Medicines & Healthcare products Regulatory Agency

CPRD

# Independent Scientific Advisory Committee (ISAC)

# Annual Report

**1 April 2020 to 31 March 2021**

NIHR | National Institute for Health Research

# Contents

# Glossary

| | |
|---|---|
| CAG | Confidentiality Advisory Group |
| CPRD | Clinical Practice Research Datalink |
| CPRD Aurum | CPRD primary care database sourced from EMIS® practices |
| CPRD GOLD | GP On-Line Database (CPRD primary care database sourced from Vision® practices) |
| EHR | Electronic Healthcare Record |
| EMIS Health® | GP system software provider |
| GP | General Practitioner |
| HRA | Health Research Authority |
| HSCIC | Health & Social Care Information Centre (operating as NHS Digital since 2016) |
| HSCN | Health and Social Care Network |
| IG | Information Governance |
| ISAC | Independent Scientific Advisory Committee |
| MHRA | Medicines and Healthcare products Regulatory Agency (“the Agency”) |
| N3 | The high-speed broadband network for the NHS |
| NDG | National Data Guardian |
| NHS | National Health Service |
| NIHR | National Institute for Health Research |
| REC | Research Ethics Committee |
| RDG | Research Data Governance |
| Vision® | GP system software provider |

# Foreword from the Chief Executive of the MHRA

The 2020/21 Annual Report of the MHRA Independent Scientific Advisory Committee (ISAC) marks the most extraordinary year in ISAC's 15-year history. The COVID-19 pandemic has changed how we all conduct our lives and the pandemic has had a major impact on ISAC activities. Never before has evidence from health data played such a pivotal and prominent role in decision making. As would be expected, demand for high quality CPRD data increased to answer questions about disease risk, health outcomes and health service usage relating to COVID-19 infection. In response, COVID-19 research data requests were expedited, and prioritised protocols reviewed by ISAC at pace to meet the pressing public health need.

Over the COVID-19 pandemic, research using CPRD data has provided evidence for policy decisions on lockdown, recommendations on priority groups for vaccination and contextualising vaccine safety signals on blood clots. Importantly CPRD data are vital to supporting the MHRA's safety surveillance of COVID-19 vaccine in the UK population. ISAC's tireless work to review and approve data requests underpin these and the hundreds of other requests during 2020/21 to access CPRD data for public health studies.

ISAC has been the backbone of CPRD's internal data governance process since 2006, providing the Agency with the assurance required for accessing CPRD data for research. While there is no doubt about the excellent job ISAC has done over the years, it is essential that processes remain fit for purpose, especially in the ever-changing data environment in which CPRD operates. The Agency is therefore adopting the recommendations of an Independent review conducted by Professor Mike Kelly, which sees ISAC replaced with a new Research Data Governance (RDG) process. The new RDG process, which went live on 1 June 2021, retains all the rigor ISAC has been renown for but builds in greater sustainability for the future.

The MHRA is indebted to the exemplary leadership and dedication of Professor Deborah Saltman who has expertly chaired ISAC since 2016. Deborah, Richard Stevens the ISAC Deputy Chair and fellow ISAC members have worked selflessly over and above their usual ISAC demands to expedite reviews of COVID-19 research applications. I would like to express my gratitude to all ISAC members, past and present, for their excellent work setting such a high standard for review of CPRD research applications. I have every confidence that their legacy will continue as they hand over the reins to the new RDG process in 2021/22.

**Dr June Raine MBE**
**Chief Executive MHRA**

# Foreword from the Chair of ISAC

This is my sixth and final foreword to the Committee's Annual Report that I have written since my appointment as Chair of the ISAC in February 2016. Over the last 5 years it has been a privilege to work with such dedicated Members as we have had on the Committee, and I look forward to continuing to work with many of them in CPRD's new Research Data Governance process, more details of which are contained within this report.

The 2020/21 reporting period was the most challenging that we have faced. The COVID-19 pandemic forced changes to working methods for both the ISAC and CPRD, and no physical meetings of the ISAC were held during 2020/21. At the same time, demand for the public health data held by CPRD increased 27% from last year, as researchers explored ways of tackling the ongoing pandemic.

In response to the pandemic, CPRD and ISAC expedited the processing and review of certain protocols relating to urgent COVID-19 research. