



100 DAYS MISSION

to respond to future pandemic threats

Reducing the impact of future pandemics
by making Diagnostics, Therapeutics and
Vaccines available within 100 days

A report to the G7 by the pandemic
preparedness partnership

12 June 2021

Foreword



Sir Patrick Vallance



Melinda French Gates

The COVID-19 pandemic has caused untold damage and continues to bring loss and hardship to communities around the world, and the world's poorest continue to suffer from unequal access to lifesaving medical tools. One cause for hope has been the unprecedented pace of the response by life sciences research and the rapid development of medical technologies to tackle this new threat. We had diagnostic tests within a week, effective therapeutics (in the form of dexamethasone) in 138 days and safe and effective vaccines in just over 300 days after the WHO declared a public health emergency of international concern. These are incredible achievements given novel medicines and medical technologies have historically taken a decade or more to develop – and often as long again to reach countries at all income levels.

The G7 countries have a crucial role to play, with a major stake in the international health system, a wealth of scientific expertise, and the resources to support the strengthening of health systems across the globe. In February 2021, the UK Prime Minister challenged the G7 to explore how we can harness scientific innovation and strengthen public and private collaboration to reduce the time from discovery to deployment of diagnostics, therapeutics and vaccines in a future health crisis.

In response, an independent group, the pandemic preparedness partnership, was established to advise the UK G7 Presidency on how to develop and deploy safe, effective diagnostics, therapeutics, and vaccines within the first 100 days of a pandemic. This is predicated on an effective global surveillance system to identify a pandemic threat quickly. Then, alongside crucial non-pharmaceutical interventions like social distancing, contact tracing and PPE, rapid deployment of effective diagnostics, therapeutics and vaccines can save countless lives.

For these reasons, the pandemic preparedness partnership has set out the 100 Days Mission for developing safe, effective diagnostics, therapeutics and vaccines at scale

and ready to be deployed equitably. This independent report sets out a roadmap for making the 100 Days Mission achievable, through recommendations for governments, international organisations, and industry partners to take forward, working collectively and collaboratively to achieve this ambitious target for the global good.

To achieve these ambitions, this work must be inclusive. We need to find solutions that will work at all income levels and will address the needs of groups who are too easily excluded, such as the diverse experiences of countries around the world, and the key needs of women and girls. We hope that the G7 will commit to giving a leading role to these voices and to representatives of developing countries in the implementation of this roadmap.

We have seen tremendous innovations from partnerships between academia, industry, international organisations, philanthropy and governments in responding to this pandemic. We don't know when or from where the next threat will emerge, so we need to work together, between sectors and across national borders, to make the exceptional, the everyday. The 100 Days Mission is ambitious but achievable and essential.

Sir Patrick Vallance



Melinda French Gates



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CHAPTER 1

The Case for a 100 Days Mission

- 1 Imagine a scenario where COVID-19 had hit, but the world was ready. A scenario where:
 - We had a sophisticated international surveillance network that alerted the world to some unusual cases of “flu” in Wuhan, China in December 2019, that was able to share the genomic sequence and disease information even quicker than the 20 days it took.¹
 - A responsive diagnostics sector swung into action, producing accurate and rapid diagnostic tests at scale to detect new cases early, monitor contacts, and guide critical public health intervention.
 - The research and development had already been completed and prototype diagnostics and therapeutics² only needed tweaking before they could be subjected, along with vaccines,³ to rapid assessment through an established international clinical trials network to quickly affirm their safety and efficacy.
 - Global manufacturing capacity was there and swiftly activated, ready to produce accurate diagnostics quickly and therapeutics and vaccines at scale to those who need them.

¹December 2019, unusually-presenting ‘pneumonia’ patients admitted to hospital in Wuhan; 10 January 2020 viral whole genome sequenced and uploaded to open-access website.

²The term therapeutics covers different types of products. For example: antivirals (agents which directly or indirectly suppress viral replication); immunomodulators (agents which modify the deleterious virus-induced host immune response); supportive care (agents which address consequences of viral replication or excessive immune stimulation e.g. anticoagulants); monoclonal antibodies (proteins that mimic a key element of the natural immune response to harmful pathogens such as viruses); and antibiotics (agents which are used to treat bacterial infections).

³Scientists were developing vaccines against coronaviruses and other infectious diseases before COVID-19 hit, one of the key factors behind the rapid development in record time of safe and effective vaccines. This is discussed further in Chapter 3.

- The World Health Organization (WHO), upon declaring a Public Health Emergency of International Concern (PHEIC), enacted agreed protocols setting out the 'rules of the road' for a pandemic, speeding up data sharing and regulatory approvals and triggering procurement pools for diagnostics, therapeutics and vaccines (DTVs).
 - There was sufficient financing available, and ready to draw down, to get DTVs to the poorest countries at the scale needed.
- 2 In this scenario, the world could have deployed safe and effective DTVs in May 2020, and hundreds of thousands of lives would have been saved, lockdowns would have been shortened, and trillions of dollars of lost economic output saved.
 - 3 This scenario may seem far-fetched, but it is possible. We can have safe and effective DTVs within 100 days of a pandemic threat being detected. This requires preparation, investment, and a no-regrets approach. It also requires a combined and concerted effort between governments, industry and international organisations. COVID-19 showcased the capacity of our scientists, healthcare and public health professionals, industry, international organisations and the public to respond quickly. For that reason, we must be ambitious.

A 100 Days Mission for Diagnostics, Therapeutics and Vaccines

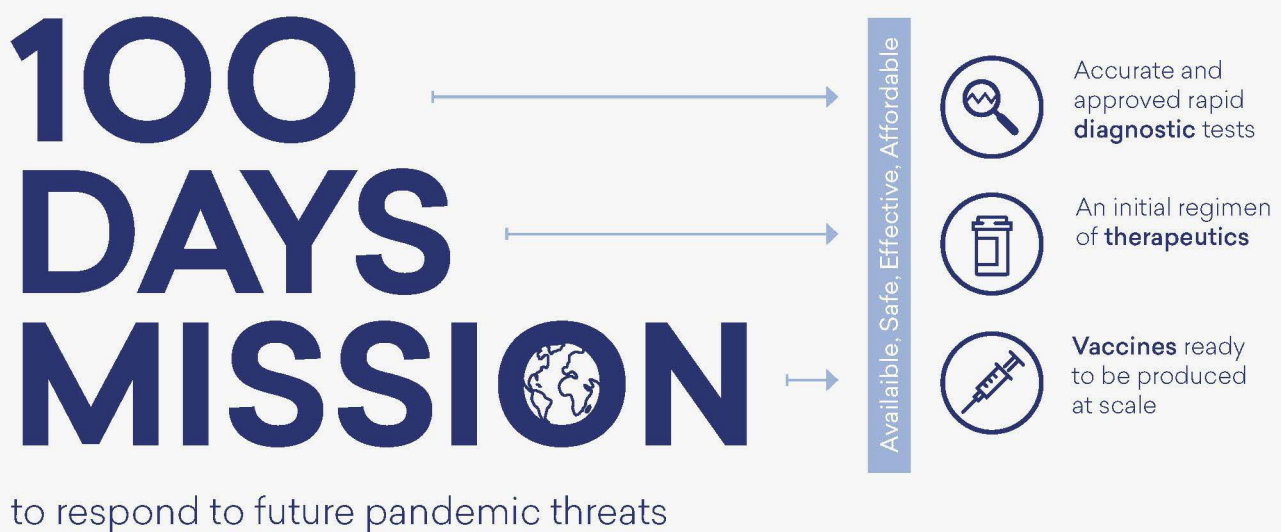
- 4 The first 100 days when faced with a pandemic or epidemic threat are crucial to changing its course and, ideally, preventing it from becoming a pandemic.⁴ In those 100 days, non-medical public health interventions like social distancing, isolation, contact tracing and personal protective equipment (PPE) are essential, but the three best weapons we have to defeat a pathogen threat are diagnostics, therapeutics and vaccines. Together, they can save millions of lives.
- 5 Building on the target set by the Coalition for Epidemic Preparedness Innovations (CEPI) - to have effective vaccines within 100 days of a pathogen being sequenced - we propose an Apollo Mission for the modern age to galvanise the international community.

⁴ CEPI, 'The Urgency of Now' Investment Case, April 2021, pages 8-9, https://cepi.net/wp-content/uploads/2021/03/CEPI_3.5_billion_investment_case_10032021.pdf

- 6 In the first 100 days from a pandemic threat being identified (defined by when WHO declares a PHEIC) we should aim for the following interventions to be **available, safe, effective and affordable**:
- a Accurate and approved rapid point of care **Diagnostic tests**;⁵
 - b An initial regimen of **Therapeutics**;⁶ and,
 - c **Vaccines** ready to be produced at scale for global deployment.⁷

DIAGRAM 1

The 100 Days Mission



⁵ This includes the rapid development and validation of molecular based tests, following the sequencing of the pathogen, and the development of Rapid Diagnostic Tests. Quality parameters linked to WHO specification.

⁶ This includes clinical trials of prioritised novel therapeutics, repurposing of existing pharmaceutical agents (directed against the pathogen and modifying the host response) and monoclonal antibodies.

⁷ This includes clinical trials, scaling manufacturing, and innovations to support rapid development and deployment of vaccines where needed in a crisis.

- 7 The 100 Days Mission is a rightly ambitious goal to aim for. That said, we accept the reality that for some pathogens there will be many years of work to get us to this position, but for others we could achieve the goal more quickly. A lot will depend on whether we know our enemy or if we are met with a surprise attack: whether it is a pathogen we are prepared to fight or a completely novel “Disease X” threat.⁸ And it will depend on how quickly the pathogen spreads and the severity of the disease it causes. The timing and nature of such threats is uncertain. This is why the first critical step is effective surveillance, coupled to pathogen analysis (with information- and sample-sharing). A global, integrated surveillance network can prevent us from being taken by surprise. A One Health approach is crucial, looking across human, animal and environmental health, given the danger posed by zoonotic (animal-originating) diseases, like COVID-19.⁹ We welcome the report by Sir Jeremy Farrar (the “Pathogen Surveillance Report”) which calls for a network of sophisticated surveillance centres; core infrastructure to sequence, analyse data and share information; modernised sampling, governance and ethics frameworks; the use of data to drive development of DTVs; and global leadership to bring this all together, integrated with public health and academic research.¹⁰ This global surveillance network should inform, through clear data disaggregation for impacts by gender and ethnicity and regular foresight planning, the development of targeted and evidenced-based guidance on public health interventions for both business-as-usual responses and pandemics.
- 8 Alongside surveillance, another prerequisite of an effective DTVs response to a pandemic is strong national, regional and international health systems with clear public health protocols to respond to health threats. These protocols should stimulate, and be informed by, research and development into the transmission modes for different pathogen classes and into non-pharmaceutical interventions.
- 9 Once a pandemic threat has been identified, we need high quality validated diagnostics first, at scale, to track and help contain the infection through non-medical interventions. We should then expect therapeutics to treat the disease and prevent deaths. And we should expect safe vaccines, regulated by a Stringent Regulatory Authority (SRA) and ready to be produced at a global scale, to build immunity and

⁸ Zoë L. Grange et al, ‘Ranking the risk of animal-to-human spillover for newly discovered viruses’, PNAS 118(15), April 2021, <https://www.pnas.org/content/118/15/e2002324118>

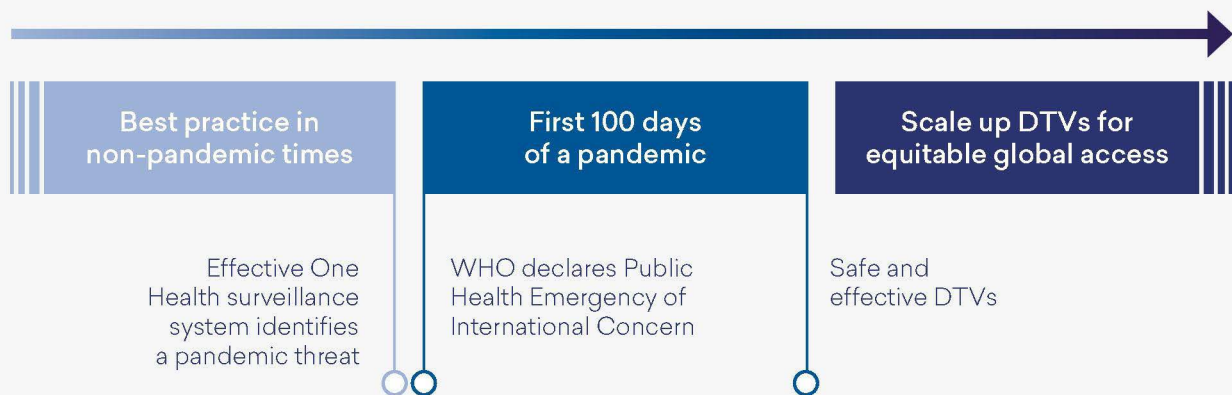
⁹ David M Morens and Anthony S Fauci, ‘Emerging Pandemic Diseases: How We Got to COVID-19’, Cell 182(5), August 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428724/>

¹⁰ Sir Jeremy Farrar, ‘A proposal to develop an equitable global pathogen surveillance network in 2021 that can prevent and respond to emerging and endemic infectious diseases at speed and at scale’, May 2021, <https://www.gov.uk/government/publications/report-proposing-enhanced-global-pathogen-surveillance>

prevent infection. Each of these medical tools must be designed with global use in mind and our ambition should be for equitable - needs-based - access. As shown in Diagram 2, our task is not finished at the 100 days mark; once safe and effective DTVs are available, we must be ready to scale up for global equitable access including ongoing evaluation of their implementation and impact.

DIAGRAM 2

Improving pandemic preparedness



Learning Lessons from COVID-19

- 10** Meeting this 100 Days Mission requires learning the lessons from COVID-19, as well as from previous epidemics and pandemics. First, we should acknowledge and celebrate the extraordinary advances made in this pandemic. The first vaccines were ready for clinical trials in under a month,¹¹ with safe and effective COVID-19 vaccines available after a mere 307 days:¹² an incredible achievement given novel vaccines often take up to 15 years to develop, and for some common infectious diseases we struggle to create effective vaccines at all. We are in the midst of the largest global adult vaccination campaign in history. There has been similar speed on diagnostics: automated polymerase chain reaction (PCR) tests were available in 64 days and the first rapid diagnostic test (RDT) gained WHO approval in 236 days. In therapeutics, on day 138, we saw the RECOVERY trial report that dexamethasone, an inexpensive and widely available steroid drug, reduced the risk of death for patients with severe disease¹³ and it has subsequently saved a million lives.¹⁴ While these achievements must be lauded, there were - and continue to be - numerous challenges and failings that undermine our response. These lessons learned from our ongoing struggle with COVID-19, as well as previous pandemics and epidemics, highlight a number of barriers to reaching the 100 Days Mission. Key failings included: the lack of existing DTVs and low manufacturing capacity; systemic inefficiencies and inequities; and a lack of preparedness and coordination that meant there were unclear demand commitments, insufficient funding, inconsistent rules and regulations, delays and inequitable access to DTVs.

¹¹ Moderna's mRNA-1273 was developed within 25 days of the PHEIC, on 24 February 2020 (45 days from the sequence of the virus being available). Moderna press release ('Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study'), February 2020, <https://investors.modernatx.com/news-releases/news-release-details/moderna-ships-mrna-vaccine-against-novel-coronavirus-mrna-1273>

¹² MHRA granted emergency authorisation for the Pfizer/ BioNTech vaccine Comirnaty COVID-19 mRNA vaccine on 2 December 2020, 307 days from 30 January, when WHO declared a PHEIC.

¹³ RECOVERY trial announced results for dexamethasone on 16 June 2020 (98 days from the trial being funded); <https://www.recoverytrial.net/results/dexamethasone-results>

¹⁴ NHS Press Release, ('COVID treatment developed in the NHS saves a million lives'), March 2021, <https://www.england.nhs.uk/2021/03/covid-treatment-developed-in-the-nhs-saves-a-million-lives/>

- 11** In many cases we were starting from a low base. Lack of demand for affordable, fast and accurate diagnostics before this pandemic resulted in limited research or market development. For therapeutics, there has been insufficient investment in specific and potent small molecules to treat common pathogen classes. As a result, there is an inadequate R&D ecosystem and pipeline for small molecule antivirals and “programmable”¹⁵ antiviral platforms. Both antiviral therapeutics and vaccines take years to develop, so waiting until a pandemic threat arises is too late. COVID-19 vaccines had a comparative head-start because vaccines against the coronavirus-caused diseases Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) were in prototype stage¹⁶ and mRNA technology had advanced rapidly but had never been scaled and was not sufficiently accessible to low- and lower-middle-income countries (LMICs) due to cost, buy-up by high-income countries (HICs), and low storage temperatures. Manufacturing for vaccines, in particular, did not have the necessary capacity to produce vaccines at the scale required.
- 12** We suffered from systemic inefficiency and a lack of preparedness, including inadequate molecular laboratory capabilities and low capacity in supply chains and manufacturing. For diagnostics the lack of high quality regulatory pathways with clear specifications and use cases has led to diagnostics of varying quality and governments’ use of tests in ways they were not intended. It took 242 days for WHO to publish its target product profile for an RDT (6 days *after* WHO gave Emergency Use Listing (EUL) to its first RDT).¹⁷ Clinical trials of treatments have often been too small, duplicative, fragmented and poor quality. For vaccines, there are continued bottlenecks in clinical trials, regulation, the availability of inputs, and scaling of manufacturing which is reducing access to those who need them. For all three areas, the response was characterised by insufficient and delayed funding, and a lack of at-risk investment driven by unwillingness to share risk, overreliance on official development assistance (ODA), and a slower multilateral development bank (MDB)

¹⁵ In this report we refer to “programmable” technologies to denote the transformative impact of new technology platforms and approaches, like mRNA, which allow scientists to rapidly amend medical tools to respond to a specific pathogen. ‘Covid-19 vaccines have alerted the world to the power of RNA therapies’, The Economist, March 2021, <https://www.economist.com/briefing/2021/03/27/covid-19-vaccines-have-alerted-the-world-to-the-power-of-rna-therapies>

¹⁶ Philip Ball, ‘The lightning-fast quest for COVID vaccines – and what it means for other diseases’, Nature, December 2020, <https://www.nature.com/articles/d41586-020-03626-1>

¹⁷ WHO, ‘Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0’ September 2020, <https://cdn.who.int/media/docs/default-source/blue-print/who-rd-blueprint-diagnostics-tpp-final-v1-0-28-09-jc-ppc-final-cmp92616a80172344e4be0edf315b582021.pdf>

response than was needed in a pandemic.¹⁸ This was compounded by the historical reduction in financing that is seen once health threats have diminished.

- 13** Precious time was also lost in the need to agree basic approaches and stand-up the necessary bodies. Slowness in sharing biological samples stymied the ability for industry to rapidly activate research and development (R&D), particularly for diagnostics. The Access to COVID-19 Tools Accelerator (ACT-A) was set up in 85 days,¹⁹ and it took another 41 days for its vaccines pillar to launch the Gavi COVAX Advance Market Commitment (AMC) to provide vaccines for LMICs.²⁰ While this is fast by any normal standards, it is too slow in a pandemic when every day counts. It is also worth noting that approaches and capacity for using diagnostics in tracing, isolation and border control continue to vary greatly within and between countries. Regulation has been faster than normal, but is internationally inconsistent and has been poor for diagnostics. For vaccines, COVAX will continue to be vital in enabling LMICs' access to vaccines. But it struggled to compete with HICs' vaccine purchases and was inadequately financed to provide sufficiently large and consistent demand commitments to manufacturers. This was compounded by it being not sufficiently integrated with the MDBs who could have used their balance sheets to finance procurement for upper-middle-income countries (UMICs) and LMICs more quickly.

