

## RESEARCH DATABASE

### Annual Report to Research Ethics Committee

*Research databases with approval from a Research Ethics Committee are required to provide the REC with an annual report on their activities. This form sets out the minimum content of the report and a template format, which may be adapted appropriately.*

#### 1. Details of the research database manager (“Data Controller”)

|            |   |
|------------|---|
| Name:      | Julia Hippisley-Cox   |
| Address:   | Nuffield Department of Primary Care Sciences,<br>University of Oxford |
| Telephone: | 10865 289 593   |
| E-mail:    | Julia.hippisley-cox@phc.ox.ac.uk                                      |

#### 2. Details of the Database

|   |   |
|---|---|
| Title:  | QResearch@Oxford Data Linkage Project   |
| Establishment responsible for management of the database:   | University of Oxford  |
| Data Custodian<br><i>This should be a senior individual, not part of the research database team, who is responsible for oversight of the database within the establishment.</i> | The Data Custodian is Dr Karen Melham, Senior Clinical Research Support Manager, Clinical Trials and Research Governance, University of Oxford. |
| Main REC:   | East Midlands – Derby Research Ethics Committee   |
| REC reference number:   | 18/EM/0400  |

### 3. Summary of activity for [period covered by report]

Please provide an overall summary of the database's activities during the year, including:

- *Data collection*
- *Use /release of data*
- *Collaborations with other databases /programmes*
- *Engagement with patients/service users and publicity*
- *Any significant developments in the database's scope, operation or governance.*

#### 3.1 Relocation to Oxford in 2019

The QResearch database moved from the University of Nottingham to the University of Oxford following the appointment of the Data Controller (Professor Julia Hippisley-Cox) as Professor of Clinical Epidemiology and General Practice at Oxford.

#### 3.2 Data collection

There have been no changes to the type or scope of data collected during the year. More recent data from general practice, cancer registry, mortality and hospital episodes has been collected during the year and uploaded onto the QResearch linked database.

#### 3.3 Collaborations with other databases or programmes

- The Oxford team collaborate with researchers using similar databases (e.g. CPRD) to undertake research projects using both databases using similar protocols. The analyses are undertaken using a similar approach and the summary results are compared. An example is the following study examining the risk of thrombosis in users of HRT (see link). <https://www.bmj.com/content/364/bmj.k4810>. This paper was awarded the BMJ Research Paper of the Year award for 2019.
- The Oxford team have also collaborated with a number of other data custodians who are potentially interested in linking their dataset to QResearch – for example, data for images such as chest x-rays or scans. At this early stage, the team is working to understand the scope of the data and the potential benefit it would bring regarding research which could not otherwise be undertaken. Once this is established and there appears to be a clear case for potential increased patient benefit, we will engage with patients/service users, advisors and stakeholders. We will then prepare an application for a substantial amendment to our ethics approval as appropriate.

#### 3.4 Database Scope, Operation and Governance.

There have been no major changes to the database scope, operation or governance. There have been some improvements to the QResearch Scientific and the QResearch Advisory Board

##### 3.4.1 QResearch Scientific Committee.

- Membership of this committee has been extended to include academics from the University of Oxford. Professor Rafael Perera-Salazar has been appointed as the Chair of the committee. More details on members are published on the relevant section of the QResearch website. <https://www.qresearch.org/about/scientific-committee/>.
- Minutes of the Scientific Committee are published [here](#).
- There is now an online application form (rather than a paper one) to improve efficiency of the application process
- There is a new process for researchers applying for grants to request a letter of support to enclose with their grant application.

### 3.4.2 QResearch Advisory Board.

- The advisory board met in October 2019. Dr Mike Walton has been appointed as the chair of the QResearch Advisory Board. Membership of the board now includes Professor Rafael Perera as Chair of the Science Committee. Further information, including minutes of meetings, is published here <https://www.qresearch.org/about/advisory-board/>

