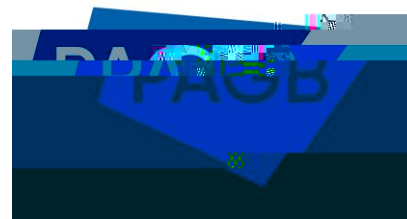


# Life Sciences Recovery Roadmap

3<sup>rd</sup> June 2020

A joint report to the Life Sciences COVID-19 Response Group



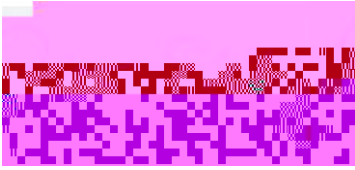
## Executive Summary

The Life Sciences COVID-19 Response Group was established in March 2020 and is co-Chaired by Lord Bethell and Nadhim Zahawi MP. This paper has been jointly developed by the Association of British HealthTech Industries (ABHI); the Association of the British Pharmaceutical Industry (ABPI); the Association of Medical Research Charities (AMRC); the British Generic Manufacturers Association (BGMA); the BioIndustry Association (BIA); the British In Vitro Diagnostic Association (BIVDA) and the Proprietary Association of Great Britain (PAGB) to provide this group with an overview of the key issues for the sector as we look towards recovery and building a new partnership between the Life Sciences sector, Government and NHS.

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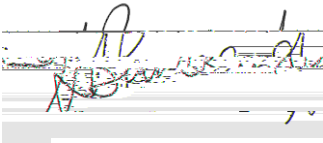




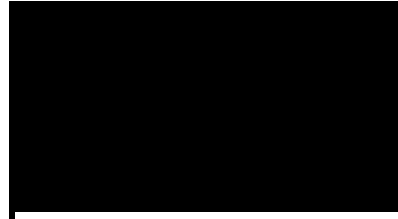
Peter Ellingworth  
Chief Executive, ABHI



Richard Torbett  
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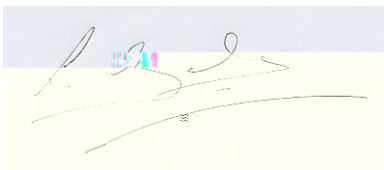
Warwick Smith  
Director General, BGMA



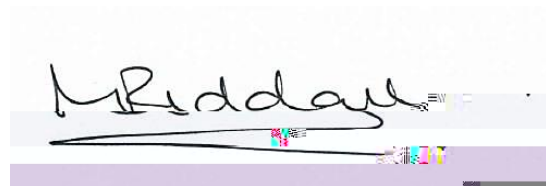
Steve Bates  
Chief Executive Officer, BIA



Doris-Ann Williams  
Chief Executive, BIVDA



Leslie Galloway  
Chairman, EMIG



Michelle Riddalls  
Chief Executive Officer, PAGB

**Introduction**



surgery could be delayed for 3+ months, on top of existing waiting list delays. In the case of orthopaedic patients, a 3-month pause will add around 48,000 joint replacement patients to the waiting list and may also lead to deterioration and reduced outcomes. There will be particular issues with some interventions, such as dentistry, where the aerosol risk is high. Access to appropriate PPE and guidance on working procedures will be critical and the appropriate royal colleges and professional societies should take a lead role in establishing protocols. In some areas there may be a need for

represents a considerable task for an already stretched system, and an area where industry can provide extensive support, working with the Health Data Research UK Hubs and the Academic Health Science Networks (AHSNs).

### **Next steps**

**Strategic Partnership.** The Life Sciences sector should be viewed as a key partner working with Government and NHS leadership to restore services, develop system resilience and support delivery



## **2. Supply Chain Resilience and Manufacturing**

**Objectives:**

implementable. Strengthening supply chain resilience is critical: the UK cannot produce thousands of medicines; and where UK-based manufacturing is in operation, it will remain reliant on raw materials and components from across the globe. The strategy should aim to support increasing diversity of supply and flexibility in capacity, enabling manufacturers to manage international inventories, particularly after the EU exit

on an agreed list of critical medicines and devices. Vaccine stockpiles could be updated every year to match circulating strains. Additionally, stockpiles could be developed or extended for adjuvants as

### 3. Life Sciences Research

**Objectives:**

**Restart:** Resumption of paused research, including clinical trials, carried out by charity, academic and industry partners.

**What changes do we need to maintain and establish?**

**Evaluation of adaptations applied during the COVID-19 pandemic.**

-COVID-19 economic and social recovery, we propose a government-charity co-investment scheme that provides a level of match funding from Government for future charity research over the next three years via a Life Sciences-Charity Partnerships Fund.

### **Next steps**

The Clinical Research Working Group (CRWG) under the Life Sciences Council structure, has the necessary expertise to play a central role in evaluating lessons learnt and advising the development, implementation and monitoring of the recovery plan for clinical research. This should be supported by the work of the MRC-NIHR Trials Methodology Research Partnership. Life Sciences Industrial Strategy recommendations for R&D should continue to be prioritised for implementation.

The Government should commit to prioritise Life Sciences in future trade negotiations to maintain the UK as a global hub for Life Sciences innovation and should develop trade deals that allow this innovation the g

## 4. Innovative approach to regulation

### Objectives:

**Restart:** Evaluate and retain positive regulatory flexibilities introduced during the COVID-19 pandemic.

**Renew:** Develop a strategy to introduce additional regulatory flexibilities that increase efficiency, remove avoidable burdens and support Life Sciences investment after the EU exit transition period.

### The response to COVID-19

The rapid introduction of regulatory flexibilities has been critical to supporting the response to the COVID-19 pandemic. The MHRA has been swift to adopt a collaborative approach with industry during this iterative process. The use of real-time safety data by regulators and industry has helped to identify opportunities and to put them rapidly in place while retaining a strong focus on patient safety.

