MEMORANDUM OF COOPERATION IN THE FIELD OF HEALTH INNOVATION BETWEEN THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN AND THE DEPARTMENT OF HEALTH AND SOCIAL CARE OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

The Ministry of Health, Labour and Welfare of Japan and the Department of Health and Social Care of the United Kingdom of Great Britain and Northern Ireland (individually referred to as a "Participant" and collectively referred to as "Participants");

DESIRING to strengthen the cooperative relationship between the two countries to benefit their people and to create an effective ecosystem for healthcare innovation between the Participants on the basis of mutual interest in strengthening health security and promoting universal health coverage;

ACKNOWLEDGING that the Hiroshima Accord: An Enhanced UK-Japan Global Strategic Partnership commits to broaden the health science and innovation partnership through continuous dialogues between the two countries to tackle shared future challenges;

RECOGNISING that the two countries have complementary goals in the areas of health innovation, including translational, clinical, and applied health and care research, international regulatory harmonization, strengthening clinical trials standards, and deploying innovative technologies in healthcare such as genomics and artificial intelligence;

PURSUANT to prevailing laws, regulations, policies, and standards of ethical conduct in their respective countries;

Have jointly decided as follows:

Paragraph 1 Objective

The objective of this Memorandum of Cooperation (hereinafter referred to as "this MOC") is to strengthen cooperation and explore new opportunities in the field of health research and innovation between the Participants and their respective institutions (the "Objective").

Paragraph 2 Implementation and Governance

- 1. To implement this MOC, when relevant, the Participants intend to involve relevant public entities and services, including but not limited to the National Institute for Health and Care Research, Medical Research Council, NHS England and the NHS Genomic Medicine Service, Office for Life Sciences, Genomics England Ltd, UK Medicines and Healthcare products Regulatory Agency, the six national centres in Japan (National Cancer Center, National Cerebral and Cardiovascular Center, National Center of Neurology and Psychiatry, National Center for Global Health and Medicine, National Center for Child Health and Development, National Center for Geriatrics and Gerontology), Japan Agency for Medical Research and Development, the institute for health security of Japan (to be established after 2025), and relevant entities of the whole genome project in Japan, in the development of joint activities.
- 2. The Participants may approve additional implementing arrangements, as appropriate, to implement this MOC. The implementing arrangements may set out inter alia, projects, duration, funding, general conditions of the cooperative activities, personnel involved and other related matters.
- 3. The Participants will designate a point of contact (the "Contact Point"). The Contact Point will serve as the primary coordinator of information and activities between the Participants.
- 4. Ministerial representatives of each Participant will provide strategic oversight and direction, as necessary, through the Health Dialogue.

Paragraph 3 Areas of Cooperation

- 1. To deliver the objective of this MOC, the Participants work together to promote cooperation in the following areas of mutual interest:
 - Health and care research develop and launch a jointly-funded partnership on translational, clinical and applied health and care research by 2025, which could include research collaboration focused on dementia, ageing and other neurodegenerative diseases; cancer; lifestyle related diseases; and genomics and rare diseases;
 - b. Clinical trials cooperate on joint clinical trials including trials based on genomic information and promote clinical trials that are well-designed and well-implemented, aligned with the best practices defined by the WHA 75.8 resolution on 'Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination';
 - c. Genomic medicine mutually support, exchange information and share best practice on systems, standards and processes for genomics programmes aimed at improving healthcare outcomes, to accelerate learning and translation of research into practice;
 - d. Digital health policy cooperate on digitally-enabled care to support ageing populations; evaluation, development and deployment of artificial intelligence;

interoperability of digital health solutions; health data challenges; inclusion of digital health services;

- e. Medicines and medical products regulatory harmonization cooperate towards the UK's 2023 international recognition framework, enabling quicker access to innovative medical products approved in Japan; and
- f. Antimicrobial resistance (AMR) exchange best practice and align vision on the development and deployment of pull incentives to create a sustainable innovation ecosystem for AMR medical countermeasures and work together to achieve progress on AMR through the multilateral fora.
- 2. Additional areas of cooperation
 - a. The Participants will encourage cooperation as per the future renewal of the Memorandum of Cooperation between the UK Health Security Agency and the Ministry of Health, Labour and Welfare of Japan.
 - b. The Participants may pursue, upon mutual written consent, additional cooperation in the healthcare sector.

