Memorandum of Understanding

between

THE CLINICAL PRACTICE RESEARCH DATALINK

And

THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

relating to

CPRD research services and production and supply of a dataset from CPRD for use in a Study

THIS MEMORANDUM OF UNDERSTANDING dated 26 February 2021

IS BETWEEN THE PARTIES:

(1) **THE CLINICAL PRACTICE RESEARCH DATALINK CENTRE** part of the MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY of 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom (on behalf of THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (acting as part of the Crown) (**"CPRD"**); and

(2) **The National Institute for Health and Care Excellence**, of Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BT (on behalf of THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE) acting as part of the Crown ("**NICE**").

1. BACKGROUND:

1.1 CPRD is an Executive Agency of the Department of Health and Social Care and has developed, controls and/or has rights to the CPRD Database, Dataset and Link Data.

1.2 NICE is an Executive Agency of the Department of Health and Social Care and desires access to the Dataset to conduct the Study, which shall be conducted in accordance with, subject to approval by ISAC, the Protocol.

1.3 CPRD has agreed to produce the Dataset for NICE and to provide research advisory support in connection with the Protocol and the Study and contribute to any Publication(s) arising from this study in accordance with the terms set out in this MOU. The Parties wish to record the basis on which they will collaborate with each other in connection with such matters.

1.4 The purpose of this MOU is to clearly identify the roles and responsibilities of each Party as they relate to the delivery of the Dataset and the research advisory support. This MOU is not a contract nor is it legally binding.

2. Interpretation

2.1 In this MOU, including in the recitals above and unless the context otherwise requires, the following expressions shall have the following meanings:

Analysis Data	Means any data or datasets derived from the CPRD Data and used for statistical analyses and to prepare any Study Results and which include only those variables (exposure(s), outcome(s), covariate(s) that are justified in the Protocol and used for the analysis as outlined in the Protocol for the Study;
Anonymised Healthcare Records	Means Data from which a patient cannot be identified by the recipient of the information;

Authorised User	Means an individual who is named in the Protocol or who is required to access and/or process the Dataset for the purpose of the Study and is a director, officer, employee of NICE;
Certificate of Destruction	Means a certificate signed by an authorised representative of NICE or specialist third party engaged to securely destroy the Dataset, which certifies that the Dataset and all hard and soft copies thereof held by NICE have been securely and permanently destroyed;
Chief Investigator	Means the individual identified as chief investigator in the Protocol and which individual shall be a direct employee of NICE;
Confidential Information	Means the Dataset and any technical or commercial information disclosed by one Party to the other and identified as confidential before or at the time of disclosure, regardless of whether the Confidential Information is marked as 'confidential' before or at the time of disclosure;
CPRD Database	Means an electronic database and all associated database build components and functions including algorithms of Anonymised Healthcare Records of general practitioners from across the United Kingdom collected, aggregated and developed by CPRD and as may be amended or updated with Data by CPRD from time to time;
Data	Means patient level records obtained from contributing general medical practices through EMIS and Vision software or other sources, including but not limited to hospitals, as are contained in the CPRD Database or Link Data;
Data Breach	Means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the Dataset;
Dataset	Means the extracts (including any updates), or part thereof, of the Data (including CPRD developed algorithms and any other functional database design or build components or tools) to be supplied by CPRD to NICE under this MOU as described in Schedule 3 including, without limitation, any copies, back-up copies and disaster recovery copies thereof and any sample or evaluative Data released to NICE at any time whatsoever to enable data specification, feasibility or for any other purpose;
Delivery Date	Means the date on which CPRD delivers the Dataset to NICE;

Dictionaries	Means those dictionaries provided by CPRD including the CPRD medical dictionary (including the MedDRA terminology) and the CPRD drugs dictionary;
Documentation	Means the operating manuals, user instructions and other related materials which CPRD may supply (whether physically or by electronic means) for aiding use of the Dataset;
Execution Date	Means the date this MOU is executed and comes into effect which shall be the date a duly authorised signatory of CPRD signs this MOU;
Field	Means population-based studies in health outcomes, drug safety, health economics, drug utilisation, public health research, drug formulary research and disease management, or such other purposes as are authorised by CPRD;
Fee	Means the fee payable by NICE as further set out in Schedule 3;
GDPR	Means the General Data Protection Regulation (Regulation (EU) 2016/679);
Incident Report	Means the information provided in a report as outlined in Schedule 2 and as may be updated by CPRD from time to time;
ISAC	Means the Independent Scientific Advisory Committee for MHRA Database Research or any successor body nominated by CPRD to review the scientific acceptability of studies;
Link Data	Means Data owned or controlled by the Link Data Owner(s) which can be linked at a patient level to the CPRD Database including but not limited to HES Data, Index of Multiple Deprivation data, Mental Health Services Data, ONS Data, PROMs Data Mother-Baby Link, Pregnancy Register, Rural Urban Classification Data and Cancer Data;

Link Data Owner(s)	Means the owner or (insofar as the Link Data constitutes Personal Data) the Data Controller of the Link Data, which: (a) in the case of HES Data, Mental Health Services Data and PROMs Data is HSCIC; (b) in the case of Index of Multiple Deprivation data is the Department for Communities and Local Government; (c) in the case of Cancer Data is PHE; and (d) in the case of ONS Data is ONS; (e) in the case of Mother-Baby Link and Pregnancy Register is CPRD; and in the case of Rural Urban Classification Data is ONS, or the Scottish Government or the Northern Ireland Statistics and Research Agency
Mental Health Services Data	Means the Mental Health Services Data Set supplied by HSCIC and containing record-level data about the care of children, young people and adults who are in contact with mental health, learning disabilities or autism spectrum disorder services;
Mother-Baby Link	Means an algorithm to identify people within the same family in the CPRD Database through a practice-specific family number;
MOU	Means this entire document, including its Schedules, as may be amended from time to time in accordance with clause 16.1;
ONS	Means the Office for National Statistics;
ONS Data	Means Townsend Score deprivation data and mortality data supplied by ONS which includes information on official date and causes of death using ICD-10 codes;
OPCS	Means OPCS-4 ‘Read codes’ which may be included with or incorporated within Linked Data;
Parties	Means CPRD and NICE or their successors in title, each of the Parties being referred to individually as a “Party”;
Personal Data	Shall have the same meaning as set out in the GDPR;

Personnel	Means all directors, officers, employees, agents, consultants and contractors of NICE, as the case may be, and who in the case of those directors, officers, employees, agents, consultants and contractors of NICE who will access the Dataset and who also be Authorised Users under this MOU;
Publication	Means any dissemination by NICE of the results or any other outcomes of the Study whether electronically or in print or any other form, including but not limited to any poster, presentation, abstract peer-reviewed journal article, book, online publication or similar;
PHE	Means Public Health England;
Pregnancy Register	Means a register identifying pregnancy episodes other pregnancy data within the CPRD Database;
PROMs Data	Means Patient Reported Outcome Measures Data capturing health-related quality of life, symptoms and other general information on common elective surgical procedures performed in the English NHS. These include data on groin hernia operations, hip and knee replacements and varicose vein repair;
Protocol	Means the study proposal document set out in Schedule 3 and subsequently the full study protocol to be developed by the Parties and which protocol, upon approval by ISAC, shall also be incorporated under Schedule 3 of this MOU as a separate document and in accordance with which protocol the Study shall be conducted;
Research	Means any investigation conducted by an Authorised User using patient level information which satisfies all of the following: (i) has the intent to answer a specific scientific question or hypothesis, (ii) is intended to benefit public health and/or advance medical science, (iii) is undertaken using a structured methodology set out in a protocol subject to appropriate ethical and scientific review and approval (iv) is intended for publication in the public domain or is of a publishable standard following peer review, via web based publication or through provision of research findings to a regulator;
Study Timelines, Responsibilities and Deliverables	Means as set out in Schedule 3;
Study	Means the single Research study in the Field as described in the Protocol only;

Term	Means the period from the Execution Date to twelve (12) months from the Delivery Date, unless: (a) such period is extended at NICE's request (such request having been received by CPRD at least two (2) months prior to the initial expiration date) and CPRD (in its sole discretion) having agreed to such extension request; or this MOU is terminated early in accordance with clause 13;
Territory	Means the UK;
UK Licensing Authority	Means the UK Medicines and Healthcare products Regulatory Agency; and
Working Day	Means any day other than a Saturday, Sunday or public holiday in England and Wales.

CPRD's RESPONSIBILITIES UNDER THIS MOU:

3. Supply of Dataset, Documentation and Dictionaries

In accordance with the terms of this MOU, CPRD will produce and supply:

3.1 the Dataset to NICE within thirty (30) Working Days from the date the data specification is agreed, unless agreed otherwise.

3.2 The Parties will conduct the Study in accordance with Protocol and work in good faith together to deliver their respective Study Milestones, Responsibilities and Deliverables as set out in Schedule 3.

NICE shall inform CPRD by way of a notice within fourteen (14) days of the Delivery Date if it considers that any modification needs to be made to the Dataset in order to conduct the Study, including the reasons for any such requested modification. CPRD shall review any such request for modification and, at CPRD's sole discretion, shall modify the Dataset and re-deliver it to NICE within such period as the Parties may agree in writing.

4. Invoicing

4.1 CPRD agrees to send invoices for the Fee and any other fee to NICE at the following address:

[redacted]

4.2 CPRD agrees to provide NICE with an invoice for the Fee within thirty (30) days of the Delivery Date.

NICE's RESPONSIBILITIES UNDER THIS MOU:

5. Use of the Dataset and results of the Study

5.1 NICE agrees to solely use the Dataset and Documentation and Dictionaries to conduct the Study in the Territory during the Term.

5.2 In using the Dataset NICE agrees to adhere to statutory requirements and best practice and comply with applicable laws and standards including data protection and freedom of information legislation.

5.3 NICE agrees to inform CPRD by way of a notice within fourteen (14) days of the Delivery Date and any subsequent delivery date if it considers that any modification needs to be made to the Dataset in order to conduct the Study, including the reasons for any such requested modification.

5.4 NICE shall ensure that their Authorised Users who are granted access to the Dataset are aware of, and comply with, the obligations (including confidentiality) and any restrictions in respect of the access and use of the Dataset as set out in this MOU.

5.5 NICE shall be responsible for any unauthorised disclosure of the Dataset made by any Personnel and shall take all reasonable precautions to prevent such unauthorised disclosure.

5.6 NICE shall be entitled to make and use copies of the Dataset during the Term and in accordance with the terms of this MOU at as many sites operated by NICE as NICE sees fit throughout the Territory, subject to NICE notifying CPRD, as per clause 15, of the location of each site at which copies of the Dataset are made or used and providing CPRD in each case with an updated Schedule 1 Part B as appropriate.

5.7 NICE agrees not to remove, suppress or modify in any way any proprietary marking, including any trade mark or copyright or database right notice on or in the Dataset or other means by which the Dataset is delivered to NICE or which is visible during the access or use of the Dataset. If NICE copies the Dataset it shall ensure that any such proprietary or rights notices are fully reproduced in any copies.

5.8 NICE agrees to notify CPRD immediately if NICE becomes aware of any unauthorised access to, use or copying of any part of the Dataset by any person.

5.9 NICE shall be free to use the results of the Study after the termination of this MOU or on its expiry for any purpose permitted by and in accordance with this MOU.

6. Restrictions on Use of the Dataset

6.1 NICE agrees not to use or attempt to use the Dataset whether on its own or in conjunction with any other data in any other form, for:

6.1.1 identifying, contacting or targeting patients or any person potentially identifiable from the Dataset and Data; or

6.1.2 identifying, profiling, contacting or targeting general medical practitioners, general medical practices or any other party connected with the Dataset, Data or any other information being supplied to NICE under this MOU

and NICE shall ensure that all reports, papers, statistical tables and any other outcomes or results that are published or released to third parties as a result of the Study and use

of the Dataset cannot be used to identify or enable others to identify patients, contributing general medical practitioners, contributing general medical practices or any other party connected with the Dataset being supplied to NICE. If at any time NICE considers that there is information in the Dataset which could be used to identify any individual, general medical practitioner, general medical practice or any other party connected with the Dataset being supplied to NICE, NICE will inform CPRD immediately in writing by way of a notice delivered in accordance with clause 05 and provide CPRD with an Incident Report.

6.2 NICE agrees not to use or attempt to use the Dataset whether on its own or in conjunction with any other data in any other form, for studying the effectiveness of advertising campaigns or sales forces.

6.3 NICE agrees not to merge the Dataset with other data.

6.4 NICE agrees not to sell, transfer, trade, or otherwise dispose of the Dataset or any part of the Dataset.

6.5 NICE agrees not to permit any third party to access, study, analyse, refer to or otherwise access use the Dataset or any part of the Dataset, or permit any third party whatsoever to reproduce it.

6.6 NICE agrees not to reproduce or modify the Dataset in any way (otherwise than as permitted by this MOU) including for the purpose of creating and/or distributing the Dataset or parts thereof in another database or form.

6.7 NICE agrees not to make any Publication without prior written approval from CPRD.

6.8 Upon the expiry or termination of this MOU NICE agrees not to use the Dataset or parts thereof except under the express instructions of CPRD and NICE will cease to use any back-up copies of the Dataset, subject to the provisions of clause 10 and will not thereafter knowingly access any back-up copies without the prior written consent of CPRD.

7. Data Security Requirements

7.1 Without prejudice to NICE's other obligations in respect of information security, NICE agrees:

7.1.1 having regard to the state of technological development, provide a level of security (including appropriate technical and organisational measures) appropriate to:

7.1.1.1 the harm that might result from unauthorised or unlawful access to or processing of the Dataset or accidental loss, destruction or damage of such Dataset; and

7.1.1.2 the nature of the Dataset;

7.1.2 to ensure that access to the Dataset is limited solely to those Authorised Users who are conducting the Study;

7.1.3 to take all reasonable steps to ensure the reliability of those Authorised Users who have access to the Dataset, which shall include:

7.1.3.1 ensuring all such Authorised Users understand all relevant terms of this MOU, the confidential nature of the Dataset and the potential harm and

personal liabilities under Law that may result from their improper care or use of the Dataset or any subsequent Data Breach;

7.1.3.2 ensuring all such Authorised Users are properly trained in data protection and to ensure that all such Authorised Users have completed such training prior to their access to or use of the Dataset. Where requested to do so NICE shall provide examples of training materials used, together with methodologies used to demonstrate that Authorised Users have understood the training; and

7.1.3.3 ensuring that all such Authorised Users comply with the obligations contained in this MOU and NICE's data protection policy;

7.1.4 to inform CPRD within twenty-four (24) hours of any Data Breach of the Dataset of which it becomes aware, and of the categories of Data and individuals which may be affected in an Incident Report.

7.2 NICE shall ensure, and in case of any uncertainty shall consult with CPRD, that:

7.2.1 it has properly configured access rights for its Authorised Users including a well-defined joiners and leavers process to ensure access rights to the Dataset are properly managed and recorded;

7.2.2 it has proper controls in place to make sure that complex alphanumeric passwords are required for access to the Dataset and that training is provided in relation to the need to keep such passwords secure;

7.2.3 it has in place procedures to identify wrongful use of the Dataset, including the monitoring of wrongful access to the Dataset;

7.2.4 suitable and effective authentication processes are established and used to protect the Dataset;

7.2.5 all back-up copies of the Dataset are subject to such vigorous security procedures as are necessary in order to protect data integrity, such security measures being commensurate to the nature of the data;

7.2.6 electronically transferred copies of the Dataset are encrypted to a standard commensurate to the nature of the data;

7.2.7 that copies of the Dataset stored on laptops or other portable media is encrypted and that NICE maintains an accurate, up to date asset register, including all such portable media used to process the Dataset;

7.2.8 that Authorised Users are not able to access the Dataset from home or via their own electronic device other than through a secure electronic network and that the Dataset may not be stored in such devices;

7.2.9 that suitable physical security measures are established commensurate to the harm that could result from the unlawful disclosure of the Dataset. Such physical security measures shall be as identified in NICE's data protection policy; and

7.2.10 without prejudice to NICE's obligations to CPRD in relation to the disposal of the Dataset, all Data which is disposed of must be disposed of pursuant to NICE's policy for the disposal of data identified in the data protection policy, including the disposal of assets containing Personal Data.

8. Payment of Fee and Invoicing Arrangements

8.1 NICE agrees to pay the Fee and any other fees shall be on receipt of an invoice from CPRD to NICE, with payment due within thirty (30) days of the date of that invoice. Invoices for the Fee will be raised in accordance with the payment schedule set out in Schedule 3.

8.2 If applicable NICE will provide CPRD the relevant purchase order number to be included on the invoice.

8.3 NICE shall, if subject to VAT, pay VAT on the Fee at the rate applicable at the time payment is made and as specified on the CPRD invoice.

9. Changes to the Study

9.1 If during the Term NICE wishes to alter the Study in any way NICE shall give notice of the proposed changes to CPRD delivered in accordance with clause 05.

9.2 If the proposed changes fall outside the scope of the Protocol, including a change to the Chief Investigator as identified in the Protocol, NICE shall re-submit the revised Protocol to ISAC for review. The Term shall be suspended pending ISAC's decision on the changes to the Study. ISAC's decision shall in no way be interpreted as the views of the UK Licensing Authority acting via CPRD. In accordance with ISAC's decision, this MOU will then be varied, remain unaltered, or terminated at the sole discretion of CPRD. For the avoidance of doubt, if the MOU is varied (which may include but is not restricted to any changes that may be required to the Dataset) the Fee payable under the MOU may also be varied to cover any incremental costs associated with the changes, and if the MOU is terminated no rebate in the Fee shall be payable except at the sole discretion of CPRD.

9.3 If during the Term NICE wishes to alter the Study in a way which falls within the scope of the Protocol the MOU may be varied at the sole discretion of CPRD and, for the avoidance of doubt, any such variation (which may include but is not restricted to any changes that may be required to the Dataset) may include a variation to the Fee payable under this MOU to cover any incremental costs associated with the changes requested by NICE.

9.4 All proposed changes to the Approved Study must be made within four (4) years of the Approval Date. Any proposed changes made outside this period shall require a new Protocol submission.

10. Destruction of Dataset

10.1 On the expiry or termination for any reason of this MOU, NICE shall ensure that:

10.1.1 the Dataset, including, without limitation, any copies, back-up copies and disaster recovery copies of the Dataset, which NICE may have under this MOU, are securely and permanently destroyed, deleted or erased promptly and in any event within fourteen (14) days of the date of termination of expiry of this MOU; and

10.1.2 within four (4) weeks of expiry or termination, confirmation of the secure and permanent destruction of the Dataset is provided to CPRD in the form of a Certificate of Destruction

save that NICE, will be entitled to retain Analysis Data in order to complete the Study or for record keeping and regulatory or audit purposes.

IT IS MUTUALLY UNDERSTOOD AND AGREED BY AND BETWEEN THE PARTIES THAT:

11. Confidentiality

11.1 Except to the extent set out in this clause 11 or where disclosure is expressly permitted elsewhere in this MOU, each Party shall treat the other Party's Confidential Information as confidential and safeguard it accordingly (which shall include complying with any protective markings on documents and instructions supplied by the other Party). In particular, neither Party will do anything that may place the other in breach of a duty of confidence owed to a third party save where expressly permitted to do so in accordance with the terms of this MOU.

11.2 The restrictions on disclosure and use contained in this clause 11 shall not apply to information to the extent that information:

11.2.1 has been disclosed to the Party by a third party (provided such third party is not in breach of any obligations of confidentiality owed to the other Party in respect of such information);

11.2.2 has been independently developed by the Party making the disclosure;

11.2.3 is in or comes into the public domain other than as a result of breach by the disclosing Party under this MOU;

11.2.4 is required by the Party in defending an action brought by a third party in respect of use of the Dataset; or

11.2.5 is required by law or any regulatory or governmental body having jurisdiction over the Parties (provided, in the case of a disclosure under the Freedom of Information Act 2000, none of the exceptions to that Act applies to the information disclosed), and the Party required to make that disclosure has informed the other, within a reasonable time after being required to make the disclosure, of the requirement to disclose and the information required to be disclosed, however no Link Data can be released without the written permission of the Link Data Owner.

11.3 The obligations of confidentiality in this clause 11 shall continue in force notwithstanding termination of this MOU.