¹⁸ The World Bank's response to COVID has been one of its fastest, and largest. The World Bank approved a \$6bn COVID-19 response programme in April 2020: World Bank Project Appraisal Document, <https://documents1.worldbank.org/curated/en/993371585947965984/pdf/World-COVID-19-Strategic-Preparedness-and-Response-Project.pdf>, April 2020. However, it took longer to approve its \$12bn vaccine specific package, which was announced in October 2020 (257 days since WHO declared a PHEIC): World Bank Press Release, 'World Bank Approves \$12 Billion for COVID-19 Vaccines', <https://www.worldbank.org/en/news/press-release/2020/10/13/world-bank-approves-12-billion-for-covid-19-vaccines>, October 2020. Regional Development Banks have shown similar comparative speed to normal, for instance with the Asian Development Bank's initial \$6.5bn COVID-19 funding starting from February 2020: ADB Press Release, 'ADB announced \$6.5 billion initial response to COVID-19 pandemic', <https://www.adb.org/news/adb-announces-6-5-billion-initial-response-covid-19-pandemic>. DTV packages came many months after the PHEIC e.g. Asian Development Bank's vaccine facility was launched 11 December 2020: ADB Press Release, '(\$9 Billion ADB Facility to Help Developing Member Countries Access and Distribute COVID-19 Vaccines)', December 2020, <https://www.adb.org/news/9-billion-adb-facility-help-members-access-and-distribute-covid-19-vaccines>

¹⁹ ACT-A was launched 24 April 2020, 85 days after 30 January when WHO declared a PHEIC.

²⁰ COVAX set out its initial goal on 3 September 2020 to purchase 2 billion COVID-19 vaccines by the end of 2021: Seth Berkley, 'COVAX explained', September 2020, <https://www.gavi.org/vaccineswork/covax-explained>

DIAGRAM 3

What could have been: comparing the COVID-19 timeline to a proposed 100 Days Mission timeline

COVID-19 Timeline

100 Days Mission Timeline



What Does Better Pandemic Preparedness Look Like?

14 We must seize the lessons from COVID-19 to improve pandemic preparedness for the future. Achieving the 100 Days Mission and improving global pandemic preparedness requires, firstly, **effective surveillance** and pathogen analysis so we can spot pandemic threats earlier and respond immediately. Once surveillance has spotted a disease risk, our best weapons are DTVs. To prepare effectively we need to:

- a Invest in R&D to fill the gaps in our DTV arsenal.** We should have a mission-focused approach to prepare for known risks, through concerted effort and collaboration between the public and private sectors and academia. The pathogens of greatest pandemic potential are represented by respiratory viruses, but we know that viruses from at least 25 viral families can cause human disease, and in theory the next pandemic could emerge from any of these families.²¹ We can, and should, prepare prototype DTVs to treat pathogens of greatest pandemic potential and progress them to a stage that can be adapted quickly to respond to a specific pathogen threat. We must also be prepared for the unexpected, and should develop vaccines and therapeutic technologies that can be readily adapted to respond to an unknown “Disease X”, including simplified and easily transferable manufacturing processes. To stimulate R&D and boost manufacturing capacity for diagnostics, we should create a market by using diagnostics as part of business-as-usual healthcare and surveillance. This will also improve care and help in the battle against antimicrobial resistance (AMR).
- b Make the exceptional routine by embedding best practice and preparation in business-as-usual activity** (when the world is not combatting a pandemic). This will not only help prepare for pandemics, but would also help in our battle against epidemics and endemic diseases. Embedding best practice as routine requires taking the best innovations from this pandemic and adopting them in day-to-day activity so that it is the norm well before a pandemic arises. This should include regionally- and internationally-networked randomised controlled trial platforms, better regulation and simplified transferable manufacturing processes, particularly for vaccines, as the norm. Embedding preparation requires international financing for LMICs’ pandemic preparedness and better oversight of global health threats, bringing together health and finance expertise. It also includes maintaining readiness with networked

²¹ See Zoë L. Grange et al, ‘Ranking the risk of animal-to-human spillover for newly discovered viruses’, PNAS 118(15), April 2021, <https://www.pnas.org/content/118/15/e2002324118>

government-industry manufacturing capacity that could be ‘kept warm’ in business as usual through global adult vaccination programmes.

- c Agree different rules of the road in a pandemic** so that no time is wasted negotiating the basics. These protocols should form part of a wider suite of guidance WHO sets out (for instance, covering travel and PPE) which must be agreed in advance and demonstrate a step-change from business as usual when a PHEIC is declared. This trigger relies on a more rapid and nuanced PHEIC declaration process. For DTVs, these rules of the road should include guidance on supply chains, indemnification and data sharing as well as a system to share data and biological samples, and utilise standardised assays. Pandemic response needs to work through existing international institutions, with the rules of the road activating a step-change in behaviour that complements the best practice and preparation established between pandemics. We would then be ready to enable rapid prioritisation, speed, scale and equitable access including activation of networked manufacturing and clinical trials, automatic DTV financing and rapid, joined-up regulatory approvals processes with pandemic-appropriate guidance.

DIAGRAM 4

Best practice before pandemics



Fill the Gaps in our Arsenal – develop DTVs for prototype pathogen classes of concern and invest in simplified manufacturing processes

Make the exceptional routine: embed best practice and preparation in business as usual

Embed best practice:

- International networks of clinical trials with effective data-sharing
- Better, joined-up regulation
- Share knowledge through transferable manufacturing processes

Embed preparation:

- Finance LMIC pandemic preparedness
- Oversight through Global Health Board
- Build in equitable access as a standard in government funding
- Create a public-private manufacturing network

Effective One Health surveillance system identifies a pandemic threat

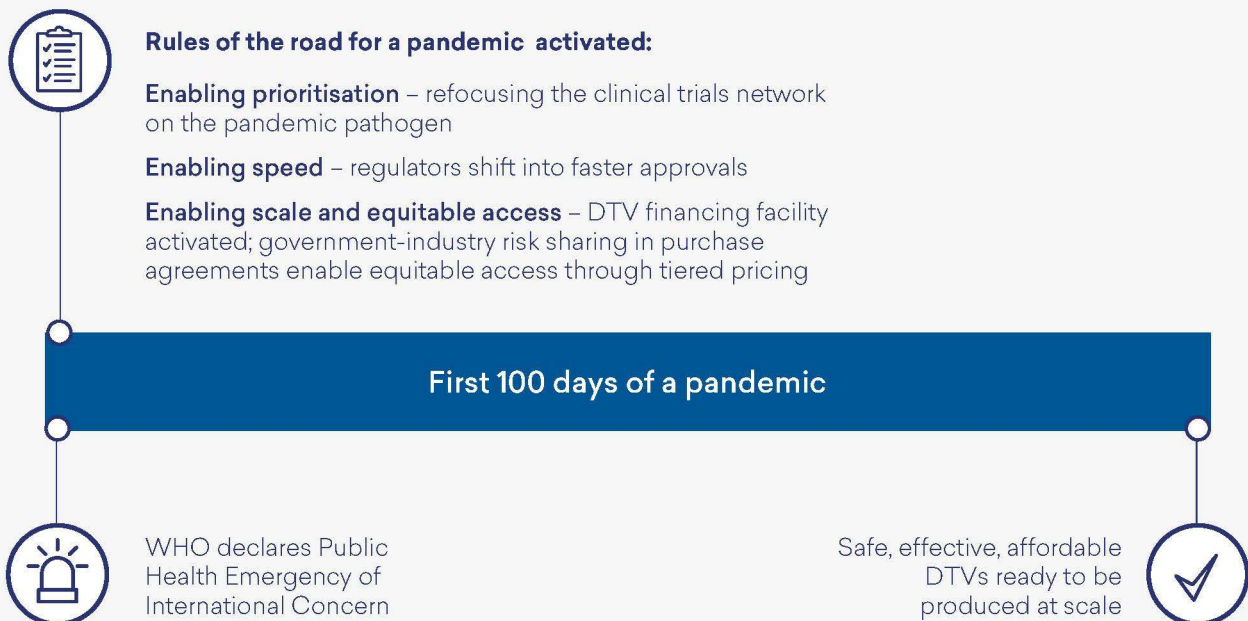


Recommendations: The Roadmap to Better Pandemic Preparedness

- 15** With a 100 Days Mission providing focus, the crucial steps that governments, industry and international organisations must take to improve our pandemic preparedness are set out below. The full list of recommendations is set out in Annex A and the detailed thinking is set out in Chapters 2-5. These recommendations will need to be underpinned by sustained financing ahead of a pandemic to achieve our 100 Days Mission.
- 16** Industry and academia should **prioritise R&D into DTVs against the WHO list of priority pathogens**, and, within this list, the respiratory viruses coronavirus and influenza, given their propensity to cause pandemics. We should aim to have prototype DTVs against the virus families of greatest pandemic threat. For instance, preparing a pan-coronavirus vaccine or antibody therapies that can be adjusted if a deadly form of coronavirus appears again. Similarly, we should embed simplified transferable vaccine manufacturing processes as the norm. The main route for this

DIAGRAM 5

The first 100 days



effort will be the private sector, with research from academia and supported by the public sector and international organisations - it will also require new partnerships or ways of working, as well as enhancing current approaches. In this regard, we believe **expanding CEPI**, which currently focuses on vaccines, will fill a crucial gap in the international system in providing R&D funding and coordination for therapeutics and diagnostics. CEPI is already planning to use a financing model inspired by Gavi's International Finance Facility for Immunisation model (IFFIm), which allows donors to frontload financing. CEPI should explore further sources of public and private financing and funders should look to meet CEPI's funding asks, including at the CEPI replenishment conference in 2022.

- 17 Industry, governments and international organisations, should explore how a **vaccine manufacturing network**, utilising the latest technology, could be rapidly activated in a pandemic. Governments and international organisations should also consider expanding **mass adult vaccination campaigns** for common diseases - both to respond to very real and pressing public health needs and to create regular demand for expanded capacity. An expanded vaccination programme would have widespread health benefits and would help address the need to 'keep warm' manufacturing and stimulate innovation in business as usual, while avoiding the trap of public money paying for empty facilities that soon become outdated. Group of 7 (G7) governments should also consider **normalising the use of diagnostics** as part of enhanced surveillance and at points of care for cost-effective use cases, which will stimulate and maintain the market. FIND, the global alliance for diagnostics, has a key role to play in ensuring access to diagnostics for developing countries by 'match-making' between industry and demand.
- 18 WHO should work with governments and stakeholders to scope an **international clinical trials network** to enable a coordinated and efficient approach to testing of new DTVs and existing therapeutics. The network should bring together national clinical trials infrastructure, interlinked regionally in a way that can be rapidly commandeered as a global resource in a pandemic. The network should enable immediate and transparent knowledge and information sharing, with appropriate confidentiality protections and clear data disaggregation standards for impact by gender and ethnicity at all stages of analysis. It will require baseline funding from countries to strengthen their own clinical trial infrastructure and create regional links, supplemented by a "user-pays" model (whether academia, public sector or industry). This clinical trials network should always be active (including between pandemics) and be able to rapidly refocus in a pandemic or epidemic, supported by a mechanism to prioritise which DTV products to trial. Regulations should allow easy

moving of clinical trials across the network at a speed that matches the migration of any epidemic or pandemic around the globe. In practice this means having clinical trials infrastructure owned in countries and networked first at a regional level.

- 19 SRAs, working with WHO and other relevant organisations, should **streamline, harmonise and simplify regulatory processes** in business as usual, and agree a faster and joined-up approach in pandemics. This should include a new look at existing rules such as the Good Clinical Practice clinical trials guidance and consider whether they are still fit for purpose. SRAs should prepare target product profiles prior to a pandemic being declared by WHO – with preferred characteristics set out by type of pathogen that may emerge or spread uncontrollably. It should also consider the development of risk-adjusted, scenario-based approaches to accelerated approvals or emergency use authorisation as soon as a DTV is shown to be beneficial.
- 20 WHO should work with governments, other international organisations and industry to set **rules of the road for pandemics**, including for supply chains, indemnification and data sharing. This guidance should set out expectations on shifting from business as usual and enable speed, scale and equitable access. Part of the rules of the road should include automatically activating a **DTV financing facility**, which could be made up of a series of **pre-negotiated, pre-funded advance commitments**. This will provide demand signals to pharmaceutical companies and ensure sufficient supply is made available quickly in a pandemic, including to LMICs, based on clinical need.
- 21 Companies should, in exchange for some risk-sharing from HIC governments, **commit to providing DTVs at not for profit for LMICs when a PHEIC is declared**. This must also be done **within a similar timeframe to when HICs are supplied**. HICs should make this a condition of Advance Purchase Agreements (APAs) during a pandemic. In business as usual, HICs should include **equitable access clauses** in their funding agreements for DTV R&D, manufacturing or other early push funding. These clauses should require production of the diagnostic, therapeutic or vaccine at not for profit and scale during a pandemic or epidemic situation. This should ensure that public money funds public good and continues to support innovation.
- 22 A **Global Health Board** should be set up under the auspices of the G20. This would be for the G20 to establish; we suggest the Board could report to a joint session of Health and Finance Ministers on an annual basis on ongoing and emerging risks to the international system from pandemic threats, and actions needed to address them. The G20 should consider including in the Board the three Chief Scientific Advisers (CSAs) or their equivalents (e.g. Chief Medical Officers) and Finance Deputies of the incumbent, previous and successive G20 Presidencies, the One Health

Organisations,²² The Global Fund, Gavi, CEPI and the International Monetary Fund (IMF) and World Bank. It could be chaired by WHO, with the Global Preparedness Monitoring Board (GPMB) acting as the secretariat, to provide independence, expertise and stability to the Board. By reporting directly to the G20, the Board would be well placed to stand up the necessary response quickly to a PHEIC, and should expect the full-political and financial backing of the full G20 membership.

Contributing to the International Dialogue

- 23** This report represents recommendations by the partnership for pandemic preparedness to the G7. The partnership was formed by public and private sector experts on the request of the UK's 2021 Presidency of the G7. It is informed by the ongoing response to COVID-19, as well as the response to epidemics and endemic diseases.
- 24** Given the number of other vital reports and reviews of the COVID-19 response (including, but not limited to, the WHO Independent Panel for Pandemic Preparedness and Response [IPPPR] and G20 High Level Independent Panel), this paper is consciously focused on a specific part of the puzzle: **the critical medical tools of diagnostics, therapeutics and vaccines**. Other elements where separate attention would be welcome include non-medical interventions and health system strengthening. The members of the partnership welcome the report by the IPPPR and its contribution to the international debate. And while we applaud the noble goal of the IPPPR that COVID-19 be the last pandemic we face, we believe the science and evidence suggests we must prepare for the worst and - in doing so - make it less likely.

²² The organisations are known as the “Tripartite Plus”, comprising the World Health Organization (WHO), the World Organisation for Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO), and the United Nations Environment Programme (UNEP).

CHAPTER 2

The Pandemic Preparedness Partnership

The Remit of the Partnership

- 25** The partnership for pandemic preparedness was formed to advise the G7 under the UK's 2021 Presidency on the practical and pragmatic steps to fight future pandemics through the three critical medical countermeasures of diagnostics, therapeutics and vaccines. The partnership is time-limited, and is made up of an advisory group of experts (set out in Annex B). It is chaired by the UK Government's CSA, Sir Patrick Vallance, and comprises nineteen representatives from industry, international organisations and sector experts in their respective fields. In addition, the partnership is grateful to Melinda French Gates, co-chair of the Bill & Melinda Gates Foundation, whose deep expertise and knowledge, convening power, and authority helped to maximise the findings of the partnership.
- 26** A key value of the partnership is its recognition that the best of the public and private sectors, academia and international organisations is needed to effectively prepare for, and respond to, future pandemics. Governments and international organisations need to set clear expectations and provide the right incentives; industry and academia need to innovate and collaborate and all actors need to agree how we work together between and in pandemics. Having good systems working effectively during usual times that can be rapidly scaled in any pandemic or epidemic is crucial.
- 27** Three pairs of expert leads were asked to lead work on three interrelated workstrands, drawing on the other members of the partnership as well as other external experts. Each of these three workstrands are crucial to the development and deployment of safe and effective DTVs:

- a Research and development, and innovation in manufacturing: Sir Andrew Witty and Professor Sir John Bell.
- b Clinical trials and data: Professor Dame Anne Johnson and Professor Martin Landray.
- c Sustainable financing: Baroness Minouche Shafik and Lord Jim O'Neill.

Looking Ahead While in the Midst of a Crisis

- 28** All those who contributed to the recommendations in this report have been simultaneously occupied with responding to COVID-19. We are grateful for their generous time. While it might seem more appropriate to await the end of the pandemic phase of COVID-19 before looking to the future, that would be a mistake. We need to take action now to put us on better footing to respond to the next pandemic. Many of the recommended actions would also help in our continued global fight against COVID-19.
- 29** COVID-19 also brings the starkest possible reminder of the importance of investing in pandemic preparedness. Over three million people²³ have tragically lost their lives, and this number could be significantly higher due to underreporting of deaths.²⁴ We have seen women and girls disproportionately suffer from the societal consequences of the COVID-19 pandemic, the full implications of which are still becoming clear. More significantly, COVID-19 has been more deadly and debilitating for specific ethnic groups.²⁵ Future pandemic responses must seek to rectify such disparities. This report uses language similar to that usually reserved for traditional, military defence. We do this for a reason: the greatest threat to humanity is not warfare; it is diseases. And when faced with microscopic enemies, the world requires collective defences in the form of strong health systems, surveillance and safe and effective DTVs.

²³ As of 30 May 2021, global deaths reported to WHO stood at 3,530,582; <https://covid19.who.int/>

²⁴ The Economist estimates 10 million deaths based on analysis of excess deaths, May 2021, <https://www.economist.com/briefing/2021/05/15/there-have-been-7m-13m-excess-deaths-worldwide-during-the-pandemic>

²⁵ UK study: Black males are 4.2 times; Black females 4.3 times; Bangladeshi and Pakistani males 1.8 times; Bangladeshi and Pakistani females 1.6 times more likely to die from COVID than White males and females respectively, Office for National Statistics, May 2020, <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/articles/coronavirusrelateddeathsbyethnicgroupenglandandwales/2march2020to10april2020>

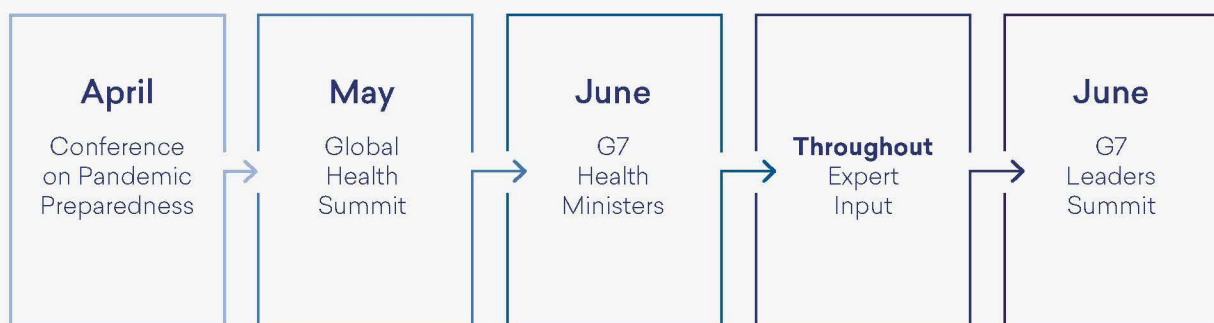
US study: American Indian or Alaska Native people 2.4 times; Black or African-American people 1.9 times; Hispanic or Latino people 2.3 times more likely to die from COVID than White, non-Hispanic people. Asian people equivalent death rate to White, non-Hispanic people, Centres for Disease Control and Prevention, April 2021, <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>

Implementation

- 30** This report sets out a series of recommendations to guide the international community on the steps that can be taken now, and over the longer-term, to move closer to achieving the 100 Days Mission of safe and effective DTVs. While there is no clear deadline by which we need to be ready for the next major health threat, this should encourage us to act fast. We believe we should aim to be ready within five years. These recommendations are neither definitive nor comprehensive. Governments, companies and organisations are encouraged to take a cue from these recommendations and continue a public-private approach to implementation. Annex A sets out proposed responsible owners for the recommendations.
- 31** The recommendations within this report were presented and discussed at various international fora, as well as drawing on conversations outside the G7 including in the G20 and at the World Health Assembly. Advice and insight has been provided by the CSAs (and their equivalents), from international organisations, regulators, academics and other experts, and representatives from across industry. It has benefited from every discussion. The key stages of its development are illustrated below.