### 3.5 Engagement with patients and service users and publicity

- **Engagement with practices:** all practices contributing to QResearch were contacted to inform them of the move from Nottingham to Oxford and provide an updated notice for patients (using the text approved by the REC).
- **Engagement with patients:** There are three patient representatives on the QResearch Advisory Board who provide feedback on aspects relevant to patients including information provided to patients, lay summaries of ongoing projects, governance and potential benefits of QResearch.
- **QResearch website lay summary:** more information about new and ongoing projects is now published here including a lay summary. This continues to be reviewed by our patient representatives on the advisory board. <https://www.qresearch.org/research/approved-research-programs-and-projects/>
- **A newsletter** has now been prepared which will be distributed to contributing practices twice a year with the first issue due in the first quarter of 2020. This will also be on the QResearch website and the relevant pages of the Oxford University website.
- **QResearch Data Showcase;** There is a new data section on the website which gives a high-level overview of the types of data collected and broad summaries for some major conditions (e.g. the total numbers of patients with cancer on the database). This is intended to provide more information to both services users and researchers interested in using the resource. <https://www.qresearch.org/data/>


### 3.6 Use and release of data

- In accordance with our protocol, all data is held on Oxford servers. No data is physically released to researchers – rather researchers who have approved projects and have met the eligibility criteria (including appropriate IG training) are provided with remote access to the server where the relevant subset of data is located. A full list of all current projects (including ongoing projects approved under the previous REC application prior to the move to Oxford) is appended.

## 4. Applications for access to data

*Please append a listing of applications made to the database for release of, or access to, data during the reporting period, together with a lay summary of the purpose of each approved project. Include any releases authorised following a further project-specific application to a REC, as well as those authorised under generic approval.*

## 5. Declaration

|                                |  |
|--------------------------------|--|
| Signature of database manager: |  |
| Date of submission:            | 24.12.2019   |

## Applications for release of data

*Please also provide a lay summary (maximum 200 words) for each project for which release of data was approved. Include both projects conducted within the research database team and by external researchers. Where further project-specific approval was given by a REC, please include the REC Reference Number in the additional comments.*

|      | <b>Project title</b>  | <b>name of chief investigator</b> | <b>lead institution</b> | <b>dataset requested</b>  | <b>QR science outcome</b> | <b>link to lay summary where data released (200 words)</b>  |
|------|---|-----------------------------------|-------------------------|---|---------------------------|---|
| Q110 | QFracture - risk of osteoporotic fracture                   | Julia Hippisley-Cox               | University of Oxford    | Risk factors for osteoporotic fracture linked to outcomes (hip, knee, wrist and spine fracture) on either GP, hospital or mortality records   | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qfracture-risk-of-osteoporotic-fracture/">https://www.gresearch.org/research/approved-research-programs-and-projects/qfracture-risk-of-osteoporotic-fracture/</a>                                     |
| Q115 | QDiabetes Risk Assessment Tool                              | Julia Hippisley-Cox               | University of Oxford    | Risk factors for diabetes from GP records linked to diagnoses of type 1 and type 2 medication   | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qdiabetes-risk-assessment-tool/">https://www.gresearch.org/research/approved-research-programs-and-projects/qdiabetes-risk-assessment-tool/</a>   |
| Q112 | QKidney - predicting the risk of chronic kidney disease     | Julia Hippisley-Cox               | University of Oxford    | Risk factors for kidney disease linked to outcomes (development of stage 3-5 kidney failure) on GP, hospital or mortality records             | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qkidney-predicting-the-risk-of-chronic-kidney-disease/">https://www.gresearch.org/research/approved-research-programs-and-projects/qkidney-predicting-the-risk-of-chronic-kidney-disease/</a>         |
| Q108 | QStroke - risk of ischaemic stroke                          | Julia Hippisley-Cox               | University of Oxford    | Risk factors for ischaemic stroke linked to outcomes recorded on GP, hospital or mortality records  | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qstroke-risk-of-ischaemic-stroke/">https://www.gresearch.org/research/approved-research-programs-and-projects/qstroke-risk-of-ischaemic-stroke/</a>   |
| Q88  | QThrombosis - risk of thrombosis                            | Julia Hippisley-Cox               | University of Oxford    | Data for risk factors for thrombosis linked to diagnoses of thrombosis on GP, hospital or mortality records                                   | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qthrombosis-risk-of-thrombosis/">https://www.gresearch.org/research/approved-research-programs-and-projects/qthrombosis-risk-of-thrombosis/</a>   |
| Q110 | QAdmissions, QFrailty and QMortality                        | Julia Hippisley-Cox               | University of Oxford    | Risk factors for unplanned hospital admissions, frailty and mortality linked to these outcomes recorded on GP, hospital or mortality records  | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qadmissions-qfrailty-and-qmortality/">https://www.gresearch.org/research/approved-research-programs-and-projects/qadmissions-qfrailty-and-qmortality/</a>   |
| Q54  | QStatin - risk of unintended effects from statin medication | Julia Hippisley-Cox               | University of Oxford    | Risk factors for unintended effects of statin medication linked to both the outcomes and prescription data for statins                        | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qstatin-risk-of-unintended-effects-from-statin-medication/">https://www.gresearch.org/research/approved-research-programs-and-projects/qstatin-risk-of-unintended-effects-from-statin-medication/</a> |
| Q102 | QCancer Risk Assessment Tools                               | Julia Hippisley-Cox               | University of Oxford    | Risk factors and symptoms which might suggest indicate an existing diagnosis of cancer or an increased risk of developing it over the next 10 | approved                  | <a href="https://www.gresearch.org/research/approved-research-programs-and-projects/qcancer-risk-assessment-tools/">https://www.gresearch.org/research/approved-research-programs-and-projects/qcancer-risk-assessment-tools/</a>   |

|      |   |                     |                           |   |          |   |
|------|---|---------------------|---------------------------|---|----------|---|
|      |   |                     |                           | years or factors which affect the survival for people who have a diagnosis of cancer. This is linked to diagnoses of cancer from GP, hospital, mortality and cancer records.  |          |   |
| Q92  | QDiabetes - risk of diabetes related complications                                      | Julia Hippisley-Cox | University of Oxford      | risk factors and outcomes for patients with diabetes from GP, HES, mortality  | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/qdiabetes-risk-of-diabetes-related-complications/">https://www.qresearch.org/research/approved-research-programs-and-projects/qdiabetes-risk-of-diabetes-related-complications/</a>   |
| Q136 | Predicting survival outcomes for patients with a new diagnosis of cancer                | Julia Hippisley-Cox | University of Oxford      | Risk factors and symptoms which affect the survival for people who have a diagnosis of cancer. This is linked to diagnoses of cancer from GP, hospital, mortality and cancer records.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/predicting-survival-outcomes-for-patients-with-a-new-diagnosis-of-cancer/">https://www.qresearch.org/research/approved-research-programs-and-projects/predicting-survival-outcomes-for-patients-with-a-new-diagnosis-of-cancer/</a>                           |
| Q71  | Validation of QPrediction scores in QResearch and CPRD                                  | Julia Hippisley-Cox | University of Oxford      | risk factors and outcomes for multiple clinical conditions on GP, HES, cancer registry and mortality data   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/validation-of-qprediction-scores-in-qresearch-and-cprd/">https://www.qresearch.org/research/approved-research-programs-and-projects/validation-of-qprediction-scores-in-qresearch-and-cprd/</a>   |
| Q104 | QRISK3 - a new cardiovascular risk score  | Julia Hippisley-Cox | University of Oxford      | GP data for risk factors for cardiovascular disease (CVD) linked to outcomes for CVD recorded on either GP, hospital or mortality data.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/qrisk3-a-new-cardiovascular-risk-score/">https://www.qresearch.org/research/approved-research-programs-and-projects/qrisk3-a-new-cardiovascular-risk-score/</a>   |
| Q81  | QBleed - risk of bleeding   | Julia Hippisley-Cox | University of Oxford      | Risk factors for bleeding linked to outcomes recorded on GP, hospital or mortality records  | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/qbleed-risk-of-bleeding/">https://www.qresearch.org/research/approved-research-programs-and-projects/qbleed-risk-of-bleeding/</a>   |
| OX4  | Epidemiology of sepsis in adults in primary care - an exploratory study using QResearch | Michael Moore       | University of Southampton | GP data linked to hospital admissions and mortality data to identify cases of sepsis and associated predictive risk factors including age, sex, chronic diseases (eg COPD, kidney failure, immunosuppression) and symptoms suggestive of infection recorded in the GP consultation  | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/epidemiology-of-sepsis-in-adults-in-primary-care-an-exploratory-study-using-qresearch/">https://www.qresearch.org/research/approved-research-programs-and-projects/epidemiology-of-sepsis-in-adults-in-primary-care-an-exploratory-study-using-qresearch/</a> |
| R109 | Prostate specific antigen (PSA) testing in the UK population and its implications       | Julia Hippisley-Cox | University of Oxford      | Anonymised subset of GP data from the QResearch database (IAR 377) including a Cohort of men aged 40-75 years registered with the GP practices between 1998 and 2017. GP data included age, deprivation score, ethnicity, body mass index, smoking status, family history prostate cancer, mental health diagnoses, diabetes, prostate specific antigen tests, urinary tract symptoms. Mortality data included cause of death and date of death; Hospital Episode | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/prostate-specific-antigen-psa-testing-in-the-uk-population-and-its-implications/">https://www.qresearch.org/research/approved-research-programs-and-projects/prostate-specific-antigen-psa-testing-in-the-uk-population-and-its-implications/</a>             |