12. Acknowledgements

12.1 NICE acknowledges that, although the Dataset shall be produced by CPRD based on the specification in Schedule 3 attached, it is NICE's responsibility to ensure that the nature of the Dataset meets NICE's requirements for conducting the Study.

12.2 CPRD acknowledges that, if there are any errors, omissions or inaccuracies in the supplied Dataset, a new copy of the Dataset will be supplied after the return of the old Dataset to CPRD. At CPRD's discretion, re-supply of the Dataset may incur a variation to the Fee.

13. Term and Suspension and Termination

13.1 This MOU shall, subject to earlier termination in accordance with this clause 13, commence on the Execution Date and continue throughout the Term. This MOU will terminate automatically at the end of the Term.

13.2 Either Party may terminate this MOU by giving at least three (3) months' notice in writing to the other Party at any time.

14. Publication

14.1 The Dataset is being made available for Research purposes only and with the expectation that the results will be disseminated by peer review or other acceptable Publication methods.

14.2 In collaboration with CPRD and in accordance with the Protocol, NICE will be responsible for leading on the writing up and preparation of the Study results for Publication with input from CPRD in accordance with Schedule 3. CPRD researchers will be named as co-authors on any Publication(s) arising from the Study. NICE will submit any Publication to CPRD for review and comment prior to publication and all reasonable comments made by CPRD will be incorporated by NICE into the Publication. Payment of any and all costs relating to Publication(s) shall be the sole responsibility of NICE.

14.3 Any Publication arising from:

14.3.1 use of the Dataset shall include the statement "*This study is based in part on data from the Clinical Practice Research Datalink obtained under licence from the UK Medicines and Healthcare products Regulatory Agency. The data is provided by patients and collected by the NHS as part of their care and support. The interpretation and conclusions contained in this study are those of the author/s alone*". NICE will ensure that the description of the Dataset in any such Publication is accurate and current, and agrees to request publication of a correction to any published description which CPRD deems to be inaccurate if so requested by CPRD;

14.3.2 use of ONS Data shall acknowledge ONS as the provider of the ONS Data contained within the Dataset and include the statement "*The interpretation and conclusions contained in this study are those of the author/s alone*";

14.3.3 use of HES Data/ONS Data shall include the statement "*Copyright © (year), re-used with the permission of The Health & Social Care Information Centre. All rights reserved".* NICE will ensure that the description of the Dataset in any such Publication is accurate and current, and agrees to request publication of a correction to any published description which CPRD or the Link Data Owner deems to be inaccurate if so requested by CPRD or the Link Data Owner;

14.3.4 use of PHE Data shall include the statement "*Public Health England (year): [Title]. [Version]. [Publisher]. [Resource Type]*; and

14.3.5 use of OPCS shall include the acknowledgement: "The OPCS Classification of Interventions and Procedures, codes, terms and text is Crown copyright (2016) published by Health and Social Care Information Centre, also known as NHS Digital and licensed under the Open Government Licence available at www.nationalarchives.gov.uk/doc/open-government-licence/open-government-licence.htm".

14.4 NICE shall ensure that any Publication derived from the Dataset complies with the following guidance:

14.4.1 Anonymisation Standard for Publishing Health and Social Care Data available at: http://content.digital.nhs.uk/isce/publication/isb1523; and

14.4.5 Anonymisation: managing data protection risk code of practice available at: http://ico.org.uk/for_organisations/data_protection/topic_guides/anonymisation

14.5 NICE shall ensure that any Publication derived from ONS Data shall also comply with the following guidance:

14.5.1 ONS Guidance for Health Statistics: https://www.ons.gov.uk/methodology/methodologytopicsandstatisticalconcepts/disclosurecontrol/healthstatistics; and

14.5.2 ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics: https://www.ons.gov.uk/methodology/methodologytopicsandstatisticalconcepts/disclosurecontrol/guidanceforbirthanddeathsstatistics

14.6 NICE shall send a copy of any Publication including any abstract arising from use of the Dataset under this MOU to CPRD within two (2) weeks of publication.

14.7 NICE shall ensure any Publication includes a reference to the Approved Study Protocol number. In the event that CPRD requires the Publication to contain any further statement or acknowledgement than those set out in this MOU, NICE will make all reasonable efforts to ensure that the relevant notices within the Publication are revised in accordance with the instructions of CPRD.