DIAGRAM 6

Timeline of the development of this report



- a** The Prime Minister of the UK, as G7 President, launched the pandemic preparedness partnership on 20 April in pursuit of the 100 Days Mission.²⁶
- b** The UK hosted a conference on pandemic preparedness attended by international experts and G7 CSAs in April 2021, with the expert leads (mentioned in paragraph 27) hosting discussions on R&D and manufacturing; clinical trials and data; and sustainable financing.
- c** Within the G7, numerous reports and discussions have informed our thinking, including the recommendations of the Science Academies of the G7 (the S7), Sir Jeremy Farrar's Pathogen Surveillance Report to the G7, the Health Ministers' Therapeutics and Vaccines Clinical Trials Charter, the Foreign & Development Ministers' Equitable Access Statement and the work of the Finance Ministers to address the market failures linked to AMR. Early finance recommendations were discussed at the G7 Finance Deputies in May and the 100 Days Mission was endorsed by pharmaceutical industry representatives as part of the G7 Health Ministers meeting in June.²⁷
- d** We have drawn on many ongoing discussions on pandemic preparedness and response outside the G7 process, notably the G20 Global Health Summit, World Health Assembly, and the G20's High Level Independent Panel on financing the global commons for pandemic preparedness and response, which will report to the G20 Finance Ministers in July 2021, after this report is published.
- e** In addition to these engagement milestones, the content and recommendations in this report have been widely discussed in individual discussions with industry and regulatory experts; the CSAs of the G7 countries; and international organisations, including WHO, CEPI, FIND, Gavi, The Global Fund, UNITAID and the Medicines Patent Pool.
- f** This report was presented to the G7 Leaders' Summit on 12 June 2021. This report sets out recommended steps governments, industry and international organisations should take to move closer to achieving those targets: steps which have been endorsed by leading industry and sector experts in the respective fields.

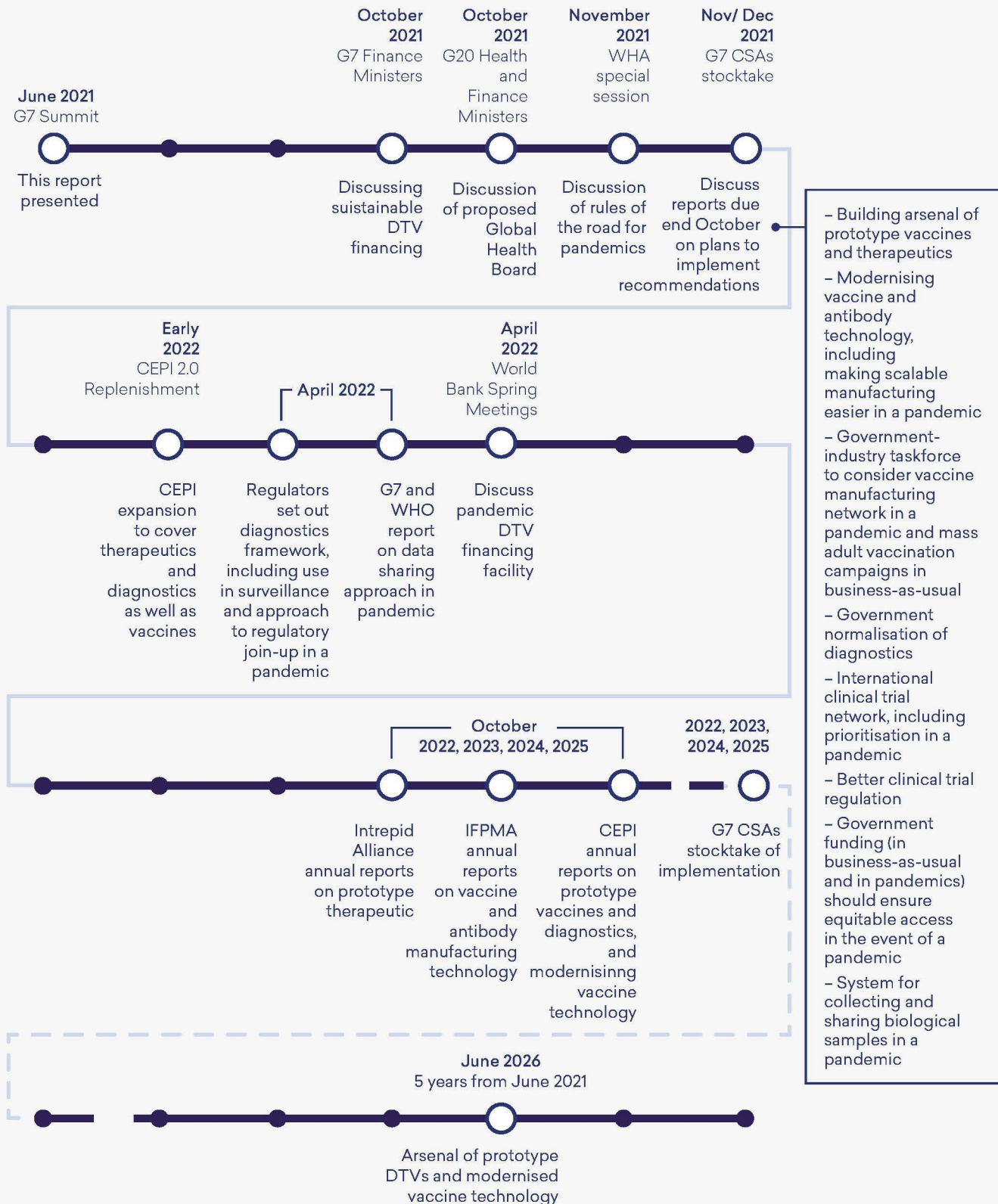
²⁶ UK Government Press Release, 'New global partnership launched to fight future pandemics', April 2021, <https://www.gov.uk/government/news/new-global-partnership-launched-to-fight-future-pandemics>

²⁷ UK Government Press Release, 'Government and life science industry join forces on 100 Days Mission for future pandemics', June 2021, <https://www.gov.uk/government/news/government-and-life-science-industry-join-forces-on-100-days-mission-for-future-pandemics>

- 32** The recommendations set out in this report constitute the start of what should be an ongoing process to improve pandemic preparedness for DTVs. Notably, many of the recommendations would confer significant financial costs, which we have not detailed and which lead organisations should seek to set out in slower time. Ultimately COVID-19 has shown that large investments in preventing and ending pandemics sooner are outstanding value for money. We stand by the need for additional financing from countries who have an ability to pay but note further discussions will be needed. Similarly, many of our recommendations set out proposed leads and groups of organisations to take forward work. Discussions will be needed between these organisations to ensure the right groups are included and that the necessary enablers are in place to facilitate joint working. **We recommend a regular review of the implementation of the recommendations in this report, beginning with an initial stocktake before the end of 2021**, to be conducted by the G7 CSAs. This first discussion should cover a progress-update on the recommendations and any further steps that are needed, working with the organisations leading on the recommendations where appropriate. The G7's implementation discussions should be seen as part of its wider commitment to pandemic preparedness and response, and in support of the work of the proposed G20 Global Health Board.

DIAGRAM 7

Roadmap to the 100 Days Mission



CHAPTER 3

Research & Development to Fill the Gaps in our Arsenal

- 33** COVID-19 has demonstrated the need to improve our baseline defences - in the form of DTVs. There were no approved vaccines or antiviral therapeutics for coronaviruses before COVID-19 hit, and the lack of a well-functioning diagnostics market meant that there was no accepted standard for RDTs.
- 34** Industry and academia, working in collaboration with governments and international organisations, should have a mission-focused approach to prepare for known threats, preparing prototype DTVs effective against pandemic-causing pathogen classes. This should be accompanied by steps to modernise our existing arsenal of therapeutic and vaccine technologies, while maintaining a diversity of technological approaches. While out of scope in this report, we note the need to future-proof health systems to deliver these DTVs. To incentivise this much-needed R&D requires a mixture of approaches: push funding through industry, foundations, governments and CEPI; and pull incentives between pandemics such as normalised use of diagnostics for cost-effective clinical and public health use cases. The recommendations included in this chapter are envisaged as building off national and regional R&D initiatives, such as the US Biomedical Advanced Research and Development Authority (BARDA) and the EU's Health Emergency Preparedness and Response Authority (HERA). The development of DTVs must also go alongside the embedding of best practice, discussed in Chapter 4.

R&D Prioritisation: Targeting Critical Viral Families

35 While we cannot be sure what - or when - the next pandemic will be, historically pandemics have come from acute respiratory viruses; the world's most deadly pandemics include COVID-19 (2019- present) and pandemic influenza (1918, 1957-58, 1968 and 2009).²⁸ Scientists have identified viruses from 25 viral families that infect humans,²⁹ and it is estimated that over 1.6 million³⁰ viral species from these viral families exist in animal hosts.³¹ WHO's priority pathogen list sets out the right prioritisation for R&D, as taken forward by WHO's R&D Blueprint.³² However, we cannot develop vaccines³³ and therapeutics against all potential viral threats; we should focus on those diseases within WHO's list with greatest epidemic potential.³⁴ The initial focus should be on the respiratory viruses (such as coronaviruses and influenza viruses) most likely to cause a future pandemic, and thereafter on Lassa, Nipah, Rift Valley, Chikungunya and Ebola, to fill the gaps in our arsenal.³⁵ This can be achieved through a concerted focus on developing prototype DTV libraries targeting the critical viral families most likely to be the source of a future pandemic. We should make the most of technologies such as advanced structural biology, antigen mapping and viral phenotyping to define likely common surface protein vaccine targets and enzyme antiviral targets to develop these prototype vaccines and therapeutics.³⁶

²⁸ Jocelyne Piret and Guy Boivin, 'Pandemics Throughout History', *Frontiers in Microbiology*, January 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7874133/>

²⁹ Nathan D. Wolfe, Claire Panosian Dunavan & Jared Diamond, 'Origins of major human infectious diseases', *Nature* 447, May 2007, <https://www.nature.com/articles/nature05775>

³⁰ Dennis Carroll et al, 'The Global Virome Project' *Science*, February 2018, <https://science.sciencemag.org/content/359/6378/872/tab-pdf>

³¹ 'Pandemic-proofing the planet' *The Economist*, June 2020, <https://www.economist.com/science-and-technology/2020/06/25/pandemic-proofing-the-planet>

³² WHO R&D Blueprint, <https://www.who.int/teams/blueprint>

³³ Barney S. Graham and Nancy J. Sullivan, 'Emerging viral diseases from a vaccinology perspective: preparing for the next pandemic', *Nature Immunology* 19, December 2017, <https://www.nature.com/articles/s41590-017-0007-9>

³⁴ WHO Priority Diseases for research and development in emergency contexts, May 2021, <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

³⁵ We support CEPI's list of prioritised pathogens for which to create prototype DTVs. CEPI's list of prototype pathogens: MERS, Lassa, Nipah, Disease X, Rift Valley, Chikungunya, Ebola; 'The urgency of now', CEPI, March 2021, https://cepi.net/wp-content/uploads/2021/03/CEPI_3.5_billion_investment_case_10032021.pdf

³⁶ Barney S. Graham and Kizzmekia S. Corbett, 'Prototype pathogen approach for pandemic preparedness: world on fire', *Journal of Clinical Investigation*, April 2020, <https://www.jci.org/articles/view/139601>

- 36** COVID-19 has demonstrated the value of developing prototype vaccines. The rapid development and mass rollout of next generation “programmable” technologies against SARS-COV-2 (the virus that causes COVID-19), such as viral vector and mRNA vaccines, was the result of years of R&D on prototype vaccines for SARS and MERS, as well as building on R&D across a range of pathogens and cancer immunology.³⁷ In early 2020, after the genetic sequence of the new coronavirus was published online, scientists refocused this research to target the genetic sequence of SARS-COV-2 and consequently slashed the time to develop vaccine candidates for clinical trials and making possible the extraordinary scientific achievement of efficacious and safe vaccines being granted emergency SRA approval within 307 days of WHO’s declaration of a PHEIC. We can use the new vaccine platforms to develop clinical-stage vaccine candidates against pathogens representing a broad range of virus families. In the event of WHO declaring a PHEIC, these candidates could be rapidly put into clinical trials (further details on clinical trials are set out in the next chapter) if needed or adapted if a novel but related threat emerges.
- 37** Vaccines will not work against every pathogen. Antiviral treatments, particularly small molecule compounds, are thus a vital component and area of focus to strengthen our pandemic preparedness arsenal. Antivirals can prevent serious illness - reducing hospitalisations in a pandemic. They can also be used as a prophylactic - reducing transmission and slowing the rate of any pandemic. The development of novel antiviral treatments for COVID-19 has been beset by challenges, largely related to the long R&D timelines to develop stable and safe pharmacological compounds that have passed initial clinical safety testing. There are benefits of using antivirals in a pandemic response: they can be manufactured at scale quickly and there is already substantial global capacity that can scale up to produce large quantities of tablets and capsules; so that, provided strategic decisions are taken at the appropriate time, the availability of antiviral medicines from manufacturers is unlikely to be a rate limiting step to patient access.³⁸
- 38** Industry and the public sector should work together to stimulate the R&D ecosystem for antivirals for infectious diseases of pandemic potential, building on the prototype approach demonstrated so effectively during the COVID-19 response for vaccine development. R&D should be prioritised for the development of therapeutic candidates that target priority viral proteins. Such a programme would

³⁷ ‘How mRNA became a vaccine game-changer’ Financial Times, May 2021.

³⁸ Rob Jacoby et. al., ‘Advanced Biopharmaceutical Manufacturing: An Evolution Underway’, Deloitte, March 2018, <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-advanced-biopharmaceutical-manufacturing-white-paper-051515.pdf>

develop antiviral candidates ready for phase 2 clinical trials, enabling accelerated development once a pandemic pathogen has been identified. Industry has a critical role to play; however, since there will often not be clear profits to make on such ventures, governments and foundations will need to share risk to allow firms to recoup their R&D investment with a reasonable return. Such risk-sharing should come with a benefit to the public good from using public money: an agreement to enable fair and equitable global access in a pandemic. Further consideration is also needed on stockpiling of components or finished products.

- 39** Prototype diagnostics should also be developed for the pathogens of greatest pandemic potential. Diagnostic tests are important in enabling fast adaptation to identify a specific pathogen of concern. A crucial step to enable prototype diagnostics is through the sharing of critical reagents. In combination with efficient delivery systems, the effective use of diagnostics could interrupt transmission chains and prevent the spread of a pathogen becoming a pandemic.
- 40** **We recommend building prototype vaccine and diagnostic libraries applicable to representative pathogens of pandemic potential.** This should be informed by analysis of which priority pathogens would benefit from prototype vaccines, particularly respiratory viruses. CEPI would coordinate this activity (see the recommendation in paragraph 49 to expand CEPI's remit to diagnostics), working closely with the surveillance super-network set out in the Pathogen Surveillance Report,³⁹ industry, biotechnology companies, research institutions, academia and other relevant organisations, supported by G7 governments. This would deliver over a five-year timeline with CEPI providing an annual public report outlining progress, the first published by the end of October 2021 setting out the delivery timeline, including key milestones.
- 41** **We recommend developing prototype antiviral therapeutics, including antibody therapies, for pathogens of pandemic potential:** principally respiratory pathogens, initially coronaviruses and influenza viruses, informed by CEPI's analysis of which priority pathogens would benefit from prototype therapeutics (see the recommendation in paragraph 49 to expand CEPI's remit to therapeutics). Research-based pharmaceutical industry initiatives to discover and develop antivirals for

³⁹ Sir Jeremy Farrar, 'A proposal to develop an equitable global pathogen surveillance network in 2021 that can prevent and respond to emerging and endemic infectious diseases at speed and at scale', May 2021, <https://www.gov.uk/government/publications/report-proposing-enhanced-global-pathogen-surveillance>

future pandemics (like the Intrepid Alliance)⁴⁰ are important for kickstarting this development, and they should work with academia (including government research labs), biotechnology companies, CEPI, The Global Fund, relevant philanthropic funders and G7 governments. These prototype therapeutic molecules need to have a broad activity spectrum and to have passed initial clinical safety testing. This would provide a rapid activation toolkit of clinic-ready compounds in preparation for large clinical trials of prototype molecules, ideally with simplified manufacturing routes so that scale up is easy. G7 governments should work with the Intrepid Alliance to **explore the value of stockpiling** in readiness for clinical trials. The Intrepid Alliance should provide an annual public report outlining progress, the first published by the end of October 2021.

Upgrading our Arsenal: Preparing for the Unknown

- 42** Alongside targeting R&D at specific viral families we should also be prepared for the unexpected: to respond to the so-called “Disease X”.⁴¹ This involves maturing readily programmable diagnostic, therapeutic and vaccine technologies that could be quickly engineered and deployed against a novel pathogen threat. The successful development of DTVs is closely linked to an effective surveillance network. The surveillance partnership set out in the Pathogen Surveillance Report would enable the speedy detection and full characterisation of pandemic pathogens. This would buy the world time to meet the 100 Days Mission and facilitate the rapid development of DTVs.
- 43** We need to continue to mature readily programmable vaccine and therapeutic technologies such as mRNA between pandemics. For example, further advances in synthetic processes (e.g. chemical synthesis of mRNA) should make it possible to identify a vaccine and then manufacture rapidly at scale for a Disease X response.⁴² The focus of R&D should also prioritise simplifying large scale synthesis and manufacturing, routes of administration (e.g. oral or inhaled) and storage, building off the transformative impact of mRNA technology (see paragraph 70). Technologies such

⁴⁰ The Intrepid Alliance is a research-based pharmaceutical industry initiative to discover and develop antivirals for future pandemics.

⁴¹ Shmona Simpson, Michael C Kaufmann, Vitaly Glozman and Ajoy Chakrabarti, ‘Disease X: accelerating the development of medical countermeasures for the next pandemic’ *The Lancet*, May 2020, [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30123-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30123-7/fulltext)

⁴² Jonas Sandbrink and Robin Shattock ‘RNA Vaccines: A Suitable Platform for Tackling Emerging Pandemics?’ *Frontiers in Immunology*, December 2020, <https://www.frontiersin.org/articles/10.3389/fimmu.2020.608460/full>

as peptide inhibitors, siRNA, or CRISPR technologies might provide new modalities that could respond to sequence information and rapidly evolve new antivirals.⁴³ Chemical/synthetic routes may not work against every pandemic pathogen; it is critical that we retain a diversity of vaccine and therapeutics platforms,⁴⁴ alongside investing in upgrading the robustness of vaccine and therapeutic technology to improve our preparedness for an unknown and unexpected epidemic or pandemic pathogen.⁴⁵ Not unduly focusing on one technology maximises the chance of quickly identifying an efficacious and safe vaccine or treatment to a novel or unforeseen pandemic pathogen where we do not have a prototype vaccine or treatment on the shelf. This involves increasing the number of licensed vaccines and novel treatments on different platforms for vaccine preventable diseases.

- 44** There is also an opportunity to focus on developing broadly neutralising antibodies that are effective against prototype viruses and reagents. For instance, RNA technology for antibody therapies⁴⁶ would decrease the complexity, time to scale and high cost of manufacturing. This proved a major challenge during COVID-19, rendering the products not practical for global use.⁴⁷
- 45** **We recommend that industry, working with biotechnology companies, research institutions, CEPI, governments and foundations, invest in modernising vaccine technology by targeting vaccine preventable diseases.** The objective, alongside treating preventable diseases, is to have improved vaccine platforms ready to respond to an unknown “Disease X”. The more high-quality vaccines available and approved by regulators, the more options for repurposing or reprogramming when a Disease X threat emerges. Our focus should be on investing in readily programmable vaccine platforms which could be used to identify a potential vaccine quickly, while making sure we still have a diversity of approaches available to us. R&D must also include simplified manufacturing and routes of administration, as

⁴³ Hongyi Li, Yang Yang et al., ‘Applications of genome editing technology in the targeted therapy of human diseases: mechanisms, advances and prospects’, *Signal Transduction and Targeted Therapy* 5, January 2020, <https://www.nature.com/articles/s41392-019-0089-y>

⁴⁴ Repurposed therapeutics will also be important as part of the diversity of platforms as discussed in Chapter 4.