|     |   |                     |                          |   |          |   |
|-----|---|---------------------|--------------------------|---|----------|---|
|     |   |                     |                          | Statistics Diagnoses of prostate cancer; Cancer Registry Diagnoses of prostate cancer and associated dates  |          |   |
| R67 | Diabetes treatments and risk of cancer: a series of nested case-control studies                       | Carol Coupland      | University of Nottingham | Anonymised subset of GP data from the QResearch database (IAR 377) including a cohort of men and women with type 2 diabetes with outcomes and exposures recorded on linked Hospital Episode Statistics Data supplied by NHS Digital, cancer registry and civil registration date  | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/diabetes-treatments-and-risk-of-cancer-a-series-of-nested-case-control-studies/">https://www.qresearch.org/research/approved-research-programs-and-projects/diabetes-treatments-and-risk-of-cancer-a-series-of-nested-case-control-studies/</a>   |
| R68 | Risk of thrombosis in women prescribed Hormone Replacement Therapy                                    | Julia Hippisley-Cox | University of Nottingham | Anonymised subset of GP data from the QResearch database (IAR 377) including GP data for women aged 40-79 years registered between 01/01/1998 and 31/01/2017 who had a thrombosis diagnosed in the study period. Variables include risk factors for thrombosis and prescriptions for HRT. Linked mortality and hospital data for diagnosis of thrombosis.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/risk-of-thrombosis-in-women-prescribed-hormone-replacement-therapy/">https://www.qresearch.org/research/approved-research-programs-and-projects/risk-of-thrombosis-in-women-prescribed-hormone-replacement-therapy/</a>   |
| R78 | Anticholinergic drugs and the risk of dementia: a nested case control study                           | Carol Coupland      | University of Nottingham | Anonymised subset of GP data from the QResearch database (IAR 377) including Men and women aged 55+ between 2004 and 2015 diagnosed with dementia or prescribed medication for dementia (cases) matched to 5 controls without dementia matched by age, sex, practice and calendar time. GP data includes diagnoses and medication for dementia along with prescriptions for anticholinergic drugs, antidepressants, antipsychotics and risk factors for dementia. Linked mortality data for diagnoses of dementia | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/anticholinergic-drugs-and-the-risk-of-dementia-a-nested-case-control-study/">https://www.qresearch.org/research/approved-research-programs-and-projects/anticholinergic-drugs-and-the-risk-of-dementia-a-nested-case-control-study/</a>   |
| Q96 | Unintended effects of novel oral anticoagulants (NOAC) vs warfarin in real world settings vs warfarin | Julia Hippisley-Cox | University of Nottingham | Anonymised subset of GP data from the QResearch database (IAR 377) cohort of men and women prescribed anticoagulants between 2011 and 2016. Outcomes were major bleeding, death, cardiovascular disease or thrombosis on GP, hospital or mortality records.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/unintended-effects-of-novel-oral-anticoagulants-noac-vs-warfarin-in-real-world-settings-vs-warfarin/">https://www.qresearch.org/research/approved-research-programs-and-projects/unintended-effects-of-novel-oral-anticoagulants-noac-vs-warfarin-in-real-world-settings-vs-warfarin/</a> |