15. Notices

15.1 All notices and other communications between CPRD and NICE relating to this MOU shall be given by personal delivery (including email) or recorded delivery, sent to the Parties' respective representatives for the receipt of notices.

15.2 The Parties' respective representatives for the receipt of notices are, until changed by notice given in accordance with this clause 15.1, as follows:

For CPRD:

Address:	CPRD Medicines and Healthcare Products Regulatory Agency 10 South Colonnade Canary Wharf London E14 4PU United Kingdom
For the attention of:	Senior Contracts Manager
Email address:	[redacted]
Emergency number:	[redacted]

For NICE:

Address:	National Institute for Health and Care Excellence Level 1A, City Tower Piccadilly Plaza Manchester M1 4BT
For the attention of:	[redacted] Programme manager - indicators

E-mail: [redacted]

cc'd to [redacted]

Emergency number: [redacted] or [redacted]

15.3 Any notice delivered personally shall be deemed to have been received at the time of delivery, any notice given by recorded delivery shall be deemed to have been received two (2) Working Days after the date of posting.

16. General

16.1 Variation. No amendments to this MOU shall be effective unless made in writing and signed by duly authorised representatives of the Parties.

16.2 Disputes. Any dispute between the Parties arising out of or in connection with this MOU shall in the first instance be resolved amicably between the authorised representatives of the Parties and, if no resolution is reached, referred to the following senior personnel (at Director level):

(i) For CPRD: [redacted]

(ii) For NICE: [redacted]

16.3 Charges and Liabilities: Except as otherwise provided, the Parties shall each bear their own costs and expenses incurred in complying with their obligations under this MOU. Both Parties shall remain liable for any losses or liabilities incurred due to their own or their employee's actions and neither Party intends that the other Party shall be liable for any loss it suffers as a result of this MOU.

16.4 Status: This MOU is not intended to be legally binding, and no legal obligations or legal rights shall arise between the Parties from this MOU. The parties enter into the MOU intending to honour all their obligations. Nothing in this MOU is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute either Party as the agent of the other Party, nor authorise either of the parties to make or enter into any commitments for or on behalf of the other Party.

Signed on behalf of **CPRD**
by its duly authorised officer:

[redacted]

Role: CPRD Director
Date:

01 Mar 2021

Signed on behalf of **NICE**
by its duly authorised officer:

Contract Manager

[redacted]

Role: Associate Director
Date: 01 Mar 2021

Budget Holder

[redacted]

Role: Acting Programme Director
Date: 03 Mar 2021

Procurement Manager

[redacted]

Role: Associate Director
Date:

03 Mar 2021

SCHEDULE 1:

DESCRIPTION OF THE DATASET, STORAGE AND REPORTING

Part A: Description of the Dataset

Shall be in accordance with Schedule 3 and the Protocol.

Part B: Site Location of Dataset

a. Processing Location(s)
Location Area: AWS cloud instance in the eu-west-2 (London) region
Organisation Address: Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BT

b. Storage Location(s)
Location Area: AWS cloud instance in the eu-west-2 (London) region
Organisation Address: Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BT

c. Territory of Analysis
UK

SCHEDULE 2:

INFORMATION REQUIRED IN AN INCIDENT REPORT

1. The categories of Data involved.
2. The database field titles for the specific data that may identify individuals (if relevant).
3. The number of individuals the incident relates to.
4. The number of individuals that have access to the data.
5. Date of the incident
6. Any other information that may be requested by CPRD.
7. Any other information that NICE believes is relevant.

SCHEDULE 3:

Medicines & Healthcare products Regulatory Agency

CPRD More Dimensions to Data

Developing QOF Antidepressant Indicators

CPRD Statement of Work – Final v2.1

Author: [redacted] Observational Research Manager, CPRD

Client: [redacted]

Date: 25th January 2021

1. Project Summary

NICE are commissioned by NHS England to develop indicators which are suitable for inclusion in the Quality and Outcomes Framework (QOF) subject to negotiation between NHS England and the BMA's GPC. This project relates to testing the construction of the following indicators focussed on antidepressant medication:

a) The percentage of patients with a new course of antidepressant in the preceding 12 months who have been reviewed not later than 14 days after their first prescription
b) The percentage of patients prescribed a long-term antidepressant who have a record of a medication review in the preceding 12 months.