⁴⁵ As set out in the context of COVID-19 by Andrew Pollard et al in ‘What defines an efficacious COVID-19 vaccine? A review of the challenges assessing the clinical efficacy of vaccines against SARS-CoV-2’ *The Lancet*, October 2020, [https://www.thelancet.com/article/S1473-3099\(20\)30773-8/fulltext](https://www.thelancet.com/article/S1473-3099(20)30773-8/fulltext)

⁴⁶ Rita M. Meganck and Ralph S. Baric, ‘Developing therapeutic approaches for twenty-first-century emerging infectious viral diseases’, *Nature Medicine* 5, March 2021 <https://www.nature.com/articles/s41591-021-01282-0>

⁴⁷ Peter C. Taylor et al, ‘Neutralizing monoclonal antibodies for treatment of COVID-19’, *Nature Reviews Immunology* 21, April 2021 <https://www.nature.com/articles/s41577-021-00542-x>

recommended in paragraph 72. Governments, CEPI and international procurement organisations, such as Gavi, should consider appropriate pull incentives to stimulate manufacturing innovations for vaccines. CEPI should support industry and research institutions - along with national and regional R&D initiatives - in the coordination and development of vaccine technology, such as through knowledge-sharing, creating consortiums, bringing together cross-border partners, scaling and ensuring LMIC suitability. To provide focus and impetus to this activity we recommend that two reports are produced annually to set out progress on this recommendation: the first authored by industry through the pharmaceutical trade association International Federation of Pharmaceutical Manufacturers & Associations (IFPMA); the second from CEPI. The timeline for this recommendation is 5 years, with the first reports in October 2021 setting out the key activities and milestones to the timeline.

- 46 We recommend investing in simplified, cheaper routes for producing monoclonal antibodies** and other new therapeutic modalities. This would be led by industry, working with biotechnology companies, research institutions, academia and other relevant organisations. The IFPMA should produce an annual public report outlining progress, the first published by the end of October 2021.

R&D Capability

- 47** Sustaining and stimulating innovation in diagnostics and novel therapeutics between pandemics will be crucial for making the 100 Days Mission achievable. For therapeutics there is an inadequate R&D system and pipeline for small molecule antivirals for pandemic pathogens. Antiviral development is expensive and takes years. Waiting until a pandemic threat arises is too late.⁴⁸ Diagnostics have also suffered from a persistent lack of global R&D funding; with the onset of COVID-19 global laboratory capacity for PCR tests was quickly overwhelmed and rapid point of care patient diagnostic tests took time to develop.⁴⁹ For the 100 Days Mission to be achievable these gaps must be filled ahead of the next pandemic to drive innovation and market development.
- 48** CEPI has come to the fore in COVID-19, showcasing its ability to rapidly prioritise investment in R&D in vaccines. CEPI's success has highlighted an equivalent gap in

⁴⁸ Norbert Pardi & Drew Weissman, 'Development of vaccines and antivirals for combating viral pandemics', *Nature Biomedical Engineering* 4, December 2020, <https://www.nature.com/articles/s41551-020-00658-w>

⁴⁹ Yap Boum, Sara Eyangoh and Marie-Claire Okomo, 'Beyond COVID-19—will self-sampling and testing become the norm?' *The Lancet*, April 2021, [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00197-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00197-3/fulltext)

diagnostics and therapeutics. CEPI was initially set up in 2017 as a multi-stakeholder initiative bringing together governments, international organisations, industry, public and philanthropic funders, academia and civil society groups. As CEPI's international work and importance increases there is a strong rationale to consider whether the organisation should be made more accountable to member state countries and at the same time enhance CEPI's mandate in the international system.

- 49 We recommend strengthening the role of the international system in R&D capability and coordination for therapeutics and diagnostics by expanding CEPI's remit to cover therapeutics and diagnostics, in addition to vaccines.** This would address the gap in global coordination for these technologies and increase its capacity to fund and advance novel platforms and stimulate demand through pull incentives. This expanded emphasis would complement the central role of industry, and initiatives like the Intrepid Alliance in R&D. To do this effectively, governments and others, such as private foundations, will need to provide additional financial support. CEPI should also explore other sustainable financing sources, including non-ODA, to deliver upon the recommendations in this report. CEPI is already planning to **use a financing facility inspired by Gavi's IFFIm model**, which will enable donors to frontload financing secured against legally binding future payments that may need to be capitalised in a pandemic. The use of a pre-commitment should also be explored, using a bond issued only in the event of a pandemic, which donors would then repay. This should be completed by 2022 as part of CEPI's revised strategic plan 2022-2026.⁵⁰

R&D Market Incentives

- 50** The COVID-19 pandemic has exposed the challenges and limitations of pull incentives for diagnostics. R&D in diagnostics and therapeutics for infectious diseases has suffered from prolonged under-investment. Lack of differential diagnostics and constant use of old antibiotics is a major driving factor behind AMR, and we note separate work being taken forward by G7 Finance Ministers to address AMR-related market failures. Linking differential diagnostics with effective therapeutics will help tackle AMR. COVID-19 has starkly shown the importance of the effective use of diagnostics in concert with public health control measures and clinical care in containing and managing an infectious disease outbreak. Yet the lack of clear demand for diagnostics before COVID-19 rendered the market under-

⁵⁰ CEPI 2022-2026 Strategy, March 2021 https://cepi.net/wp-content/uploads/2021/03/CEPI-2.0_Strategy-2022-26-Mar21.pdf

prepared.⁵¹ This has underlined the importance of investing between pandemics to stimulate the global diagnostics market and ensure innovation and industry investment is sustained, particularly for scaling up quickly in a crisis. There is also an opportunity to better embed diagnostics in surveillance and public health responses and other activity between pandemics. Greater use of diagnostics in this way would help provide improved healthcare outside pandemics. For instance, there is currently no commercial test available for around 60% of WHO's priority pathogens.⁵²

- 51** Governments and international organisations, like UNITAID and The Global Fund, will play a critical role in stimulating market incentives. They should incentivise the private sector to develop low-cost diagnostic products for the commercial market, through normalising the use of testing in business as usual practice. COVID-19 has transformed the use and application of diagnostic tests; the legacy of COVID-19 should be to mainstream the use of testing across populations for surveillance, diagnosis and treatment. The new familiarity with self-use diagnostics may also herald a new era in the management of winter respiratory pathogens as rapid diagnosis opens up opportunities to use interventions such as antivirals early in these diseases, potentially leading to significant economic and financial benefits by reducing illness.
- 52** We therefore recommend that, building off strengthening global R&D capability for diagnostics, we **create and stimulate the global diagnostic market between pandemics by:**
- a** **Governments normalising the use of accurate diagnostics** for coronavirus and influenza in point of care and non-clinical settings. Governments could drive these changes, working with FIND and other relevant organisations, by signalling that coronavirus and influenza tests will be prioritised for demonstrably cost-effective clinical and public health use cases. It is also important that increased use of diagnostics goes hand-in-hand with appropriate non-pharmaceutical interventions (such as self-isolation) or treatments. A market for point of care diagnostics for these and other common infectious diseases would stimulate the diagnostics industry. FIND would play a key role in providing LMIC market information to diagnostics manufacturers to enable policy makers to make

⁵¹ The limited capacity was highlighted by resources being diverted away from other infectious diseases once the market for COVID-19 products became clear. See Priya Venkatesan, 'COVID-19 diagnostics—not at the expense of other diseases' *The Lancet*, June 2020, [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(20\)30041-0/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(20)30041-0/fulltext)

⁵² Testing for Healthy and Safe Lives: FIND Strategy 2021, May 2021, page 6 https://www.finddx.org/wp-content/uploads/2021/05/FIND-strategy-2021_FINAL.pdf

informed procurement decisions relative to demand. This activity would dovetail with strengthened global surveillance of infectious diseases as set out in the Pathogen Surveillance Report. G7 CSAs should report at the proposed stocktake before the end of 2021 on their respective country's policy on the ramping up of the use of coronavirus and influenza tests and discuss and agree next steps.

- b WHO supporting an enhanced role for diagnostics in the surveillance of pandemic threats.** As set out in the Pathogen Surveillance Report, enhanced surveillance of pandemic pathogen threats and the sharing of emerging pathogens and their data is vital. Establishing close cooperation between the public and private sectors on linking surveillance of pandemic threats, including the immediate and unhindered access to samples and data,⁵³ with the diagnostics industry is critical to the diagnostics market between pandemics. WHO should coordinate this activity, through the Implementation Group recommended as part of the Pathogen Surveillance Report, reporting on progress in early 2022 to the G7 Presidency. WHO should work closely with industry leaders to ensure integration, transparency and collaboration. This should also include working closely with existing industry-led initiatives, such as Abbott's Pandemic Defense Coalition which brings together a scientific and public health network dedicated to the early detection of and rapid response to future pandemic threats.⁵⁴

⁵³ This report sets out a recommendation on sample sharing. See paragraph 96.

⁵⁴ Press release: 'Abbott announces its pandemic defense coalition: a global network of expert collaborators designed to help prevent future pandemics, currently searching for COVID-19 variants' (March 2021) <https://abbott.mediaroom.com/2021-03-11-Abbott-Announces-its-Pandemic-Defense-Coalition-A-Global-Network-of-Expert-Collaborators-Designed-To-Help-Prevent-Future-Pandemics-Currently-Searching-for-COVID-19-Variants>

CHAPTER 4

Embedding Best Practice Between Pandemics

- 53** The previous chapter set out the importance of ensuring we have DTVs for prototype pathogen classes of concern and simplified manufacturing processes in place ahead of pandemics. However, this improved arsenal of technology will only go so far if we do not also improve the way we do things. To achieve the 100 Days Mission and improve global pandemic preparedness we need to make the exceptional routine by embedding best practice and preparation in business-as-usual activity, when the world is not battling a pandemic. This also has the added benefit of improving how we respond to epidemics and endemic diseases.
- 54** COVID-19 showcased extraordinary speed in adapting processes to get safe and effective DTVs produced at scale. It also cast a spotlight on the systemic inefficiencies undermining our global response. We need to learn from COVID-19 to bottle the best of our global response and improve the processes holding us back. Three major areas where we need to embed best practice are clinical trials, regulation and manufacturing. We should seek to have internationally-networked, active randomised controlled trial platforms (with processes for prioritisation in a pandemic), streamlined regulatory approaches and simplified, transferable modular manufacturing processes as the norm.
- 55** COVID-19 has also proven that lack of preparation is a major set-back. This goes beyond best-practice as it must be done with an eye to a potential epidemic or pandemic threat. Embedding preparation requires normalising public health as part of global governance (and especially macroeconomic considerations), building in equitable access in government funding and 'keeping warm' or enabling scaled-up manufacturing when needed. These DTV-centred preparation measures are also predicated on robust surveillance and public health response capability.

Embedding Best Practice

International network of clinical trials with effective data-sharing

- 56** Capability for high quality, efficient and rapid clinical trials and regulation is crucial to enable effective preparation for pandemics as well as rapid responses during pandemics. There are a number of improvements we can make to clinical trials capability and regulation processes to embed best practice between pandemics. Enhancing clinical trials infrastructure and use will enhance healthcare by providing a stronger evidence base and sharing of best practice globally.
- 57** The success of clinical trials depends on how well they are designed and the extent to which busy healthcare staff, patients, and healthy volunteers are able and willing to participate. Trials need to be set up in a way that focuses on the aspects that are critical to the generation of actionable results and keeps additional work to a minimum.
- 58** During COVID-19 large, randomised controlled trials were transformational in identifying which interventions were effective and how best they should be used - the discovery that dexamethasone reduces mortality for patients in hospital is estimated to have saved one million lives worldwide.⁵⁵ Innovations in trial design and trial methodologies expedited robust evidence. Adaptive platform trials were particularly successful as they enabled many different treatments to be studied simultaneously, giving researchers and regulators the evidence needed to make decisions on which treatments were effective (and which were not). Incorporating data that was already being routinely collected via health systems also streamlined significantly what needed to be collected manually at a patient's bedside. These new ways of designing randomised controlled trials should be embedded as best practice.
- 59** Not all clinical trials were as successful. Most failed to yield actionable evidence because they were poorly designed, wasteful and inadequate in scale.⁵⁶ The absence of global collaboration and coordination meant that a large number of clinical trials were focused on a small number of questions without any realistic prospect of answering them reliably. Many trials failed to enrol diverse populations,

⁵⁵ NHS Press Release, ('COVID treatment developed in the NHS saves a million lives'), March 2021, <https://www.england.nhs.uk/2021/03/covid-treatment-developed-in-the-nhs-saves-a-million-lives/>

⁵⁶ Asher Mullard, 'RECOVERY 1 year on: a rare success in the COVID-19 clinical trial landscape', Nature, April 2021, <https://www.nature.com/articles/d41573-021-00068-w>

with ethnic minority groups significantly underrepresented.⁵⁷ A lack of infrastructure and an absence of data-sharing agreements hindered the ability to share or pool data, making it difficult to analyse and interpret data across clinical studies and countries. Perverse incentives also drove the proliferation of uninformative trials and premature use of unproven medical countermeasures.

- 60** These lessons illustrate the need for a pre-existing and agile trials infrastructure and capability to improve our global clinical research capabilities.⁵⁸ Existing initiatives have also demonstrated that internationally-networked regional or local platforms can be an effective means of strengthening and sustaining clinical research capacity, particularly across LMICs.⁵⁹ We should therefore invest now in improving countries' trials infrastructure and capabilities to be used routinely to answer important public health questions. Establishing clinical trial platforms much more widely and embedding them in routine health systems would enable collective evaluation of the utility, efficacy and effectiveness of DTVs in a variety of settings in between pandemics for infectious and non-infectious diseases. These platforms could be linked regionally and brought together internationally in a pandemic so there is adequate global surge capacity to initiate, conduct and complete trials quickly, generating actionable evidence so that DTVs can be developed and deployed safely and effectively. An international network could also enable trials to move as pandemics or epidemics do, and to trial the DTVs that are prioritised for testing (set out in paragraph 90) across diverse populations (including, pregnant/breastfeeding mothers, children and the very elderly, HIV+, immunocompromised). Industry would benefit from more efficient platforms for clinical trials, but there are also other actors who would welcome the accelerated approvals, standardised definitions and protocols, prioritisation of trials, better sharing of information and enhanced coordination with regulators which would come with better regional linkages.
- 61** As the G20 Global Health Summit Scientific Expert Panel's report noted, empowering and earning the trust of people is critical for ensuring the success of pandemic preparedness and response measures.⁶⁰ We believe a transparent approach to sharing information on clinical trial design, progress and results is a critical building

⁵⁷ Daniel B. Chastain et al, 'Racial Disproportionality in Covid clinical trials', The New England Journal of Medicine, August 2020, <https://www.nejm.org/doi/10.1056/NEJMp2021971>

⁵⁸ Jay J. H. Park et. al., 'How COVID-19 has fundamentally changed clinical research in global health' Lancet Global Health 9,5, May 2021, [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(20\)30542-8/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30542-8/fulltext)

⁵⁹ See Drugs for Neglected Diseases Initiative: <https://dndi.org/>

⁶⁰ Report of the Global Health Summit Scientific Expert Panel, May 2021, https://global-health-summit.europa.eu/panel-scientific-experts_en

block in empowerment and trust. This includes ensuring that key documents such as protocols, analysis plans, operating procedures and progress reports are in the public domain, alongside open communication and close engagement with communities to socialise clinical trial participation and optimise recruitment across diverse communities and demographics to maximise benefits, access and uptake. Appropriate data-sharing agreements coupled with standardised data collection processes should be embedded as part of best practice to ensure that clinical trial results and data are findable, accessible, interoperable and reusable.⁶¹ Trials must also be based on data which can be disaggregated for impacts with respect to gender and ethnicity at all stages of analysis.

- 62** In their March 2021 report, The Science Academies of the Group of 7 (the S7) recommendations called for an international approach to effective data sharing during health emergencies and beyond.⁶² We support their focus on principle-based, privacy-preserving approaches to secure safe sharing and equitable use of data. We also welcome their drive towards common governance mechanisms, improved data infrastructures and systems, and enhanced skills and capabilities for trusted and accurate use of data. To achieve this vision, a concrete plan must be developed to address the challenges in health data sharing, highlighted by the COVID-19 pandemic. The first step will be to develop and implement a roadmap with data and analytics as its bedrock. Safeguarding the readiness of ongoing global health data systems will ensure a more effective timely response during future health crises.
- 63** **We recommend that WHO, working with G20 governments, industry, philanthropic organisations and academia should scope out how an international network of clinical trial platforms could be implemented to enable a coordinated and efficient approach to testing of DTVs.** A network of clinical trial platforms (both hospital and community-based) that are regionally linked should be set up to run during non-pandemic periods to address ongoing relevant public health questions (e.g. evaluating interventions for endemic infections such as tuberculosis, malaria, HIV or non-communicable diseases of public health importance such as common cancer, cardiovascular disease, mental health). The platforms should have access to real-time epidemiological intelligence and be designed in a way that enables them to pivot at speed and scale in the face of a pandemic threat – acting as a

⁶¹ FAIR guiding principles for scientific data management and stewardship: <https://www.go-fair.org/fair-principles/>

⁶² Science Academies of the Group of Seven (S7), 'Data for international health emergencies: governance, operations and skills,' March 2021, <https://royalsociety.org/-/media/about-us/international/g-science-statements/G7-data-for-international-health-emergencies-31-03-2021.pdf>

global emergency response network – and adaptable to respond to changes in the pandemic (e.g. new variants, spread to new countries) and improvements in scientific understanding (e.g. role of the host-response to the pathogen). The platforms would need to have strong local ownership and leadership to respond to the needs of the local community where they are located. Smart data capture and flexible trial management information systems that integrate diverse health datasets should be the norm to support trial set-up and patient enrolment and ensure that information is transparent and easily accessible for subsequent decision-making and licensing, in line with appropriate confidentiality protections. The network would require baseline funding from countries to strengthen their own clinical trial infrastructure and create regional links, supplemented by a “user pays” model, across the public and private sector. The network could be modelled on, and draw learning from, existing collaborative platforms such as the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC),⁶³ the Drugs for Neglected Diseases Initiative and the VACCELERATE clinical research network.⁶⁴ WHO, working with the G20, industry, philanthropic organisations and academia, should complete the scoping by October 2021 and present a proposal at the proposed G7 CSA (or equivalents) stocktake before the end of 2021.

Better regulation

- 64** We must transform our approach to regulation, which is a key enabler for the development and deployment of high quality and effective DTVs. During COVID-19 we saw a proliferation of poor quality and inaccurate diagnostics because of an inadequate regulatory and licensing framework. Companies did not have clear target product profiles to work towards, diagnostic assessment protocols were duplicative and cumbersome, and countries did not have clear use cases setting out how to use tests in a pandemic situation for both treatment and control alongside test, trace and isolation programmes. Insufficient quality assurance processes for diagnostics (from design through to use)⁶⁵ hampers industry’s ability to respond quickly at scale and diagnostics being used incorrectly.