|      |   |                     |                           |  |          |   |
|------|---|---------------------|---------------------------|--|----------|---|
| OX1  | Improving Early Recognition of Motor Neurone Disease                    | Julia Hippisley-Cox | University of Oxford      | Anonymised subset of GP data from the QResearch database linked to Hospital Episode Statistics Data supplied by NHS Digital.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/improving-early-recognition-of-motor-neurone-disease/">https://www.qresearch.org/research/approved-research-programs-and-projects/improving-early-recognition-of-motor-neurone-disease/</a>                                   |
| OX2  | ADEPTS: Accelerated Diagnosis in neuroEndocrine and Pancreatic TumourS. | Steve Pereira       | University College London | GP data linked to hospital, mortality and cancer registry data for pancreatic tumours. Data will include tumour characteristics (type, stage, grade), risk factors and symptoms which might indicate a diagnosis of pancreatic cancer  | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/adepts-accelerated-diagnosis-in-neuroendocrine-and-pancreatic-tumours/">https://www.qresearch.org/research/approved-research-programs-and-projects/adepts-accelerated-diagnosis-in-neuroendocrine-and-pancreatic-tumours/</a> |
| OX3  | Choosing the right antidepressant for depressive disorder               | Andrea Cipriani     | University of Oxford      | Anonymised subset of GP data from the QResearch database. Data sets to be shared include: 1. QResearch GP data for patients aged 18-100 with a first recorded diagnosis of depression between 1998 and 2018; associated diagnoses and symptoms including diagnoses of depression; symptoms; clinical outcomes and baseline co-morbidities; prescription data antidepressants; antipsychotic drugs; lithium   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/choosing-the-right-antidepressant-for-depressive-disorder/">https://www.qresearch.org/research/approved-research-programs-and-projects/choosing-the-right-antidepressant-for-depressive-disorder/</a>                         |
| OX6  | Evaluation of the NHS Health Checks in England 2013-2017                | Julia Hippisley-Cox | University of Oxford      | Anonymised subset of GP data from the QResearch database (IAR 377) The cohort include adults aged 40-74 years between 2009 and 2017. Variables includes diagnoses and medication relevant to the NHS Health Checks from GP data linked to mortality and hospital data  | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/evaluation-of-the-nhs-health-checks-in-england-2013-2017/">https://www.qresearch.org/research/approved-research-programs-and-projects/evaluation-of-the-nhs-health-checks-in-england-2013-2017/</a>                           |
| OX11 | Hormone replacement therapy and risk of breast cancer                   | Julia Hippisley-Cox | University of Oxford      | Anonymised subset of GP data from the QResearch database (IAR 377) including Women aged 40-79 registered during the study period (1998-2017) with a diagnosis of breast cancer each matched to 5 controls by age, practice and calendar time. GP data includes diagnoses, risk factors and medication relevant to breast cancer. Hospital, mortality and cancer registry data includes diagnoses and operations relevant to breast cancer (eg mastectomy; hysterectomy). | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/hormone-replacement-therapy-and-risk-of-breast-cancer/">https://www.qresearch.org/research/approved-research-programs-and-projects/hormone-replacement-therapy-and-risk-of-breast-cancer/</a>                                 |
| OX17 | QResearch CRUK Cancer Platform  | Julia Hippisley-Cox | University of Oxford      |  | approved |   |



|      |  |                |                          |  |          |   |
|------|--|----------------|--------------------------|--|----------|---|
| OX20 | Antidepressant Decision Aid Tools and Risk Assessment                      | Carol Coupland | University of Nottingham | GP data for patients prescribed antidepressants; linked hospital and mortality data for mental health diagnoses.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/antidepressant-decision-aid-tools-and-risk-assessment/">https://www.qresearch.org/research/approved-research-programs-and-projects/antidepressant-decision-aid-tools-and-risk-assessment/</a>   |
| OX22 | Dietary or weight loss advice for hypertension in diabetes in primary care | Carmen Piernas | University of Oxford     | GP data for patients aged 40-74 who are eligible for health checks from 2009-2017 and have a diagnosis or treatment for hypertension or diabetes. Data will include age, sex, ethnicity, social class, BMI, behavioural advice or support for weight loss or diet, information on diagnosis and treatment of hypertension and diabetes | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/dietary-or-weight-loss-advice-for-hypertension-in-diabetes-in-primary-care/">https://www.qresearch.org/research/approved-research-programs-and-projects/dietary-or-weight-loss-advice-for-hypertension-in-diabetes-in-primary-care/</a>                     |
| OX28 | Validating a postpartum venous thromboembolism risk prediction model       | Joe West       | University of Nottingham | Anonymised subset of GP data from the QResearch database linked to Hospital Episode Statistics Data supplied by NHS Digital.   | approved | <a href="https://www.qresearch.org/research/approved-research-programs-and-projects/validating-a-postpartum-venous-thromboembolism-risk-prediction-model-using-qresearch/">https://www.qresearch.org/research/approved-research-programs-and-projects/validating-a-postpartum-venous-thromboembolism-risk-prediction-model-using-qresearch/</a> |