

MEMORANDUM OF UNDERSTANDING

BETWEEN

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

AND

CENTERS FOR MEDICARE & MEDICAID SERVICES

AND

ISIS INNOVATION LTD.

This Memorandum of Understanding (MoU) memorializes the shared expectations of the Office of the National Coordinator for Health Information Technology (ONC), a Staff Division within the Office of the Secretary for the U.S Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), an Operating Division within HHS, and Isis Innovation Ltd., the research and technology commercialisation company of the University of Oxford, and operating (in relation to this MoU) under the activity called “iOutcomes”, a business activity within Isis Innovation Ltd. dedicated to the provision and support of health questionnaires (iOutcomes) (the “Parties”) to provide Medicare or Medicaid enrolled providers participating in any Centers for Medicare & Medicaid Services quality program access to the health outcomes questionnaires titled, “the Oxford Hip Score”(OHS) and “the Oxford Knee Score”(OKS).

This MoU was entered into pursuant to a 2014 MoU between HHS, the Secretary of State for Health, NHS England, and the Health and Social Care Information Centre (hereafter referred to as the US & UK MoU) that described a collaboration to share common values across health information and health data. In particular, the signatories recognized the importance of the development of clinical outcome measures, standard harmonization and increased interoperability.

In furtherance of the US & UK MOU, HHS identified that the OHS and OKS had empirical support – both longitudinally and across the world – but were not freely accessible to “Program Members” as defined below. To enable such accessibility, HHS initiated discussions with iOutcomes (representing the University of Oxford) to make such tools available.

1. This MoU uses the following definitions:

- a. “Program Members” are defined as Medicare or Medicaid enrolled providers participating in any CMS quality program.
- b. “Questionnaires” are defined as the OHS and OKS health outcomes questionnaires.
- c. “Intended Use” is defined as strictly limited to where the Questionnaires and the Questionnaires’ results will only be used to participate in any CMS quality program or for publication in peer-reviewed journals.

2. The Parties anticipate that iOutcomes will:

- a. provide a royalty free license to the Questionnaires to Program Members solely for the Intended Use; and

- b. make available a web-based portal that grants access to the Program Members to use or download the PDF or Word versions of the Questionnaires, scoring guides and other support materials as deemed appropriate by iOutcomes solely for the Intended Use.
- 3. The Parties anticipate that ONC and CMS, in collaboration with other divisions of HHS as applicable, will:
 - a. make available through respective website(s) accessible to Program Members information about the availability of the Questionnaires for the Intended Use;
 - b. provide access to subject matter experts within ONC and CMS to assist iOutcomes personnel and/or University of Oxford researchers to facilitate the connection of the Questionnaires to relevant health data standards, such as standard terminologies, needed to promote compatibility of Questionnaire data with interoperable health records technology as deployed in the United States; and
 - c. facilitate feedback to iOutcomes from US-based organizations that use the health outcomes questionnaires.
- 4. This MoU is not intended to create legally binding obligations, under domestic law of any nation or under international law. All activities undertaken pursuant to this MoU are at the discretion of each of the Parties and are subject to applicable laws and regulations that may govern a given Party. Activities of ONC, CMS or other divisions of HHS that may be undertaken pursuant or related to this MoU are subject to the availability of appropriated funds. HHS divisions participate in this MoU and activities hereunder pursuant to Section 301 of the Public Health Service Act.
- 5. This document does not replace existing business plans, reporting systems or accountability lines of any Party and does not preclude engagement of the Parties in additional activities authorized pursuant to applicable legal authorities.
- 6. The MoU is effective from the date of the signature of each Party, and is intended to continue for a period of three (3) years unless discontinued by any Party. A Party or Parties wishing to discontinue this MoU should provide written notice to the other(s). A review of the experience of Parties with activities pursuant to the MoU, if not conducted sooner by mutual consent of the Parties, is anticipated near the end of the three (3) years.
- 7. The MoU may be modified at any time by mutual written consent of the Parties. Following the initial 3-year period, the MoU may be renewed for additional periods of one year.

Signed in duplicate at Washington, DC and Oxford, UK, respectively, on dates indicated below.

_____ /S/ P. Jon White MD Deputy National Coordinator Office of the National Coordinator for Health Information Technology U.S. Department of Health and Human Services	_____ Date
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_____ /S/ Kate Goodrich, MD Director, Center for Clinical Standards and Quality Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services	_____ Date
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_____/S/_____
Linda Naylor
Managing Director
Isis Innovation Ltd.

Date