⁶³ ISARIC provides a collaborative platform through which global, patient-orientated clinical studies can be developed, executed and shared: <https://isaric.org/>

⁶⁴ VACCELERATE is a clinical research network for the coordination and conduct of COVID-19 vaccine trials in Europe: <https://www.vaccelebrate.eu/>

⁶⁵ Olivier Vandenberg et. al., ‘Considerations for diagnostic COVID-19 tests’, Nature Reviews Microbiology 19, October 2020, <https://www.nature.com/articles/s41579-020-00461-z>

- 65** Inefficient and overly complex regulatory systems and processes slowed the activation and overburdened the conduct of clinical trials, and hampered the implementation and adoption of their results. More simplified and proportionate approaches are needed that include the perspectives of all those involved (including regulatory agencies, commercial and non-commercial health technology and clinical trials organisations, healthcare providers, clinicians, and members of the public). This should build on existing initiatives which are adopting a collaborative approach to developing new guidance to support a more effective regulatory environment for clinical trials.
- 66** **We recommend developing a common regulatory framework that better defines criteria and standards for effectiveness, quality and use cases for diagnostics.** SRAs should work together to define international assessment protocols and develop guiding principles, alongside more effective quality assurance processes that link diagnostic tests into care and prevention pathways. Implementation trials can provide the necessary data to demonstrate how diagnostics can be best used to improve surveillance, clinical management and critically to reduce pathogen transmission. SRAs, through the International Medical Device Regulators Forum, should report on progress by April 2022.
- 67** **We recommend transforming the approach to clinical trial regulation, shortening the time to authorise trials and streamlining the requirements and guidelines relating to trial conduct.** We should refocus regulatory guidelines on the fundamental scientific and ethical principles that underpin randomised trials, whilst embracing flexibility and innovation across a range of health threats and technologies. We should build on models established by the US Food and Drug Administration (FDA) Clinical Trial Transformation Initiative and the Good Clinical Trials Collaborative (supported by the Bill & Melinda Gates Foundation, Wellcome Trust, and African Academy of Science). The Good Clinical Practice for clinical trials guidance should be revised to focus on what matters for the generation of actionable information about effects of an intervention, rather than what is easy to check but less relevant, placing an emphasis on principles and purpose rather than process. Regulations should also allow easy moving of clinical trials across the recommended international network of clinical trial platforms (in paragraph 63) at a speed that matches the migration of the disease. SRAs, in partnership with WHO and the Good Clinical Trials Collaborative should report on progress by October 2021 for the proposed G7 CSA (or equivalents) stocktake before the end of 2021.

Sharing knowledge through transferable manufacturing processes

- 68** As we have seen with COVID-19, after a safe and efficacious vaccine is identified against a new pandemic pathogen, a tremendous challenge - both in terms of technology and capacity - is the speed and scale of manufacturing required to alter the trajectory of a pandemic. A plethora of initiatives to boost global vaccine manufacturing capacity have been launched in response, including regional initiatives such as the African vaccine manufacturing initiative.
- 69** The long lead times and variability in traditional vaccine platform manufacturing, sometimes with hundreds of steps, all complicate manufacturing and hinder speed in a crisis.⁶⁶ Besides the need for the public sector to swiftly indicate demand at the onset of a pandemic (through activating an automatic mechanism to procure and distribute DTVs recommended in paragraph 102), this complexity and variability of traditional vaccine manufacturing processes is the main bottleneck for rapid technology transfer, due to the capability and expertise required to manufacture vaccines.⁶⁷
- 70** Newer technologies should allow manufacturing to be done in a very different way to traditional methods.⁶⁸ There are opportunities to hide complexity in a 'black box', hidden from what then becomes a more generic chemical engineering manufacturing process.⁶⁹ By making the manufacturing process more systematised and generic, it is possible to make technology transfers easier by reducing the requirement for a highly skilled workforce. Similarly, scale-up for "fill and finish" is amenable to vastly simplified engineering solutions. There is therefore an opportunity to prioritise R&D investment by industry (and the public sector) to simplify high quality vaccine manufacturing and technology transfer. While a focus on mRNA and other new 'synthetic' vaccine technologies is the best way to build in an ability to meet the 100

⁶⁶ Nicholas A. C. Jackson et al, 'The promise of mRNA vaccines: a biotech and industrial perspective' NPJ Vaccines 5, February 2020, <https://www.nature.com/articles/s41541-020-0159-8>

⁶⁷ WHO, 'Increasing Access to Vaccine Through Technology Transfer', January 2011, page 2 https://www.who.int/phi/publications/Increasing_Access_to_Vaccines_Through_Technology_Transfer.pdf

⁶⁸ IFPMA 'Towards Vaccinating the World: Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible "Solution Space"', March 2021, page 6 https://www.ifpma.org/wp-content/uploads/2021/03/Summit_Landscape_Discussion_Document.pdf

⁶⁹ Zoltán Kis et al, 'A model-based quantification of the impact of new manufacturing technologies on developing country vaccine supply chain performance: A Kenyan case study', Journal of Advanced Manufacturing and Processing 1,3, June 2019, <https://aiche.onlinelibrary.wiley.com/doi/epdf/10.1002/amp2.10025>

Days Mission, we must retain the diversity of platforms approach set out in Chapter 3; an investment in mRNA must not put an end to existing vaccine platforms.

- 71** Another critical investment in best practice is simplifying the downstream engineering elements of “fill and finish” and the manufacturing supply chain (vials, syringes, etc.), and to stimulate innovation in delivery and deployment. Innovations such as oral or nasal delivery will make deployment easier and cheaper - removing large and costly supporting infrastructure in healthcare systems, which is especially important for countries with limited capability and resources.⁷⁰ Given its importance, investment in technologies for these innovations should be a priority. This could save significant development, manufacturing and regulatory time in a crisis and consequently make the 100 Days Mission more achievable.
- 72** **We recommend stimulating a move towards innovative technologies** to reduce the complexity of vaccine manufacturing processes and make technology transfer and scalable manufacturing easier in a pandemic by investing in R&D. This must include simplified modular manufacturing and routes of administration (e.g. oral) and storage (room temperature). This should be taken forward by industry, in partnership with biotechnology companies, CEPI, Gavi, research institutions, academia, the public sector and other relevant organisations. IFPMA should produce an annual report on progress, the first of which should be published in October 2021.

Embedding Preparation

- 73** Last year it took many months before new money flowed into our global health organisations; April 2021 marked one year from when ACT-A was set up - it was quick to bring together partners and stimulate research and development of new technologies, but ACT-A relies on traditional funding from wealthy donor countries, all of which suffered a major economic shock from the pandemic. It also took time for MDB support and loans to be readily accessible to countries.⁷¹ The result is a funding shortfall and unequal access to DTVs. COVID-19 has shown financing across DTVs to be one of the main constraints that hinders quick global distribution,

⁷⁰ Andrew Pollard and Else Bijker, 'A guide to vaccinology: from basic principles to new developments', Nature Reviews Immunology 21, December 2020, <https://www.nature.com/articles/s41577-020-00479-7>

⁷¹ The World Bank's response to COVID has been one of its fastest, and largest. The World Bank approved a \$6bn Covid health specific response programme in April 2020: World Bank Project Appraisal Document, <https://documents1.worldbank.org/curated/en/993371585947965984/pdf/World-COVID-19-Strategic-Preparedness-and-Response-Project.pdf>, April 2020. However, it took longer to approve its £12bn vaccine specific package, which was announced in October 2020 (257 days since WHO declared a PHEIC (World Bank Press Release, 'World Bank Approves \$12 Billion for COVID-19 Vaccines'), <https://www.worldbank.org/en/news/press-release/2020/10/13/world-bank-approves-12-billion-for-covid-19-vaccines>, October 2020

which has significantly impacted current supply and manufacturing capacity. Being better prepared would have meant having a ready and 'warm' global network of manufacturing capacity and a better mechanism for global financing and distribution.

Financing pandemic preparedness

- 74** There is a pattern of underinvestment in health, with spikes in donor funding during and after the start of epidemics and pandemics.⁷² This goes beyond DTVs - with a need to ensure health systems are strengthened across the world as a first defence against disease. What COVID-19 has shown, unequivocally, is that investment in our health defences is extraordinarily good value for money. The 2021 World Economic Outlook projected that the global economy will grow at 6 percent in 2021, moderating to 4.4 percent in 2022, following a contraction of 3.3 percent in 2020.⁷³ This improvement on previous forecasts is driven by the vaccine rollout, but this is not the case for many emerging markets and developing economies where deployment of vaccines is slower; the IMF expects medium-term scarring effects on their economies. Faster progress on ending the health crisis, including through more rapid vaccine deployment in advanced economies, emerging markets and developing economies, would raise global income cumulatively by \$9 trillion over 2020–25, with over 40 percent of this gain going to advanced economies.⁷⁴ In other words, the IMF estimates that significantly accelerating the global vaccine rollout could help the global economy avoid almost half of the baseline projected loss in cumulative GDP over this period. The economic case for being better prepared is clear.
- 75** Better preparation requires bringing together expertise, key organisations, and existing groups such as the Global Health Security Agenda (GHSA, who focus on improving country capacity and leadership in the prevention and early detection of, and effective response to, infectious disease threats) and the IPPPR's proposal for the WHO to formalise universal periodic peer reviews of national pandemic preparedness and response capacities.

⁷² 'Fragmented health systems in COVID-19: rectifying the misalignment between global health security and universal health coverage'; *The Lancet* 397, 10268, December 2020, pages 61-67, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32228-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32228-5/fulltext)

⁷³ The World Economic Outlook, International Monetary Fund, April 2021, <https://www.imf.org/en/Publications/WEO/Issues/2021/03/23/world-economic-outlook-april-2021>

⁷⁴ Kristalina Georgieva, Gita Gopinath, and Ruchir Agarwal 'A Proposal to End the COVID-19 Pandemic' May 2021 <https://blogs.imf.org/2021/05/21/a-proposal-to-end-the-covid-19-pandemic/>

- 76** While **we support the recommendation set out in the IPPPR for the IMF to explore expanding their Article IV consultation with member countries to include a pandemic preparedness assessment**, we believe these assessments should draw on the analysis and expertise of others, including the GHSA and the WHO's universal periodic peer reviews. The current crisis has highlighted the economic and financial impact that a health crisis can have on the global economy and the disproportionate burden borne by women and girls and certain ethnic groups. We believe that the IMF should play its role, in conjunction with others, in warning of the impact that future threats can have, and, as such, we see an important role for them on the proposed Global Health Board (see paragraph 79 for more details). Consistent with its mandate, the IMF should be prepared to provide emergency financing to countries that need support for pandemic response. Consistent with their mandates, **we also suggest the MDBs continue to support investment to strengthen and prepare health systems as part of their core day-to-day business - treating public health security as importantly as they treat financial stability, including a plan to improve public health security in all their country strategies**, drawing on the analysis and expertise of the GHSA and the WHO's universal periodic peer reviews. This should be discussed by the 2022 Annual Meetings.

Oversight for pandemic preparation

- 77** The international system is critical in enabling global coordination across the health, finance and political architecture before and during a crisis. We need better political accountability in non-pandemic times, bringing together governments and key organisations. There is often a temptation to create new institutions as a theorised fix for problems in the international response. But creating new institutions takes time and money, and adds to the existing bureaucracy. We should use existing ones where possible and expand remits where there are important gaps in the international architecture. It is important to ensure effective coordination between existing institutions. We saw from the creation of ACT-A that there is a breadth of existing expertise, but clear mandates and sufficient governance from capitals are also required.
- 78** The ACT-Accelerator was launched just over a year ago in response to the G20's call for a global mechanism to accelerate the development of tests, treatments and

vaccines and to ensure their equitable distribution.⁷⁵ There are varying views as to whether the world would benefit from making ACT-A permanent. Our view is that such a large institution would bring added complexity and inefficiency in business as usual, as well as use valuable resources. Instead, we should keep oversight small with a potential for rapid upscaling, so that a similar network of health organisations and governments can come together in response to a pandemic threat, automatically enacting a health crisis plan. Such oversight would complement WHO in their role establishing global standards and guidance to countries on public health measures. Any oversight group should also work with existing initiatives and governance such as the GPMB, which should continue its role of independent monitoring and providing accountability to ensure preparedness for global health crises. In times of business as usual we must have greater political accountability and global coordination to review risks, plan and implement preparations needed ahead of a pandemic.

79 We recommend establishing a Global Health Board reporting to the G20 to provide oversight of pandemic readiness on an annual basis. The set up and function of the Board would need agreement by the G20 and we suggest they consider asking the Board to report annually to the joint meeting of Health and Finance Ministers on the outcomes of global surveillance, ongoing and emerging risks to the international system from pandemic threats, and actions needed to address them. The Board could be made up of the three CSAs (or their equivalents, e.g. Chief Medical Officers) and Finance Deputies of the incumbent, previous and successive G20 Presidencies, the One Health Organisations (WHO, OIE, FAO, and UNEP), The Global Fund, Gavi, CEPI, and the IMF and World Bank. The G20 should also ensure there is sufficient independence within the Board to hold governments, industry and international organisations to account. We view this as important for its effective operation. It could be chaired by WHO, with the GPMB acting as the secretariat, to provide independence, expertise and stability to the Board whilst ensuring political accountability of decisions made by Health and Finance Ministers. When WHO declares a PHEIC, the Board could coordinate the international response and could take a decision on standing up a network of international organisations (similar to ACT-A), governed by the Global Health Board, to manage the response to the crisis. This should be discussed at the October 2021 joint meeting of the G20 Health and Finance Ministers, for consideration for adoption as soon as possible.

⁷⁵ WHO Press Release, ('G20 leaders boost support of the Access to COVID-19 Tools (ACT) Accelerator but urgent and immediate action is needed to maintain momentum. Press Release'), May 2021, [https://www.who.int/news/item/21-05-2021-g20-leaders-boost-support-of-the-access-to-covid-19-tools-\(act\)-accelerator-but-urgent-and-immediate-action-is-needed-to-maintain-momentum](https://www.who.int/news/item/21-05-2021-g20-leaders-boost-support-of-the-access-to-covid-19-tools-(act)-accelerator-but-urgent-and-immediate-action-is-needed-to-maintain-momentum)

Public-private burden sharing for manufacturing and enabling equitable access

- 80** An additional step that can be taken to embed preparation is to plan for potential pandemics through government research funding. Public financing is typically needed to support R&D into areas where there is a lack of commercial opportunity, or the market is not responding fast enough (including for diseases that typically affect LMICs) and will likely have a greater public benefit than financial profit (a positive externality in consumption). When these ideas pay off, pharmaceutical companies often take forward the work. An example from the COVID-19 pandemic is the work initially funded by the UK government and CEPI in the University of Oxford, which was then taken up by AstraZeneca. The US National Institutes of Health's National Institute of Allergy and Infectious Diseases and Moderna also co-developed the mRNA-1273 vaccine, which is currently authorised by the FDA for emergency use.
- 81** As set out in paragraph 72, a key focus for vaccine manufacturing should be to simplify and reduce the complexity of manufacturing processes. Building on this, we need to consider how the public and private sectors can work together to stimulate the creation of a global vaccine manufacturing network capable of scaling quickly in response to a pandemic. This can be built on the expansion that has taken place in both private and public sectors in the past year. We must ensure that any network encompasses the latest technologies and is maintained by those with the appropriate expertise. As outlined in paragraph 69, despite the impressive speed of scaling up vaccine manufacturing for COVID-19, the complexity and variability of manufacturing processes and equipment coupled with the technical expertise required to run vaccine manufacturing facilities has been a critical barrier to technology transfer, hindering equitable access to COVID-19 vaccines. We must seek to address these production bottlenecks in the context of the 100 Days Mission. Simplified transferable processes, interoperable equipment and designing a modular network must be a priority for industry, governments and relevant organisations.
- 82** Pandemic-ready manufacturing processes, best practice and capacity must be embedded into business as usual. There are a number of areas where greater vaccine production capacity could be utilised between pandemics to effect positive health outcomes and to justify maintaining surge manufacturing capacity for a pandemic. Mass adult vaccination drives for a range of diseases where vaccination is a proven cost-effective measure but for which there is currently low provision saves lives and is one option to enable 'keeping warm' manufacturing capacity. Similarly, extending influenza and coronavirus adult vaccination programmes could both serve a vital public health need and utilise the significant capacity that has been built in the

current pandemic and enable a network to be sustained in between pandemics.⁷⁶ This manufacturing capacity would need to be managed as a global, coordinated network to maintain standards, and must utilise the significant increase in capacity that has been built in the private sector.

- 83** Governments might consider stockpiling essential supplies, in addition to offering incentives to the private sector to develop low-cost diagnostic and therapeutic products for the commercial market. Stockpiling of reagents for diagnostics would allow automated PCR tests for equitable distribution and use in a couple of weeks for point of care (rather than months as in the COVID-19 pandemic) if laboratory capacity is available. Governments have an interest in sustaining innovation in the academic and private sectors to drive discovery of DTVs and improve manufacturing efficiency. Creating manufacturing capacity is primarily the responsibility of the private sector but without public funding and incentives there will not be sufficient financing or sustained supply. The return on investment for the world is likely to be prodigious: the benefits of increasing supply of vaccines alone is significant - for this crisis it is estimated \$8.7 trillion in GDP alone, \$17.4 trillion in overall benefits.⁷⁷ There is a need for both networked regional manufacturing capacity and a modular engineering model to build resilience. Push funding for more supply and designing contracts that create more manufacturing capacity (as opposed to bidding up prices or rationing existing supply differently) is key.
- 84** **We recommend that governments should build in conditions into their DTV funding arrangements to ensure LMIC access to DTVs at not for profit and scale, which is to be enacted if a PHEIC is declared.** Governments should look to benefit from the risk they are taking in making these investments, by having conditions on their investment to require some sort of public benefit pay-back during pandemics if the research does become commercially viable. Including equitable access considerations in business as usual investment should be mirrored by similar equitable access efforts during a pandemic (as set out in paragraph 103). G7 CSAs (or equivalents) should provide an update at the proposed stocktake before the end of 2021.

⁷⁶ Peter Piot et al, 'Immunization: vital progress, unfinished agenda', Nature 575, November 2019, <https://www.nature.com/articles/s41586-019-1656-7>

⁷⁷ Juan Camilo Castillo et. al., 'Market design to accelerate COVID-19 vaccine supply' Science, March 2021, pages 1107-1109, <https://science.sciencemag.org/content/371/6534/1107>

- 85 We recommend governments and industry should share risk to maintain vaccine manufacturing capacity.** The COVAX Manufacturing Task Force should work with industry and G7 governments to publish a report in October 2021 setting out a plan:
- a Exploring how a vaccine manufacturing network, utilising the latest technology, could be brought online to deliver production at scale rapidly in a pandemic.** This includes simplified transferrable manufacturing processes, interoperable equipment and supplies and a modular network.
 - b Considering options for keeping facilities in regular use between pandemics, including possible mass adult vaccination campaigns.**

CHAPTER 5

Rules of the Road

- 86** The previous two chapters set out the crucial recommended steps to improve our preparedness for the 100 Days Mission ahead of a PHEIC being declared. Once a pandemic threat has been identified, we need to be ready to make the most of this preparation and act quickly and decisively, with the G20 Global Health Board activating an ACT-A inspired network of organisations and rapid re-prioritisation of the networked manufacturing and clinical trials network. Collaboration must be quicker and more effective. The faster all countries can coordinate and indicate demand for DTVs, the faster industry can respond and the quicker access can be assured for developing countries. There is therefore a need for pre-agreement to pandemic rules of the road to build on the best practice set out in Chapter 4 and provide for better coordination between governments, health organisations and the financial institutions much earlier and well before a PHEIC is declared. Both the private and public sectors are crucial to prevent a future pandemic but, if one is declared, rules of the road should allow us to be ready and respond quickly and effectively within 100 days with DTVs.
- 87** COVID-19 showed that countries having their own separate responses hindered the speed and coordination of the global response. This extended to DTVs, with many months lost to working out and negotiating the basics: from target product profiles for diagnostics to the architecture of the ACT-Accelerator. We should not need to start from scratch in a pandemic. Instead, as part of the recommendations set out by the IPPPR for WHO to improve its guidance for pandemics, we should ensure this extends to DTVs. Such rules of the road should enable rapid prioritisation, speed, scale and equitable access (based on need); for which sustained finance ahead of and during pandemics is necessary.
- 88** Governments, industry and international organisations should be able to draw from a set of agreed rules of the road on how to respond in a pandemic. While there will always need to be adjustments for specific diseases, we can predict the key issues we are likely to face, learning from COVID-19 and past pandemics, and agree on guidance. The IPPPR recommends WHO sets out expanded guidance

on containing a health threat.⁷⁸ **We recommend** that as part of the proposed WHO Treaty on Pandemic Preparedness, **WHO should define ‘rules of the road’ and set out guidance on good practice for all relevant stakeholders in a pandemic, pre-negotiated with governments, industry and international organisations.** The protocols should cover the breadth of essential practices that need to be agreed across countries, including, amongst other things, supply chains, indemnification and data sharing, as well as for financing mechanisms. This should be led by WHO, and discussed as part of the WHO Treaty discussions at the special session of the WHA in November, in collaboration with global health organisations and other relevant international organisations, such as WTO, and with industry. The recommended rules of the road for pandemics must enable prioritisation, speed, scale and equitable access for DTVs. We also support the IPPPR’s recommendation that the PHEIC alert system needs to operate more rapidly and clearly, not least as this report identifies a PHEIC as activating the 100 Days Mission and the rules of the road recommended in this chapter.

