As set out below in response to specific recommendations, many of these regulatory updates will allow MHRA to achieve the aims of the report's recommendations. The government is aiming for core aspects of the future regime for medical devices to apply from 2025.

Identifying and implementing solutions for any ongoing areas of concern will be a broad task and require system-wide collaboration. We welcome future relevant work and initiatives in this complex and multidisciplinary field - be that ongoing work on polygenic risk scores, the development of appropriate integrated data systems, or other new and innovative technologies.

In this response, we highlight the government action backing the overarching principal of the report: all parties - manufacturers, regulators and healthcare systems across the world - will need to work together to tackle and prevent unfair biases occurring in the design and use of medical devices.

Summary of the government response to each of the recommendations

Recommendation 1

Regulators, developers, manufacturers and healthcare professionals should take immediate mitigation actions to ensure existing pulse oximeter devices in the NHS can be used safely and equitably for all patient groups across the range of skin tones.

Government response

The government is committed to ensuring that pulse oximeters are safe and effective for all patients. Work is already underway to mitigate any inaccuracy in these devices,

fulfilling many of this recommendation's sub-recommendations.

Recommendation 2

MHRA and approved bodies for medical devices should strengthen the standards for approval of new pulse oximeter devices to include sufficient clinical data to demonstrate accuracy overall and in groups with darker skin tones. Greater population representativeness in testing and calibration of devices should be stipulated.

Government response

MHRA has a new validation process for clinical investigations in the UK that requests applicants demonstrate how they intend to address bias, in response to the commissioning of the equity in medical devices: independent review.

Other strands of work by MHRA in this area include creating joint diversity and inclusion guidance with the Health Research Authority (HRA) and contributing internationally to updating the International Organization for Standardization (ISO) 80601-2-61:2017 standard.

Recommendation 3

Innovators, researchers and manufacturers should co-operate with public and patient participants to design better, smarter oximeters using innovative technologies to produce devices that are not biased by skin tone.

Government response

The National Institute for Health and Care Research (NIHR) ensures patients and the public are involved in all aspects of the research process. NIHR welcomes funding