Paragraph 4 Methods of Cooperation

- 1. The cooperation in the framework of this MOC will be conducted in the following forms:
 - a. Exchange of information, knowledge and technology on the areas of cooperation;
 - b. Exchange of delegations, experts and other officials;
 - c. Participation in congresses, conferences or other events held jointly or by one of the Participants;
 - d. Execution of joint projects and training, including those requiring joint financial resources;
 - e. Promotion of direct communication and cooperation between government departments and ministries, government agencies, research institutes, private companies and other relevant entities of the two countries;
 - f. Additional methods for cooperation in the healthcare sector, upon mutual written consent.

Paragraph 5 Financial Considerations

- 1. The implementation of cooperation activities under this MOC will be subject to the availability of financial and human resources of each Participant.
- 2. Each Participant will bear its own costs in implementing this MOC. Where financial commitments, cooperation or co-funding are jointly decided by the Participants as necessary under this MOC, then the Participant(s) will create a separate arrangement.

Paragraph 6 Resolution

Any differences concerning the interpretation or implementation of this MOC will be resolved amicably and in good faith by consultations between the Participants and will not be referred to any national or international tribunal. Participants may consult each other at any time to address any matter related to the interpretation or implementation of the MOC.

Paragraph 7 Data sharing and protection

- 1. All information shared or produced by the Participants under this MOC will be classified as confidential and will not be disclosed to third parties, without the prior written consent of the Participant from which it originated.
- 2. The Participants do not intend to exchange, under this MOC, personal information and data. Each Participant will endeavour to protect and maintain the confidentiality and integrity of any data or information communicated to it under this MOC, subject to overriding statutory or other legal obligations. The Participants acknowledge that each may be obliged to disclose information under respective national legislation governing access to information and international obligations that may require disclosure of such information.
- 3. Where data or information needs to be shared, this will only be done under a separate data sharing arrangement between the Participants and after an appropriate data protection impact assessment has been conducted.

Paragraph 8 Intellectual Property

- 1. Each Participant will respect intellectual property rights (IPR) of the other Participant consistent with the domestic laws, rules, and regulations concerning IPR in force in their respective countries and international agreements to which their respective countries are participants and in line with further arrangements made between the Participants.
- 2. Any IPR created by a Participant independently of the activities under this MOC whether before, during or after the term of this MOC, will remain the property of the Participant that created it. However, the Participant will ensure that the IPR has not infringed the IPR of any third party in respect of the ownership and legality of the use of the IPR, which is brought in by the Participant for the implementation of activities under this MOC.
- 3. Both Participants will be allowed to use any outcome, data and information resulting from activities conducted under this MOC for non-commercial purposes only, free of royalty despite which Participant owns the IPR.

Paragraph 9 General

- 1. This MOC will come into operation on the day of its signature by both Participants and will remain in operation for a period of five (5) years.
- 2. This MOC will automatically renew for another five (5) years, unless either Participant gives the other Participant written notice of its intention to discontinue this MOC at least six (6) months prior to the intended date of its discontinuation.

- 3. Revisions and supplements may be introduced to this MOC by mutual written consent of the Participants.
- 4. The discontinuation of this MOC will not affect any cooperative projects and initiatives approved prior to discontinuation, unless otherwise decided in writing by the Participants.
- 5. This MOC serves only as a record of the Participants' intentions to carry out collaborative and cooperative activities on the basis of the shared recognition set out herein. This MOC does not, and does not intend to, constitute, or create obligations under domestic or international law, will not give rise to any legal process, and will not be deemed to constitute or create any legally binding or enforceable obligations express or implied.
- 6. All activities conducted under this MOC will be carried out in accordance with the Participants' respective domestic laws, international laws, regulations, and international agreements to which their respective countries are both parties.

IN WITNESS WHEREOF, the undersigned have **SIGNED** in two duplicates in Tokyo, Japan, on the 4 December in the year 2024 in the English language. In case of any divergences on the interpretation of this MOC, the English text will prevail.

FOR THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN FOR THE DEPARTMENT OF HEALTH AND SOCIAL CARE OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

SAKOI Masami Vice-Minister for Health and Chief Medical Officer and Global Health Officer Sir Chris Wormald Permanent Secretary