Prioritisation

89 Once WHO has declared a PHEIC, our best practice business as usual systems need to rapidly refocus to respond to the pandemic pathogen. This includes appropriate mechanisms to prioritise clinical trials on the most promising DTV interventions. During COVID-19, resources and time were wasted on testing therapies that had no prospect of providing significant benefit at scale, or of using poor quality diagnostics without evidence of clinical or public health benefit. There was also considerable duplication of effort with similar interventions being studied across multiple small trials.⁷⁹ Prioritisation must take account of the available scientific data both on the intervention and the disease to consider probability of success and relevance to the public health need. A common set of principles for prioritisation would support the open exchange of information between international, regional and national organisations on DTVs. Several good examples of prioritisation methods emerged during the current pandemic (e.g. the US National Institutes of Health Accelerating COVID-19 Therapeutic Interventions and Vaccines initiative,

⁷⁸ The Independent Panel for Pandemic Preparedness & Response, ‘COVID-19: Make it the Last Pandemic’, May 2021, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

⁷⁹ Kevin Bugin and Janet Woodcock, ‘Trends in COVID-19 Therapeutic Trials’, Nature Reviews Drug Discovery, February 2021, <https://www.nature.com/articles/d41573-021-00037-3>

the UK COVID-19 Therapeutics Advisory Panel) which can be used as a blueprint for such prioritisation processes.

- 90 We recommend exploring the creation of regional mechanisms to coordinate and prioritise clinical trials of DTVs to respond to a future pandemic pathogen.** It will be critical to rapidly undertake trials with repurposed medicines as an immediate step to identify effective therapeutics. Prioritisation will also be necessary for new drugs and diagnostics, and possibly even vaccines. There should be an agreed system to coordinate and prioritise which medicines and interventions are entered into the international network of clinical trial platforms set out in paragraph 63. These mechanisms should be designed in a way to combine regional autonomy and flexibility with international knowledge exchange on prioritisation decisions, product assessments. They should be supported by a professional administrative and technical team to provide due diligence, preparation of dossiers, programme management, and information sharing (including with the public). Options should be explored as part of the recommendation to undertake a scoping exercise for the international network of clinical trial platforms in paragraph 63, for the proposed G7 CSA (or equivalents) stocktake before the end of 2021.

Speed

- 91** Speed is vital during a crisis and is the essence of the 100 Days Mission. Rules of the road can enable speed by setting clear expectations for regulatory approvals and data-sharing. Regulatory approval of DTVs should happen as quickly as possible in a pandemic without compromising assurances on safety and effectiveness. In COVID-19, SRAs learned to work in more agile ways and shifted their approach from one of “watchdog” to “enabler”, but they failed to agree in advance how they would approach regulatory approval, including mutual recognition, DTV use cases and good clinical trial design. This resulted in multiple requirements from different regulators and varying degrees of pragmatism. As SRAs traditionally operate independently there was also a disconnect between national approaches and emergency authorisation processes led by international and regional agencies. There is a need for SRAs to coordinate globally in a pandemic to support effective and relevant regulatory efforts.⁸⁰ This should include exchanging knowledge and information on technical development and manufacturing specifications, good clinical trial design

⁸⁰ OECD, ‘Regulatory Quality and COVID-19: Managing the Risks and Supporting the Recovery’, April 2020, [https://www.oecd.org/regreform/regulatory-policy/Regulatory-Quality-and-Coronavirus%20-\(COVID-19\)-web.pdf](https://www.oecd.org/regreform/regulatory-policy/Regulatory-Quality-and-Coronavirus%20-(COVID-19)-web.pdf)

and post-authorisation safety and efficacy data, and a commitment to providing consistent and rapid feedback. These pandemic-specific rules of the road can be designed in advance.

- 92** Whilst large, pragmatic, randomised controlled trials provide the greatest assurance of efficacy and safety, human challenge trials and immunogenicity studies can play an important role in accelerating and improving vaccine testing and development in a pandemic. Greater exchange of experience and best-practice amongst SRAs on regulatory evaluation of such studies will help to build the evidence base and support the development of appropriate protocols and guidelines.
- 93** Speed can also be enabled by a more systematic approach to how data and samples are captured, shared and analysed. Real-time data collection, distribution and use is critical in a pandemic (as well as between pandemics as part of embedding best practice), but requires robust infrastructure and operational systems, supported by appropriate governance models.⁸¹ We should continue to embrace the opportunities digital transformation provides to better detect, prevent and respond to epidemics and pandemics.⁸² The application of cloud-based data sharing platforms can support speedy and flexible recruitment of clinical trial sites in response to shifting pandemic waves and enable more efficient patient recruitment for preventive and therapeutic trials and diagnostic use cases. The use of these types of platforms would also support prompt review of the results of completed trials by regulators and policy-makers. We can embed new digital technology and data management in diagnostics by linking serial numbers to a digital system which would be transformational for quality assurance and deployment, allowing manufacturers to recall faulty kits by preventing those kits from providing a test result.⁸³ Greater collaboration on data standards and platforms could also increase the utility of testing data so that results can be linked to surveillance systems, clinical care and public health responses for control, tracing and isolation. Utility of data will also benefit from clear disaggregation for impacts with respect to gender and ethnicity at all stages of surveillance and analysis. The samples and data stored in biobanks

⁸¹ The Royal Society: 'Data for international health emergencies: governance, operations and skills', March 2021, <https://royalsociety.org/-/media/about-us/international/g-science-statements/G7-data-for-international-health-emergencies-31-03-2021.pdf>

⁸² OECD, 'Beyond Containment: Health systems responses to COVID-19 in the OECD, April 2020, <https://www.oecd.org/coronavirus/policy-responses/beyond-containment-health-systems-responses-to-covid-19-in-the-oecd-6ab740c0/>

⁸³ Thomas F. Scherr, Sparsh Gupta, David W. Wright, and Frederick R. Haselton 'An embedded barcode for "connected" malaria rapid diagnostic tests' Lab on a Chip 17,7, March 2017, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6474256/>

is critical for the development of DTVs⁸⁴ but existing international protocols present a major challenge to enable effective sharing of specimens.⁸⁵ Standardised assays for the key immunological and viral measurements developed and agreed in advance would also allow for comparison and harmonisation of datasets. The S7 recommendations are an important step forward to realise a better level of 'data readiness' for future health emergencies and should be endorsed.

- 94 We recommend that SRAs and WHO should form an international alliance in a pandemic** to support timely exchange of knowledge and information relating to standards and guidelines for DTVs. This should include the development of risk-adjusted, scenario-based approaches to accelerated approvals or emergency use authorisation as soon as a DTV is shown to be beneficial, including clearer guidelines on WHO EUL. The International Coalition of Medicines Regulatory Authorities (ICMRA) should consider setting up a working group to review the Framework for the Involvement of Health Regulatory Authorities in the Management of Global Health Crises, to ensure that it reflects best-practice and lessons learned from COVID-19. SRAs, in partnership with WHO and ICMRA, should report on progress by April 2022.
- 95 We recommend SRAs and WHO exchange experience and best-practice on regulatory evaluation of other types of studies (e.g. human challenge trials, immunogenicity studies) during pandemics to support the development of appropriate protocols and guidelines.** This should build on good practices that have emerged from the current pandemic such as WHO's R&D Blueprint initiative. SRAs and WHO should report on progress by April 2022.
- 96 We recommend exploring the scope for a system that enables biological samples to be collected and shared immediately and unhindered in a pandemic.** This could be used to commence research to create high-quality DTVs - particularly tests - and track pathogen evolution. The system would need to be based on adapted Nagoya protocol principles⁸⁶ to operate effectively. WHO should lead this scoping work, identifying what could be possible with respect to the Nagoya protocol and report

⁸⁴ Daniel Simeon-Dubach & Marianne K. Henderson, 'Opportunities and Risks for Research in the COVID-19 Era and Beyond', *Biopreservation and Biobanking*, 18,6, December 2020, <https://www.liebertpub.com/doi/10.1089/bio.2020.0079>

⁸⁵ Prof Rosanna W Peeling PhD; Deborah Boeras, PhD; Prof Annelies Wilder-Smith, MD; Amadou Sall, PhD & John Nkengasong, PhD, 'Need for sustainable biobanking networks for COVID-19 and other diseases of epidemic potential', *The Lancet*, July 2020, [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30461-8/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30461-8/fulltext)

⁸⁶ 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity', October 2014, <https://www.cbd.int/abs/>

on progress by October 2021 for discussion at the proposed G7 CSA (or equivalents) stocktake before the end of 2021.

- 97 We support the recommendations of the S7 and endorse the development of a roadmap towards a more systematic approach to data capture, standards, sharing and analysis for health emergencies.** The roadmap will build on efforts to embed best practice on data sharing and focus on unlocking data to support progress in three priority areas for the G7: better global disease surveillance, the use of social-behavioural insights and public health response data to inform policy responses to epidemics, and accelerated development, manufacturing, and deployment of diagnostics, therapeutics and vaccines. The S7 and WHO together with partners should report on progress by April 2022.

Scale and Equitable Access

- 98** The current pandemic has shown the most successful DTV responses have been fast and effective, but not all have been delivering on wider global access. Whilst we have seen organisations come together under new networked structures to coordinate a response, with the formation of ACT-A and COVAX, the overall response suffered from a lack of advanced planning in the setting up of the structures that would ensure that there was sufficient scale in production of DTVs to ensure global access and the necessary finance to make it a reality. Designing DTVs and their manufacturing processes to produce at scale is key. When a PHEIC is declared, reaching global scale will be partly about activating the public-private manufacturing network recommended in paragraph 85. An automatic finance response is also crucial to make these measures achievable; we need sustainable funding approaches so that when a PHEIC is declared we have sufficient financing automatically available to enable equitable access to DTVs. The International Financial Institutions (IFIs) need to be able to respond flexibly to future health crises. Facilities housed with IFIs must be available in future with automatic disbursement so that when a PHEIC is declared money should be more quickly and widely available.
- 99** COVID-19 has demonstrated the importance of entering into vaccine purchase agreements as early as possible, long before the product gains regulatory approval, and to take a portfolio approach. However, the ability of governments to make this happen differed: most HICs were able to shoulder the financial risk of constructing a diversified portfolio that included products of unknown efficacy, whilst most UMICs and all LMICs were not in the same position. The current pandemic has favoured those countries able to take risks and therefore get to the front of the queue the quickest.

- 100** We therefore need to ensure that countries that can afford to take risks do so in a way that benefits those countries who cannot. Any response to a future pandemic must be able to quickly bring together countries to ensure sufficient supply of DTVs and provide clear, and large, demand signals to industry. Ahead of a pandemic being declared, governments can agree how they will approach DTV purchases during a health crisis: countries should agree to a global advance commitment within a funding facility that can purchase DTVs rapidly in the event of a pandemic, with its funding already committed. If HICs and UMICs opt in to this commitment, with LMICs automatically opted in, risk and cost will be spread along with the benefits from early access to DTVs. We judge that the World Bank is best placed to manage such a financial facility, though this would need to be informed by the DTV procurement expertise of Gavi and The Global Fund, and would need to be fast and expert. The nature of the facility could be structured in such a way that the risk of failure is absorbed by wealthier countries (and non-ODA budgets). Such an approach would enable large scale investment in manufacturing at risk, ahead of knowing if the DTV product works, with contractual obligations to sell DTVs via the facility.
- 101** For LMICs, the current pandemic has largely relied on donor financing, principally through ACT-A, to meet the costs of purchasing and deploying DTVs. As has been demonstrated by the frequent calls for additional donor financing, ODA has not been a sustainable source of funding with too few countries meeting their burden-share (based on ability to pay);⁸⁷ and although the financing from MDBs has improved compared to previous crises, it has not been as sufficiently flexible as the situation has demanded. This crisis has demonstrated that there is a strong economic, financial and health case to having funding mechanisms in place before a pandemic to allow UMICs and LMICs to purchase DTVs at speed, at scale, and at risk when a threat materialises.
- 102** **We recommend** a PHEIC should trigger the automatic activation of an **automatic mechanism to procure and distribute DTVs. Further work is needed to determine how such a facility could operate** and we recommend considering basing this on **advance commitments that are pre-negotiated well before a pandemic.** The World Bank should take forward conversations with Gavi, The Global Fund and CEPI to consider how such a facility could be designed and implemented. This should be

⁸⁷ WHO, 'The ACT Accelerator Funding Tracker', May 2020, <https://www.who.int/initiatives/act-accelerator/funding-tracker>

agreed by the 2022 Spring Meetings, providing a report to the G20. As part of these conversations, we recommend considering:

- a Automatic activation of DTV procurement through advance commitments.** This is crucial to enable global procurement with greater ease, and to give clear demand signals to pharmaceutical companies and manufacturers and ensure sufficient supply is made available. Advance commitments could be made on behalf of all countries who opt in, with LMICs automatically opted in. This would have to be done in a way that ensures fair burden sharing between the World Bank's shareholders and thereby sharing of risk with the support of client countries. Any such procurement facility should enable earlier deals with manufacturers, putting global equitable access at the heart of the next response;
- b** Whether it is appropriate for **regional versions of the proposed facility** to be triggered in response to epidemics;
- c** Enabling DTVs to be produced for at least **30% of the populations of countries who opt in, over the first year of the pandemic**;
- d** Financing ahead of time, including through **financial commitments (with sufficient levels of front-loading) from countries with an ability to pay that can be called upon when PHEIC is declared**; and,
- e** Enabling distribution of DTVs to **LMICs through The Global Fund for diagnostics and therapeutics, and Gavi for vaccines, with WHO determining equitable apportionment.**

103 Beyond the 30% minimum population coverage provided for by the DTV financing facility:

- a** HICs and UMICs will of course be expected to enter into bilateral deals to meet their needs. **We recommend that as part of countries' bilateral DTV procurement, any advance purchase agreements with manufacturers should include a requirement for products provided to LMICs to be provided at not for profit.** This must also be done **within a similar timeframe to when HICs are supplied.** By taking on risk for products that have not been proven to work, HICs can effectively subsidise LMIC access through their APAs. This is in line with the recommendation in paragraph 84, which recommends including equitable access clauses in upstream funding from governments. G7 CSAs (or equivalents) should provide an update at the proposed stocktake meeting before the end of 2021.

- b** We recommend MDB loans should be made available so LMICs can purchase DTVs above the 30% provided through the DTV financing facility (recommended in paragraph 102). **Normal access limits or policies applied by MDBs should not prevent countries receiving urgent finance during a pandemic.** Once WHO declares a PHEIC, countries should immediately be able to access rapid financing from the IFIs, including the regional development banks. While this should not be limited to DTV purchases, it should enable countries to make bilateral deals or make purchases through the proposed global DTV financing facility. We should also consider adding contingent clauses to allow repurposing of existing grants/loans or automatic triggering of debt service suspensions for official and private creditors to enable finance ministries in developing countries to have immediate access to funds to purchase emergency supplies. This should be discussed by the Spring Meetings of the World Bank and IMF in 2022, providing a report to the G20.

ANNEX A

Summary of Recommendations

These recommendations are predicated on an effective global surveillance system and public health response capability. For each recommendation to work effectively we recommend a true partnership between the public and private sectors. We have also focused on existing institutions, with simplified accountability wherever possible. There are a large number of existing, and excellent, international health institutions and our approach has been to recommend better use of what we have, rather than creating additional international organisations. These recommendations should undergo further development by the proposed leads, including to ensure the right organisations are included and to assess costs and financing sources.

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|---|---|---|---|
| Overall Better Pandemic Preparedness | Implementation of the recommendations in this report. | 1. A regular review of the implementation of the recommendations in this report, beginning with an initial stocktake before the end of 2021. This first discussion should cover a progress-update on the recommendations and any further steps that are needed, working with the organisations leading on the recommendations where appropriate. The G7's implementation discussions should be done in concert with the recommended G20 Global Health Board. | <u>G7 Chief Scientific Advisers</u> or equivalents When: to meet before the end of 2021, and discuss progress reports due by end October 2021. Thereafter regularly until satisfied. |
| R&D to fill the gaps in our arsenal – through a mission-focussed approach to prepare for known pathogens of pandemic potential, and upgrade our technology as a means to help us prepare for both our known and unknown risks. | R&D prioritisation on pathogens of pandemic -potential and modernising technology recommendations in this report. | 2. Build prototype vaccine and diagnostic libraries applicable to representative pathogens of pandemic potential. This should be informed by CEPI's analysis of which priority pathogens would benefit from prototype vaccines, particularly respiratory viruses. | <u>CEPI</u> , to coordinate working with the surveillance super-network set out in the Pathogen Surveillance Report, industry, biotechnology companies, research institutions and academia and other relevant organisations, supported by G7 governments. When: This would deliver over a 5 year timeline with CEPI publishing an annual report setting out the delivery timeline, including key milestones, the first published by the end of October 2021. |

