic recovery and preparedness, they must be available quickly and be manufacturable at scale. The VTF has demonstrated its contribution to the current pandemic recovery, and the lessons learned should be applied to our future preparedness.

A series of lessons learned and recommendations around the following topics has been produced for ongoing internal discussion across Government:

- Organisation and co-ordination of industrial and public sector assets.
- National capability for vaccine formulation and delivery
- UK clinical trial capability
- UK manufacturing capability, responsiveness and breadth
- Domestic antibody production
- Future funding
- International engagement and collaboration

These will be considered by Government over the coming months.

Annex A: VTF Organisation

The VTF is a team within the Department for Business, Energy and Industrial Strategy (BEIS) consisting of a mix of civil servants, military, external secondees from industry, and contractors. This is to make sure that the VTF has access to the deep, specialist expertise in vaccine preclinical and clinical development, regulatory issues, manufacturing and project management necessary to deliver its objectives. As of December 2020, the VTF has just over 200 staff.

Decisions on all vaccine supply contracts and major investments in manufacturing and clinical opportunities are taken by the relevant government ministers through the Ministerial Investment Panel. Day to day procurement decisions and contracting are handled by the civil service in line with usual processes. Steering Group Membership of the VTF is as follows:

Kate Bingham	VTF Chair
Clive Dix PhD	VTF Deputy Chair
Nick Elliott MBE	Director-General, BEIS
Ruth Todd	Director, BEIS
Madelaine McTernan	Director, UK Government Investments (UKGI)
Tim Colley	Director, BEIS
Dan Osgood	Director, BEIS
Divya Chadha Manek	National Institute for Health Research (NIHR)
Ian McCubbin OBE	Manufacturing Advisor - former Senior Vice President for Global Manufacturing and Supply at GSK
Steve Bates OBE	Chief Executive Officer, BioIndustry Association (BIA)
Professor Jonathan Van-Tam MBE	Clinical and public health Adviser to the VTF, Deputy Chief Medical Officer, Department of Health and Social Care (DHSC)

Representatives of other government departments and public sector organisations attend VTF Steering Group meetings as required.

Ministerial Investment Panel

Chair: Secretary of State for BEIS, Alok Sharma

Members Chief Secretary to the Treasury, Steve Barclay

Secretary of State for DHSC, Matt Hancock

Minister of State in the Cabinet Office, Lord Agnew

The significant progress made since May 2020 would not have been possible without the contributions of so many critical partners from within Government, the NHS, and from the wider life sciences sector experts in both academia and industry. They all came together at pace and in the spirit of collaboration and innovation needed to respond to the pandemic. Particular acknowledgement goes to the Department of Business, Energy and Industrial Strategy; Department of Health and Social Care; HM Treasury; Cabinet Office and Number 10; the Foreign, Commonwealth and Development Office; UK Research and Innovation; the National Institute for Health Research; NHS England; the Office for Life Sciences & NHS Digital.

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