**Temporary regulatory flexibilities introduced.** Temporary regulatory flexibilities have been put in place to support the Life Sciences sector to respond at speed to the COVID-19 pandemic.

**Global regulatory cooperation.** The COVID-19 pandemic has seen global regulatory authorities collaborate via the International Coalition of Medicines Regulatory Authorities (ICMRA) on a set of common principles to ease the introduction of therapies to treat the disease whilst a vaccine is being

Agreements with other global regulators to assess benefit-risk, facilitate sound and transparent decision-making and avoid creating overlapping processes or requirements. A regulatory framework that rapidly makes medicines and medical technologies available to UK patients will also improve the attractiveness of the UK to Life Sciences companies.

**New regulatory responses for emerging threats.** Building on the collaboration across global regulatory authorities, the UK can benefit from work-sharing opportunities across national competent authorities (NCAs) in line with sovereignty of decision-making. This could produce an interactive, fast but rigorous system. This mechanism should be maintained beyond management of the current pandemic and can become an established collaborative pathway to address new emerging threats (such as anti-microbial resistance), future pandemics or common unmet clinical needs.

**The** The Bill is welcomed as it gives the UK power to update/revise regulatory directives as needed. Following its passing, the Bill should reflect the innovative regulatory approaches introduced by the MHRA in secondary legislation.

### **Next steps**

The Health Technologies and Pharmaceuticals (HTP) Programme, the Life Sciences Council Clinical Research Working Group (CRWG) and the MHRA Industry Liaison Group should take forward an analysis of the above recommendations.



## 5. Patient access to COVID-19 vaccines, treatments and diagnostics

### Objectives:

**Restart:** Closer engagement and alignment between DHSC, NIHR, MHRA, HRA, NICE, NHSE and the Life Sciences sector to capitalise on new opportunities identified across regulation, manufacturing, health technology assessment and commissioning.

**Renew:** Develop a multi-agency, cross-sector strategy to maximise patient access to future COVID-19 treatments, vaccines and diagnostics.

### The response to COVID-19

**Development of vaccines and treatments.** A key focus of the UK Life Sciences sector during the pandemic has been participation in the global effort to develop vaccines, treatments and diagnostics for COVID-19. One treatment and several antibody tests have now been approved for use in the UK, and investigations into further repurposing of existing medicines and

**Rapid evolution of NICE methods.** The production of rapid NICE guidance offers a powerful route to deliver rapid re-start of clinical procedures as the height of the COVID-19 pandemic passes, enabling consistency in delivery of care across the country and reducing inequalities. The learning from the COVID-19 response should be factored into a rapid evolution of NICE methods to support patients getting faster access to new treatments. This is an opportunity to be ambitious in what NICE seeks to achieve through the methods review, to truly future-proof HTA in England for COVID-19 and non-COVID-19 medicines. NICE has de-prioritised some engagement processes in relation to non-COVID-19, non-cancer treatments and it will be important for evaluations to restart alongside the continuation of the NICE Methods Review. A more flexible approach to technology assessment enabli-

## Workforce

### Objectives:

**Restart:** Supporting the NHS and Life Sciences workforce to return to work safely.

**Renew:** Develop and resource skills development programmes to meet NHS and life science sector workforce priorities, together with a renewed focus on the Science Industry Partnership (SIP) 2030

### The response to COVID-19

**Sharing of expertise.** The skills and experience of the Life Sciences sector workforce have been essential in supporting the NHS and Government to respond to the COVID-19 pandemic. From scientific and manufacturing expertise, to medical and clinical staff, employees in the Life Sciences sector have worked in partnership to support the national effort to combat COVID-19.

**Maintaining manufacturing and research capabilities.** The Life Sciences sector has continued to operate manufacturing and research facilities throughout the period of the pandemic, operating social distancing measures and implementing new practices to protect the health of staff. This has been critical t50 g0 GRw3BT/F7



## 6. Global Trade and Supporting UK Exports

### Objectives:

**Restart:** the global sales pitch for the UK as a prime location for life science investment into research, development and manufacturing.

**Renew:** Commitment by the Government to Life Sciences and biomedical innovation at the heart of as a future engine of economic growth.

### The response to COVID-19

**Appendix 1: Supporting delivery of the NHS Long Term Plan**

**Respiratory Disease:**

- Development of enhanced patient education tools to reduce cultural and health literacy challenges in collaboration with NHSE-I and patient organisations
- Industry and patient organisations routinely integrated into working groups developing self-care

## References

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<sup>ii</sup><https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/second-phase-of-nhs-response-to-covid-19-letter-to-chief-execs-29-april-2020.pdf>

<sup>iii</sup> <https://www.pagb.co.uk/policy/self-care-white-paper/>

<sup>iv</sup><https://www.theguardian.com/society/2020/apr/29/extra-18000-cancer-patients-in-england-could-die-in-next-year-study>

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<sup>vi</sup> Features of 16,749 hospitalised UK patients with COVID-19 using the ISARIC WHO Clinical Characterisation Protocol (Preprint article published 28 April 2020 as part of a study funded by UKRI

<sup>vii</sup> <https://www.england.nhs.uk/publication/type-1-and-type-2-diabetes-and-covid-19-related-mortality-in-england/>

<sup>viii</sup> Export and hoarding of restricted medicines, <https://www.gov.uk/guidance/parallel-export-and-hoarding-of-restricted-medicines>

<sup>ix</sup> MedCity SME [survey](#), April 20<sup>th</sup> 2020, 54 SME respondents. Conducted by One Nucleus and SEHTA

<sup>x</sup> <https://www.nihr.ac.uk/documents/qanda-on-the-impact-of-covid-19-on-research-funded-or-supported-by-nihr/24467>