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|------|------------------------|---|--|
| | | <p>3. Develop prototype antiviral therapeutics, including antibody therapies, for respiratory pathogens of pandemic potential: principally respiratory pathogens, initially coronaviruses and influenza viruses, informed by CEPI's analysis of which priority pathogens would benefit from prototype therapeutics. These prototype therapeutic molecules need to have a broad activity spectrum and to have passed initial clinical safety testing. This would provide a rapid activation toolkit of clinic-ready compounds in preparation for large clinical trials of prototype molecules, ideally with simplified manufacturing routes so that scale up is easy. G7 governments should work with the Intrepid Alliance to explore the value of stockpiling in readiness for clinical trials.</p> | <p>Research-based pharmaceutical industry initiatives to discover and develop antivirals for future pandemics (like the Intrepid Alliance) are important for kickstarting this development, and they should work with academia (including government research labs), biotechnology companies, CEPI, The Global Fund, relevant philanthropic funders and G7 governments.</p> <p>When: 2026 (5 years). The Intrepid Alliance to provide an annual public report outlining progress and the timeline, the first published by the end of October 2021.</p> |
| | | <p>4. Invest in modernising vaccine technology by targeting vaccine preventable diseases. The objective, alongside treating preventable diseases, is to have improved vaccine platforms ready to respond to an unknown "Disease X". The more high-quality vaccines available and approved by regulators, the more options for repurposing or reprogramming when a Disease X threat emerges. Our focus should be on investing in readily "programmable" vaccine platforms which could be used to identify a potential vaccine quickly, while making sure we still have a diversity of approaches available to us. R&D must also include simplified manufacturing and routes of administration, as recommended in recommendation 12. Governments, CEPI and international procurement organisations, such as Gavi, should consider appropriate pull incentives to stimulate manufacturing innovations for vaccines. CEPI should support industry and research institutions - along with national and regional R&D initiatives - in the coordination and development of vaccine technology, such as through knowledge-sharing, creating consortiums, bringing together cross-border partners, scaling and ensuring LMIC suitability.</p> | <p>Industry, with biotechnology companies, research institutions, CEPI and supported by G7 governments. Two reports produced annually: the first authored by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and industry-led; the second from CEPI.</p> <p>When: The timeline for this recommendation is 5 years, with CEPI and IFPMA reporting in October 2021, and thereafter annually, on the timeline and setting out key milestones.</p> |
| | | <p>5. Invest in simplified cheaper routes for producing monoclonal antibodies and other new therapeutic modalities.</p> | <p>Industry, working with biotechnology companies, research institutions, academia and other relevant institutions.</p> <p>When: The IFPMA should produce an annual public report outlining progress, the first published by the end of October 2021.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|------|--|---|---|
| | Strengthen R&D capability and coordination for therapeutics and diagnostics. | <p>6. Strengthen the role of the international system in R&D capability and coordination for therapeutics and diagnostics by expanding CEPI's remit to cover therapeutics and diagnostics, in addition to vaccines. This would address the gap in global coordination for these technologies and increase its capacity to fund and advance novel platforms and stimulate demand through pull incentives. This expanded emphasis would complement the central role of industry, and initiatives like the Intrepid Alliance in R&D. To do this effectively, Governments and others, such as private foundations, will need to provide additional financial support. CEPI should also explore other sustainable financing sources, including non-ODA, to deliver upon the recommendations in this report. CEPI is already planning to use a financing facility inspired by Gavi's IFFIm model, which will enable donors to frontload financing secured against legally binding future payments that may need to be capitalised in a pandemic. The use of a pre-commitment should also be explored, using a bond issued only in the event of a pandemic, which donors would then repay.</p> | <p>CEPI, with funding support from G7/G20 governments.</p> <p>When: This would be completed by 2022 as part of CEPI's revised strategic plan 2022-2026.</p> |
| | Create and stimulate the global diagnostic market between pandemics. | <p>7. Governments should normalise the use of accurate diagnostics for coronavirus and influenza in point of care and non-clinical settings. Governments could drive these changes, working with FIND and other relevant organisations, by signalling that coronavirus and influenza tests will be prioritised for demonstrably cost-effective clinical and public health use cases. It is also important that increased use of diagnostics goes hand-in-hand with appropriate non-pharmaceutical interventions (such as self-isolation) or treatments. A market for point of care diagnostics for these common infectious diseases would stimulate the diagnostics industry. FIND would play a key role in providing LMIC market information to diagnostics manufacturers to enable policy makers to make informed procurement decisions relative to demand. This activity would dovetail with strengthened global surveillance of infectious diseases as set out in the Pathogen Surveillance Report.</p> | <p>G7 governments, working with FIND and other relevant organisations.</p> <p>When: G7 Chief Scientific Advisers (or equivalents) should report at the proposed stocktake before the end of 2021 on their respective country's policy on the ramping up of the use of coronavirus and influenza tests and discuss and agree next steps.</p> |
| | | <p>8. WHO should support an enhanced role for diagnostics in the surveillance of pandemic threats. As set out in the Pathogen Surveillance Report, enhanced surveillance of pandemic pathogen threats and the sharing of emerging pathogens and their data is vital. Establishing close cooperation between the public and private sectors on linking surveillance of pandemic threats, including the immediate and unhindered access to samples and data (see recommendation 21), with the diagnostics industry is critical to the diagnostics market between pandemics.</p> | <p>WHO Implementation Group</p> <p>When: to report on progress in early 2022 to the G7 Presidency as part of the implementation of the recommendations of the Pathogen Surveillance Report.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|--|--|---|--|
| | | <p>WHO should coordinate this activity, through the Implementation Group recommended as part of the Pathogen Surveillance Report, working closely with industry leaders to ensure integration, transparency and collaboration. This should also include working closely with existing industry-led initiatives, such as Abbott's Pandemic Defense Coalition which brings together a scientific and public health network dedicated to the early detection of and rapid response to future pandemic threats.</p> | |
| <p>Make the exceptional routine by embedding best practice and preparation in business-as-usual activity – taking the best innovations from our response to COVID-19 and normalising them, while unpicking systemic complexity.</p> | <p>Embed best practice from COVID-19 experience across clinical trials, data, regulation and transferable manufacturing.</p> | <p>9. Scope out how an international network of clinical trial platforms could be implemented to enable a coordinated and efficient approach to testing of DTVs. A network of clinical trial platforms (both hospital and community-based) that are regionally linked should be set up to run during non-pandemic periods to address ongoing relevant public health questions (e.g. evaluating interventions for endemic infections such as tuberculosis, malaria, HIV or non-communicable diseases of public health importance such as common cancer, cardiovascular disease, mental health). The platforms should have access to real-time epidemiological intelligence and be designed in a way that enables them to pivot at speed and scale in the face of a pandemic threat - acting as a global emergency response network - and adaptable to respond to changes in the pandemic (e.g. new variants, spread to new countries) and improvements in scientific understanding (e.g. role of the host-response to the pathogen). The platforms would need to have strong local ownership and leadership to respond to the needs of the local community where they are located. Smart data capture and flexible trial management information systems that integrate diverse health datasets should be the norm to support trial set-up and patient enrolment and ensure that information is transparent and easily accessible for subsequent decision-making and licensing, in line with appropriate confidentiality protections. The network would require baseline funding from countries to strengthen their own clinical trial infrastructure and create regional links, supplemented by a “user pays” model, across the public and private sector. The network could be modelled on, and draw learning from, existing collaborative platforms such as the International Severe Acute Respiratory and emerging Infection Consortium, the Drugs for Neglected Diseases Initiative and the VACCELERATE clinical research network.</p> | <p>WHO, working with G20 governments, industry, philanthropic organisations and academia should scope a collaboration model.</p> <p>When: Scope by end of October 2021. Present the proposal at the proposed G7 Chief Scientific Advisers (or equivalents) stocktake before the end of 2021.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|------|------------------------|---|--|
| | | <p>10. Develop a common regulatory framework that better defines criteria and standards for effectiveness, quality and use cases for diagnostics. Stringent Regulatory Authorities should work together to define international assessment protocols and develop guiding principles, alongside more effective quality assurance processes that link diagnostic tests into care and prevention pathways. Implementation trials can provide the necessary data to demonstrate how diagnostics can be best used to improve surveillance, clinical management and critically to reduce pathogen transmission.</p> | <p>Stringent Regulatory Authorities through the International Medical Device Regulators Forum.</p> <p>When: Report on progress by April 2022.</p> |
| | | <p>11. Transform the approach to clinical trial regulation, shortening the time to authorise trials and streamlining the requirements and guidelines relating to trial conduct. We should refocus regulatory guidelines on the fundamental scientific and ethical principles that underpin randomised trials, whilst embracing flexibility and innovation across a range of health threats and technologies. We should build on models established by the US Food and Drug Administration Clinical Trial Transformation Initiative and the Good Clinical Trials Collaborative (supported by the Bill & Melinda Gates Foundation, Wellcome Trust, and African Academy of Science). The Good Clinical Practice for clinical trials guidance should be revised to focus on what matters for the generation of actionable information about effects of an intervention, rather than what is easy to check but less relevant, placing an emphasis on principles and purpose rather than process. Regulations should also allow easy moving of clinical trials across the recommended international network of clinical trial platforms (recommendation 9) at a speed that matches the migration of the disease.</p> | <p>Stringent Regulatory Authorities in partnership with WHO and the Good Clinical Trials Collaborative.</p> <p>When: Report on progress by October 2021 for the proposed G7 Chief Scientific Advisers (or equivalents) stocktake before the end of 2021.</p> |
| | | <p>12. Stimulate a move towards innovative technologies to reduce the complexity of vaccine manufacturing processes and make technology transfer and scalable manufacturing easier in a pandemic by investing in R&D. This must include simplified modular manufacturing and routes of administration (e.g. oral) and storage (room temperature).</p> | <p>Industry in partnership with biotechnology companies, CEPI, Gavi, research institutions, academia, the public sector and other relevant organisations.</p> <p>When: IFPMA produce an annual public report outlining progress, the first published by the end of October 2021.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (<u>Lead</u>) |
|------|---|---|--|
| | Embed preparation by financing pandemic preparedness... | <p>13. While we support the recommendation set out in the IPPPR for the IMF to explore expanding their Article IV consultation with member countries to include a pandemic preparedness assessment, we believe these assessments should draw on the analysis and expertise of others, including the Global Health Security Agenda and the WHO's universal periodic peer reviews. The current crisis has highlighted the economic and financial impact that a health crisis can have on the global economy, and we believe that the IMF should play its role, in conjunction with others, in warning of the impact that future threats can have, and, as such, we see an important role for them on the proposed Global Health Board (recommendation 14). Consistent with its mandate, the IMF should be prepared to provide emergency financing to countries that need support for pandemic response. Consistent with their mandates, we also suggest the multilateral development banks continue to support investment to strengthen and prepare health systems as part of their core day-to-day business - treating public health security as importantly as they treat financial stability, including a plan to improve public health security in all their country strategies, drawing on the analysis and expertise of the Global Health Security Agenda and the WHO's universal periodic peer reviews.</p> | <p>IMF When: as outlined in the IPPPR report, as part of Article IV consultation with member countries, Q3-4 2021 should include the first annual pandemic preparedness assessment.</p> <p>Multilateral development banks (including regional development banks). When: by the Annual Meetings 2022.</p> |
| | ...improving oversight for pandemic preparation... | <p>14. Establishing a Global Health Board reporting to the G20 to provide oversight of pandemic readiness on an annual basis. The set up and function of the Board would need agreement by the G20 and we suggest they consider asking the Board to report annually to the G20 Health and Finance Ministers on the outcomes of global surveillance, ongoing and emerging risks to the international system from pandemic threats, and actions needed to address them. The Board could be made up of the three Chief Scientific Advisers (or their equivalents) and Finance Deputies of the incumbent, previous and successive G20 Presidencies, the One Health Organisations (WHO, FAO, OIE, UNEP), The Global Fund, Gavi, CEPI, and the IMF and World Bank. The G20 should also ensure there is sufficient independence within the Board to hold governments, industry and international organisations to account. We view this as important for its effective operation. It could be chaired by the WHO, with the GPMB acting as the secretariat, to provide independence and stability to the Board whilst ensuring political accountability of decisions made by Finance and Health Ministers. When WHO declares a PHEIC, the Board could coordinate the international response and could take a decision on standing up a network of international organisations (similar to ACT-A), governed by the Global Health Board, to manage the response to the crisis.</p> | <p>G20 When: The October 2021 meeting of the G20 Health and Finance Ministers should develop further for consideration for adoption by the G20 governments in 2022.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|---|--|--|--|
| | <p>...and through public-private burden sharing for manufacturing and enabling equitable access.</p> | <p>15. Governments should build in conditions into DTV funding contracts for LMIC access to access DTVs at not for profit and scale, which is to be enacted if a Public Health Emergency of International Concern is declared. Governments should look to benefit from the risk they are taking in making these investments, by having conditions on their investment to require a public benefit ‘pay-back’ during pandemics if the research does become commercially viable. Including equitable access considerations in business-as-usual investment should be mirrored by similar equitable access efforts during a pandemic (set out in recommendation 24).</p> | <p>G7 governments When: G7 Chief Scientific Advisers (or equivalents) should provide an update at the proposed stocktake before the end of 2021.</p> |
| | | <p>16. Governments and industry should share risk to maintain vaccine manufacturing capacity. The COVAX Manufacturing Task Force should produce a plan:</p> <p>a. Exploring how a vaccine manufacturing network, utilising the latest technology, could be brought online to deliver production at scale rapidly in a pandemic. This includes simplified transferrable manufacturing processes, interoperable equipment and supplies and a modular network.</p> <p>b. Considering options for keeping facilities in regular use between pandemics, including possible mass adult vaccination campaigns.</p> | <p>COVAX Manufacturing Task Force, with industry and G7 governments. When: Publish a plan on how to do this by October 2021.</p> |
| <p>Agree different rules of the road to come into effect in a pandemic - agreeing these ahead of time so no time is wasted negotiating the basics.</p> | <p>Overall, we should agree rules of the road for pandemics, to enable...</p> | <p>17. As part of the proposed WHO Treaty on Pandemic Preparedness setting guidance for pandemics, WHO should define ‘rules of the road’ and set out guidance on good practice for all relevant stakeholders in a pandemic, pre-negotiated with governments, industry and international organisations. The protocols should cover the breadth of essential practices that need to be agreed across countries, including, amongst other things, supply chains, indemnification and data sharing. The recommended rules of the road for pandemics must enable prioritisation, speed, scale and equitable access for DTVs. We also support the WHO Independent Panel for Pandemic Preparedness and Response’s recommendation that the Public Health Emergency of International Concern alert system needs to operate more rapidly and clearly, not least as this report identifies a Public Health Emergency of International Concern as activating the 100 Days Mission.</p> | <p>WHO, working with industry, CEPI, Gavi, FIND, The Global Fund, and other relevant organisations. When: This should be led by WHO and discussed as part of the WHO Treaty discussions at the special session of the World Health Assembly in November, in collaboration with global health organisations and other relevant international organisations, such as WTO.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (<u>Lead</u>) |
|------|------------------------|--|--|
| | ...Prioritisation | <p>18. Explore the creation of regional mechanisms to coordinate and prioritise clinical trials of DTVs. It will be critical to rapidly undertake trials with repurposed medicines as an immediate step to identify effective therapeutics. Prioritisation will also be necessary for new drugs and diagnostics, and possibly even vaccines. There should be an agreed system to coordinate and prioritise which medicines and interventions are entered into the international network of clinical trial platforms set out in recommendation 9. These mechanisms should be designed in a way to combine regional autonomy and flexibility with international knowledge exchange on prioritisation decisions, product assessments. They should be supported by a professional administrative and technical team to provide due diligence, preparation of dossiers, programme management, and information sharing (including with the public). Options should be explored as part of the recommendation to undertake a scoping exercise for the international network of clinical trial platforms.</p> | <p><u>WHO</u> working with G20 governments, industry, philanthropic organisations and academia.</p> <p>When: Report on progress by October 2021. Present a proposal at the proposed G7 Chief Scientific Advisers (or equivalents) stocktake before the end of 2021.</p> |
| | ...Speed | <p>19. Stringent Regulatory Authorities and WHO should form an international alliance in a pandemic to support timely exchange of knowledge and information relating to standards and guidelines for DTVs. This should include the development of risk-adjusted, scenario-based approaches to accelerated approvals or emergency use authorisation as soon as a DTV is shown to be beneficial, including clearer guidelines on WHO emergency use listing. The International Coalition of Medicines Regulatory Authorities should consider setting up a working group to review the Framework for the Involvement of Health Regulatory Authorities in the Management of Global Health Crises to ensure that it reflects best-practice and lessons learned from COVID-19.</p> | <p><u>Stringent Regulatory Authorities</u> in partnership with WHO and ICMRA.</p> <p>When: Report on progress by April 2022.</p> |
| | | <p>20. Stringent Regulatory Authorities and WHO exchange experience and best-practice on regulatory evaluation of other types of studies (e.g. human challenge trials, immunogenicity studies) during pandemics to support the development of appropriate protocols and guidelines. This should build on good practices that have emerged from the current pandemic such as WHO's R&D Blueprint initiative.</p> | <p><u>Stringent Regulatory Authorities</u> in partnership with WHO.</p> <p>When: Report on progress by April 2022.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (Lead) |
|------|---------------------------------------|---|--|
| | | <p>21. Explore the scope for a system that enables biological samples to be collected and shared immediately and unhindered in a pandemic. This could be used to commence research to create high-quality DTVs - particularly tests - and track pathogen evolution. The system would need to be based on adapted Nagoya protocol principles to operate effectively.</p> | <p><u>WHO</u>, identifying what could be possible with respect to the Nagoya protocol. When: Report on progress by October 2021 for the proposed G7 Chief Scientific Advisers (or equivalents) stocktake before the end of 2021.</p> |
| | | <p>22. Support the recommendations of the Science Academies of the G7 and endorse the development of a roadmap towards a more systematic approach to data capture, standards, sharing and analysis for health emergencies. The roadmap will build on efforts to embed best practice on data sharing and focus on unlocking data to support progress in three priority areas for the G7: better global disease surveillance, the use of social-behavioural insights and public health response data to inform policy responses to epidemics, and accelerated development, manufacturing, and deployment of diagnostics, therapeutics and vaccines.</p> | <p><u>S7</u> and WHO together with partners. When: Report on progress by April 2022.</p> |
| | <p>...Scale and Equitable access.</p> | <p>23. A PHEIC should trigger the automatic activation of an automatic mechanism to procure and distribute DTVs. Further work is needed to determine how such a facility could operate and we recommend considering basing this on advance commitments that are pre-negotiated well before a pandemic. The World Bank should take forward conversations with Gavi, The Global Fund and CEPI to consider the needs for such a facility and how it could be designed. As part of these conversations, we recommend considering:</p> <p>a. Automatic activation of DTV procurement through advance commitments. This is crucial to enable global procurement with greater ease, and to give clear demand signals to pharmaceutical companies and manufacturers and ensure sufficient supply is made available. Advance commitments could be made on behalf of all countries who opt in, with LMICs automatically opted in. This would have to be done in a way that ensures fair burden sharing between the World Bank's shareholders and thereby sharing of risk with the support of client countries. Any such procurement facility should enable earlier deals with manufacturers, putting global equitable access at the heart of the next response;</p> <p>b. Whether it is appropriate for regional versions of the proposed facility to be triggered in response to epidemics;</p> | <p><u>World Bank</u>, Gavi, The Global Fund, CEPI, WHO. When: by the 2022 Spring Meetings should agree on a financing mechanism and provide a report to the 2022 G20.</p> |

| Goal | What We Should Aim for | How We Should Get There | Who and When (<u>Lead</u>) |
|------|------------------------|--|---|
| | | <p>c. Enabling DTVs to be produced for at least 30% of the populations of countries who opt in, over the first year of the pandemic;</p> <p>d. Financing ahead of time, including through financial commitments (with sufficient levels of front-loading) from countries with an ability to pay that can be called upon when a Public Health Emergency of International Concern is declared; and,</p> <p>e. Enabling distribution of DTVs to LMICs through The Global Fund for diagnostics and therapeutics, and Gavi for vaccines, with WHO determining equitable apportionment.</p> | |
| | | <p>24. As part of countries' bilateral DTV procurement, any advance purchase agreements with manufacturers should include a requirement for products provided to LMICs to be provided at not for profit. This must also be done within a similar timeframe to when HICs are supplied. By taking on risk for products that have not been proven to work, HICs can effectively subsidise LMIC access through their advance purchase agreements. This is in line with recommendation 15, which recommends including equitable access clauses in upstream funding from governments.</p> | <p><u>G7 governments</u> When: G7 report at the G7 Chief Scientific Advisers (or equivalents) stocktake meeting before the end of 2021.</p> |
| | | <p>25. Multilateral development bank loans should be made available so LMICs can purchase DTVs above the 30% provided through the DTV financing facility in line with recommendation 23. Normal access limits or policies applied by multilateral development banks should not prevent countries receiving urgent finance during a pandemic. Once WHO declares a Public Health Emergency of International Concern, countries should immediately be able to access rapid financing from the international financial institutions, including the regional development banks. While this should not be limited to DTV purchases, it should enable countries to make bilateral deals or make purchases through the proposed global DTV financing facility. We should also consider adding contingent clauses to allow repurposing of existing grants/loans or automatic triggering of debt service suspensions for official and private creditors to enable finance ministries in developing countries to have immediate access to funds to purchase emergency supplies.</p> | <p><u>Multilateral development banks.</u> When: by the Spring Meetings of the World Bank and IMF in 2022, providing a report to the G20.</p> |

ANNEX B

Members of the Pandemic Preparedness Partnership

SRO and Chair of the partnership

Sir Patrick Vallance (Chair) - UK Government Chief Scientific Adviser

Members of the partnership

Expert Leads

- 1 Sir Andrew Witty, CEO, UnitedHealth Group**
Previously Special Envoy at WHO co-leading the effort to accelerate responses to COVID-19; Former CEO of GSK (until 2017).
- 2 Sir John Bell, Regius Professor of Medicine, University of Oxford**
Chair of the Bill & Melinda Gates Foundation Scientific Advisory Committee
- 3 Professor Martin Landray, Professor of Medicine & Epidemiology, University of Oxford**
Significant experience in therapeutics trials. Co-Chief Investigator for the RECOVERY trial
- 4 Dame Anne Johnson, Professor of Infectious Disease Epidemiology University College London**
Significant infectious disease epidemiology and public health experience. Co-investigator of the UCL I-Sense project to develop novel diagnostics. President of the Academy of Medical Sciences.
- 5 Lord Jim O'Neill, Chairman, Chatham House**
Former Chairman of Goldman Sachs Asset Management. Former Commercial Secretary to the Treasury (until 2016).
- 6 Baroness Minouche Shafik, Director London School of Economics**
Deputy Governor of the Bank of England until 2017. IMF Deputy Managing Director until 2014. Former VP at the World Bank, and former Permanent Secretary of DFID.