CPRD is asked to deliver data and expert advice to support analysts at NICE to conduct the following:

a) Using the pre-developed business rules (including SNOMED codes), construct and run queries to estimate the cohort size of patients which would fall into the denominators of the indicators for 2019/20. Provide results stratified by list size (small, medium, large) and deprivation classification linked via the practice postcode (IMD 2015 quintile).
b) Develop and test alternative approaches for estimating the denominators, varying the definitions of "a new course" and "long term" in relation to antidepressant exposure. Provide results stratified by list size (small, medium, large) and deprivation classification linked via the practice postcode (IMD 2015 quintile).
c) Undertake statistical validation of the results and provide details of the analysis and findings in a written report, and via presentation at a committee meeting.

2. Deliverables

Deliverable	Description
ISAC protocol	The research protocol will be developed by NICE with up to 4 days of expert input provided by a CPRD Senior Researcher. SNOMED codelists have been developed by NICE and NHS Digital for mapping to CPRD Aurum by the CPRD Senior Researcher, with review by clinical experts nominated by NICE. The protocol will be submitted to the Independent Scientific Advisory Committee by NICE. The CPRD Senior Researcher will be named as a co-applicant.
Data Specification	CPRD will provide a data specification to define the primary care and linked data that will be delivered to NICE via SFTP.
Expert advice	Up to [redacted] of CPRD Senior Researcher expert input will be provided to support the development of a statistical analysis plan and/or table shells, to review results tables and contribute to reports and presentations. The CPRD Senior Researcher will be a named author on resulting reports and acknowledged in all presentations.

Publication	The manuscript will be developed by NICE in collaboration with the CPRD Senior Researcher and submitted to a peer reviewed journal for open access publication. NICE will be responsible drafting all content. The CPRD Senior Researcher will be responsible for revising the manuscript critically for important intellectual content. The CPRD Senior Researcher will be required to meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship: • Substantial contributions to the conception or design of the research; or the acquisition, analysis, or interpretation of data; AND • Drafting the manuscript or revising it critically for important intellectual content; AND • Final approval of the version to be published; AND • Agreement to be accountable for all aspects of the research in ensuring that questions related to the accuracy or integrity of any part of the research are appropriately investigated and resolved. The CPRD Senior Researcher will not act as first, last or corresponding author. However, their position in the sequence of authors will be determined by their relative overall contribution to the manuscript and will be agreed between CPRD and NICE.

3. Data Requirements

Primary care data:

- CPRD Aurum

Area level practice postcode linked data:

- Index of Multiple Deprivation

4. Estimated Cost

Research Service	**Estimated Cost**
Access to CPRD Data	[redacted]
CPRD Senior Researcher Expert Advice [redacted]	[redacted]
TOTAL (excl. VAT)	£30,350

Costs are provided exclusive of VAT. NICE shall, if subject to VAT, pay VAT on the Fee at the rate applicable at the time payment is made and as specified on the CPRD invoice.

5. Timelines

Provisional timelines are for the results from sections (a) and (b) to be completed by the end of April 2021, with the validation work (c) completed by the end of May 2021, and a committee meeting in June 2021. The publication would be developed after this point. CPRD will inform NICE of any deviation to agreed timelines that arises due to unforeseen circumstances.

6. Payment Schedule

CPRD shall invoice NICE for [redacted] for Access to CPRD Data [redacted] of CPRD Senior Researcher Expert Advice ([redacted]) upon execution of this MOU. The remaining amount of [redacted] for [redacted] of CPRD Senior Researcher Expert Advice shall be invoiced at the end of June 2021.

Costs associated with face to face meetings (including travel, accommodation and subsistence costs, and cost-recovery of researcher time) and costs related to the production of a poster and/or conference attendance (including conference attendance fees, travel, accommodation and subsistence costs, and cost-recovery of researcher time) are not included in the Fee and will be treated as pass through costs and charged to NICE.

NICE shall pay all invoices in accordance with clause 4.

Produced by CPRD

Signable

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Parties involved with this document

Document processed	Party + Fingerprint
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