International Organisations

- 7 Aurelia Nguyen, Managing Director Office of the COVAX Facility, Gavi**
Managing Director Office of the COVAX Facility, Gavi.
Leads coordination of procurement and delivery of Covid-19 vaccines.
Previously Managing Director Vaccines & Sustainability at Gavi and former Director of Global Vaccine Policy at GSK.
- 8 Sir Jeremy Farrar, Director Wellcome Trust**
Formerly Director of the Oxford University Clinical Research Unit at the Hospital for Tropical Diseases in Vietnam, focussing on advancing understanding of TB, malaria, typhoid, dengue and influenza. Current chair of the Scientific Advisory Group of the WHO R&D Blueprint.
- 9 Professor John-Arne Rottingen, Co-chair, Access to COVID-19 Tools Accelerator (ACT-A)**
Member of the G20 High Level Independent Panel (HLIP) on financing for pandemic preparedness and response. Ambassador for Global Health, Norwegian Ministry of Foreign Affairs. Former Chief Executive of the Research Council of Norway.
- 10 Peter Sands, Executive Director at the Global Fund**
Former Group Chief Executive Officer of Standard Chartered PLC and Research Fellow at the Harvard Global Health Institute / Mossavar-Rahmani Centre for Business and Government at Harvard Kennedy School.
- 11 Richard Hatchett, Chief Executive Officer, Coalition for Epidemic Preparedness Initiatives (CEPI)**
Former Director and Chief Medical Officer of the U.S. Biomedical Advanced Research and Development Authority (BARDA). Focus was the development of VTDs for emerging infectious diseases including influenzas, MERS, Ebola.
- 12 Dr. Sergio Carmona, Acting Chief Executive Officer and Chief Medical Officer, Foundation for Innovative New Diagnostics (FIND)**
Acting Chief Executive Officer and Chief Medical Officer at FIND. Extensive experience across diagnostic innovation and access. Previously specialised in diagnostics at the National Health Laboratory Service (NHLS) in South Africa.
- 13 Dr. Soumya Swaminathan, Chief Scientist World Health Organisation**
Dr Soumya Swaminathan was appointed WHO's first Chief Scientist in March 2019. Dr Swaminathan was Secretary to the Government of India for Health Research and Director General of the Indian Council of Medical Research from 2015 to 2017.

A paediatrician from India and a globally recognised researcher on tuberculosis and HIV, she brings with her 30 years of experience in clinical care and research.

Industry

14 Dr. John Tsai, Head of Global Drug Development and Chief Medical Officer, Novartis

Oversees the development pipeline and approval of medicines in the US and other markets at Novartis. Former Chief Medical Officer at Amgen and from 2017 to 2018 and Global Head of late phase Clinical Development at Bristol-Myers Squibb.

15 Sir Mene Pangalos, Executive Vice President Biopharmaceuticals R&D, AstraZeneca

Oversees Research and Development for BioPharmaceuticals at AstraZeneca with extensive experience across all our therapy areas, including cardiovascular, metabolic and renal, respiratory and immunology and oncology.

16 Dr. Mikael Dolsten, Chief Scientific Officer, Pfizer

Oversight of small-molecule medicines, biotherapeutics, gene therapies and vaccines, as well as strategic R&D priorities. Previously President of Wyeth Research until 2009.

17 Dr. Paul Stoffels, Vice Chairman and Chief Scientific Officer, Johnson & Johnson

Oversees J&J R&D and product pipeline. Previously World Chairman, Pharmaceuticals at J&J.

Extensive experience in HIV and tropical diseases research, and focussed on innovative science and technology

18 Roger Connor, President Global Vaccines, GlaxoSmithKline

Extensive background in manufacturing, including Former President, Global Manufacturing & Supply, restructuring of the Manufacturing organisation and Site Director at the GSK Barnard Castle site

Regulation

19 Dr. June Raine, Chief Executive for Medicines and Healthcare products Regulatory Agency

Chief Executive of MHRA, Chairs the Executive Committee at MHRA. Previously Director of Vigilance and Risk Management of Medicines.

Glossary of Terms

- **ACT-A** - Access to COVID-19 Tools Accelerator, launched by WHO and partners in April 2020
- **Adaptive platform trials** - clinical trials that enable many different treatments to be studied simultaneously
- **Advance commitment** - a promise or agreement to take some future action. It here refers to the buying or selling of an asset (DTVs) at some future time, with pre-agreed terms
- **Advanced structural biology** - see structural biology
- **AMC** - Advance Market Commitment, a donor commitment to subsidise a future purchase (DTVs) that is not yet available. It is an innovative mechanism to incentivise private manufacturers to invest in R&D and/or building manufacturing capacity to supply to developing countries
- **AMR** - Antimicrobial Resistance occurs when bacteria, viruses, fungi and parasites change over time and no longer respond to medicines, making infections harder to treat and increasing the risk of disease spread, severe illness and death
- **Antibiotics** - medicines that treat or prevent infections caused by bacteria
- **Antibody therapy** - treatment that uses antibodies, in this report referring to their use in infectious diseases, for instance by binding to viral surface proteins to block entry into human cells
- **Antigen mapping** - mapping the binding sites (epitopes) of an antibody on its target antigen. In this report, the antigen refers to a surface protein on a pathogen that human antibodies would bind to as part of the immune response (or antibody therapy)
- **Antiviral therapeutics** - therapeutics to treat or prevent viral infections
- **APA** - Advance Purchase Agreement, a commitment to purchase (DTVs) for a certain volume, at a price, ahead of the product being on the market, helping to cover industry risks needed to e.g. upscale manufacturing
- **Assessment protocols** - guidance used by regulators to assess DTVs for approval
- **BARDA** - Biomedical Advanced Research and Development Authority (US)
- **Biobanking** - the process by which samples of bodily fluid or tissue are collected for research use to improve our understanding of health and disease
- **Biological samples** - such as blood samples, cell cultures or organisms. Such biological products are vital in the preparation of DTVs
- **Business as usual/ business-as-usual** - in this report, referring to the time when the world is not combatting a pandemic
- **CEPI** - Coalition for Epidemic Preparedness Innovations, an

organisation that provides R&D funding for vaccines to stop future epidemics

- **Clinical trial** - a type of research that studies new tests and treatments and evaluates their effects on human health outcomes
- **Clinical trial platforms** - bring together different stakeholders to facilitate clinical research
- **Clinical Trials Transformation Initiative** - a public-private partnership to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials
- **CMO** - Chief Medical Officer (or Chief Medical Officer-equivalent) of a government
- **COVAX** - The vaccine pillar of ACT-A, co-led by Gavi and CEPI. Also the COVID-19 vaccine procurement pool led by Gavi and CEPI
- **COVAX Manufacturing Task Force** - a group set up from 14 May 2021 as part of ACT-A's vaccine pillar, COVAX, to identify and resolve issues impeding equitable access to vaccines through COVAX
- **COVID-19** - the disease caused by the virus SARS-COV-2
- **CRISPR technologies** - Clustered regularly interspaced short palindromic repeats gene editing technology, which can be used to target pathogen infections
- **CSA** - Chief Scientific Adviser (or Chief Scientific Adviser-equivalent) of a government
- **Diagnostics** - products which diagnose diseases, commonly known as tests
- **Disease** - a deviation from normal healthy functioning, in this report typically refers to infectious diseases that affect humans
- **Disease X** - represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease (WHO definition)
- **DTVs** - Diagnostics, Therapeutics and Vaccines
- **Endemic** - a disease that is regularly found in a population or area
- **Enzyme antiviral targets** - enzymes produced by a virus that antiviral therapeutics can work against, for instance by interfering with an enzyme that is involved in synthesis of new viruses
- **Epidemic** - a disease that affects a large number of people within a region, population or community
- **Equitable access** - when those with equal needs have equal access. In this report usually referring to DTVs such that DTVs are distributed globally based on clinical need
- **EUL** - Emergency Use Listing, a WHO procedure that makes a risk-based assessment on DTVs to expedite access to these products in a public health emergency. EUL has been used in the COVID-19 pandemic to assess the safety of DTVs, especially for use in LMICs where domestic or regional

regulatory systems are not in place or not sufficiently robust

- **FAO** - Food and Agriculture Organization of the United Nations, an agency leading on nutrition and food security
- **FDA** - Food and Drug Administration (USA), in this report referred to in its capacity as a health regulator
- **Fill and Finish** - also known as fill-finish, the process of filling vials with vaccines and packaging for distribution
- **FIND** - the Diagnostics Alliance, an organisation aiming to ensure equitable access to reliable diagnostics around the world
- **Framework for the Involvement of Health Regulatory Authorities in the Management of Global Health Crises** - standard operating procedures produced by ICMRA in 2019 on health regulatory authorities' responses in health crises; <http://www.icmra.info/drupal/sites/default/files/2019-04/ICMRA%20SOP%20for%20Crisis%20Management.pdf>
- **G7** - the Group of 7 nations, an intergovernmental organisation consisting of Canada, France, Germany, Italy, the United Kingdom, the United States and the representatives of the European Union
- **G20** - the Group of 20, a forum for international economic cooperation between 19 countries and the European Union
- **Gavi** - the Vaccine Alliance, an organisation aiming to increase access to immunisation in developing countries
- **GCP** - Good Clinical Practice, the international ethical, scientific and practical standard to which all clinical research is conducted
- **GDP** - Gross Domestic Product
- **GHSA** - Global Health Security Agenda, a group of 70 countries, international organisations, non-government organisations and private sector companies that discuss global health threats posed by infectious diseases
- **Global Fund** - an international financing and partnership organisation fighting AIDS, Tuberculosis and Malaria epidemics
- **GPMB** - Global Preparedness Monitoring Board, an independent monitoring and accountability body for preparedness for global health crises, co-convened by the WHA and World Bank
- **HERA** - Health Emergency Preparedness and Response Authority (EU), launched in 2020 and aimed at improving Europe's capacity and readiness to respond to health emergencies
- **HICs** - High-Income Countries
- **HIV** - Human Immunodeficiency Virus
- **Human challenge trial** - clinical trials in which participants are intentionally challenged with an infectious disease organism
- **ICMRA** - International Coalition of Medicines Regulatory Authorities, a voluntary coordinating and advocacy group of regulatory authorities

- **IFFIm** - International Finance Facility for Immunisation is a means of front-loading aid flows and reducing volatility. Pioneered by the Gavi Alliance, it converts funding pledges into AAA-rated bonds that can be sold to boost short-term funding and provide a stable long-term financial platform.
- **IFIs** - International Financial Institutions, including the multilateral development banks, the Bretton Woods institutions (including the IMF) and regional development banks
- **IFPMA** - International Federation of Pharmaceutical Manufacturers & Associations, an international industry association representing research-based pharmaceutical companies and associations
- **IMF** - International Monetary Fund
- **Immunogenicity study** - measures any adverse immune response generated by a therapeutic or vaccine such as reduced efficacy or autoimmune, allergic and anaphylactic reactions in the body
- **Indemnification** - a contractual obligation to cover another party's risk of loss whereby the 'insurers' pay the compensation in the event of complications. Commonly discussed with respect to vaccines being rolled out before being fully approved, whereby the vaccine company will often require protection against legal cases for any severe side effects
- **Infectious diseases** - diseases, caused by pathogens, that can be spread between organisms
- **International Medical Device Regulators Forum** - a voluntary forum for medical device regulators to accelerate international medical device regulatory harmonisation and convergence
- **Intrepid Alliance** - the research-based pharmaceutical industry initiative to discover and develop antivirals for future pandemics
- **IPPPR** - the WHO Independent Panel for Pandemic Preparedness and Response, tasked in September 2020 to examine why COVID-19 became a global health crisis. It presented its findings in May 2021
- **ISARIC** - International Severe Acute Respiratory and emerging Infection Consortium, a global federation of clinical research networks
- **LICs** - Low-Income Countries
- **LMICs** - Low- and Lower-Middle-Income Countries
- **MDB** - Multilateral Development Bank, an international financial institution chartered by two or more countries, with a purpose to encourage economic development in developing countries
- **MERS** - Middle East Respiratory Syndrome
- **MHRA** - Medicines and Healthcare products Regulatory Agency (UK)
- **MICs** - Middle-Income Countries
- **Modular manufacturing processes** - using an assembly line type process for

manufacturing, in this report referring particularly to vaccine manufacturing

- **mRNA** - Messenger ribonucleic acid: in vaccines it stimulates/teaches cells to make a specific protein which generates an immune response
- **Mutual recognition** - an agreement between health regulators to recognise a decision by one as binding in the other
- **Nagoya Protocol** - 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity' is an international agreement aiming at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way
- **NIH** - National Institutes of Health (USA)
- **NPIs** - non-pharmaceutical interventions, such as wearing a face-covering, social distancing or self-isolation
- **ODA** - Official Development Assistance, often referred to as 'aid', is concessional resources flowing to developing countries. ODA is a definition provided by the Organisation for Economic Co-operation and Development (OECD)'s Development Assistance Committee
- **OIE** - World Organisation for Animal Health, an intergovernmental organisation focused on animal health
- **One Health Initiative** - a collaborative, multisectoral, and transdisciplinary approach—working at the local, regional, national, and global levels—with the goal of achieving optimal health outcomes recognising the interconnection between people, animals, plants, and their shared environment
- **Pandemic** - an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people
- **Pathogen** - an organism causing disease to its host
- **Pathogen Surveillance Report** - shorthand for the report by Sir Jeremy Farrar, 'A proposal to develop an equitable global pathogen surveillance network in 2021 that can prevent and respond to emerging and endemic infectious diseases at speed and at scale', published in May 2021⁸⁸
- **PCR** - Polymerase chain reaction, in this report referenced mainly for its use in diagnostic tests
- **Peptide inhibitors** - a type of therapeutic treatment which block a virus from binding to human cells and therefore prevent disease
- **Pharmacological compounds** - a chemical compound that is pharmacologically (medicinally) active and therefore likely to be useful as a therapeutic

⁸⁸ <https://www.gov.uk/government/publications/report-proposing-enhanced-global-pathogen-surveillance>

- **Phase 2** - the second phase of clinical trials, following phase 1 safety studies. Phase 2 trials look at safety as well as how well the product works. It precedes (and is sometimes combined with) large-scale phase 3 trials which test effectiveness
- **PHEIC** - Public Health Emergency of International Concern, declared by WHO
- **PPE** - Personal Protective Equipment for infection control refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness
- **“Programmable” technologies** - denotes the transformative impact of new technology platforms and approaches, like mRNA, which allow scientists to rapidly amend medical tools to respond to a specific pathogen
- **Prophylactic** - a medication or a treatment designed and used to prevent a disease from occurring
- **Prototype diagnostic/therapeutic/vaccine** - the preparation of DTVs for prototype pathogens, such that they are broad-spectrum or generic in response to a class of pathogen e.g. a coronavirus vaccine, that could be rapidly adapted to respond to a specific type of pathogen e.g. COVID-19
- **Prototype pathogen** - pathogen groups or families with similar characteristics, against which it is possible to produce prototype DTVs
- **Pull incentives/ funding** - create incentives for private sector engagement by creating viable market demand, paying for “results”
- **Push funding** - incentivising industry via reducing industry’s costs usually during the research and development stages
- **R&D** - Research and Development
- **Randomised controlled trial** - a trial in which subjects are randomly assigned to one of two groups: one (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or control) receiving an alternative (conventional) treatment
- **RDT** - Rapid Diagnostic Test
- **Reagent** - a substance for use in chemical analysis, for instance used in diagnostics to react to the presence of a particular pathogen
- **RECOVERY** - an international trial started in the UK, aiming to identify treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19
- **Risk-sharing** - where the risk of failure is spread more widely, so spreading the potential impact across more actors
- **Rules of the road** - in this report we refer to rules of the road to denote the need to agree different rules of the road in a pandemic so that no time is wasted negotiating the basics. These protocols should form part of a wider suite of guidance WHO sets out (for instance, covering travel and PPE) which must be agreed in advance

and demonstrate a step-change from business as usual when a PHEIC is declared.

- **S7** - the Science Academies of the G7
- **SARS** - Severe Acute Respiratory Syndrome
- **siRNA** - small interfering ribonucleic acid, can be used as a therapeutic to effect “RNA interference” including preventing viral replication
- **Small molecule therapeutics** - chemical compounds typically comprising only 20-100 atoms. These drugs can enter cells easily due to low molecular weight
- **SOLIDARITY** - an international clinical trial to help find an effective treatment for COVID-19, launched by WHO and partners
- **Spring Meetings** - comprised of the joint World Bank-IMF Development Committee and the IMF's International Monetary and Financial Committee events. The World Bank Group and the IMF also organise and host a number of related meetings of groups of country delegations, such as the G20, G-24, Commonwealth, the Civil Society Policy Forum, Brazil, Russia, India, China, and South Africa (BRICS), and other events.
- **SRA** - Stringent Regulatory Authorities are national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as defined by WHO
- **Standardised assays** - an assay is an analytical procedure, in this report referring to determining the efficacy of therapeutics and vaccines through clinical trials. Standardisation refers to the use of common assays across countries, regulators or companies so that the results are directly comparable
- **Structural biology** - a branch of biology focused on the molecular structure of biological substances. In this report referring to its use to define likely common surface protein targets or enzyme targets, so as to aid in the development of prototype vaccines and therapeutics
- **Surface protein vaccine target** - the process of identifying the target proteins of a virus to generate an immune response
- **Synthetic vaccine technology** - such as mRNA, contains a synthetic strand of genetic code to prime the immune system
- **Technology transfer** - in this report, referring to the complex process of transferring the knowledge, physical objects, skills and technology management required to manufacture DTVs with a particular emphasis on the challenges and complexity of vaccine manufacturing technology transfer
- **The Global Fund** - an international financing and partnership organisation accelerating the end of AIDS, tuberculosis and malaria as epidemics
- **The Good Clinical Trials Collaborative** - a partnership launched in June 2020 to develop guidance to enable and promote informative, ethical

and efficient randomised controlled clinical trials

- **Therapeutics** - the branch of medicine concerned with the treatment of disease and the action of remedial agents. Commonly referred to a medicines or treatments
- **TPP** - Target Product Profile, outlines the desired profile or characteristics of a target product that is aimed at a particular disease or diseases, often set out by regulators and WHO
- **UK COVID-19 Therapeutics Advisory Panel** - an independent group of experts that advise on what treatments should be proposed for testing in clinical trials
- **UMICs** - Upper-Middle-Income Countries
- **UNEP** - UN Environment Programme
- **UNITAID** - international organisation that invests in new ways to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria.
- **VACCELERATE** - a clinical research network for the coordination and conduct of COVID-19 vaccine trials in Europe
- **Vaccine** - A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease
- **Viral families** - the taxonomy of different viruses, classified according to characteristics
- **Viral phenotyping** - the phenotype of a virus describes its physical features or structures which can be observed. It is a way to measure or predict how effective a new antiviral therapeutic or vaccine might be. Currently, it is used mostly in research for HIV treatments
- **Viral vector vaccine** - these vaccines use the body's own cells to produce antigen. They do this by using a modified virus (the vector) to deliver genetic code for antigen into human cells. By infecting cells and instructing them to make large amounts of antigen, which then trigger an immune response, the vaccine mimics what happens during natural infection with certain pathogens - especially viruses
- **Virus** - a submicroscopic infectious agent that replicates only inside the living cells of an organism
- **WHA** - World Health Assembly, the decision-making body of the World Health Organisation
- **WHO** - UN World Health Organisation, dealing with major health issues around the world. Sets standards for disease control, healthcare, and medicines; conducts education and research programs; and, publishes scientific papers and reports
- **WHO priority pathogens** - a global priority pathogens list of antibiotic-resistant bacteria, developed by WHO to help in prioritising the research and development of new and effective antibiotic treatments
- **World Economic Forum** - international organisation that brings together its membership of political and business leaders on a yearly basis to discuss major issues concerning the world political economy.
- **Zoonotic disease** - (also known as zoonoses) are caused by pathogens that spread between animals and humans

Notes



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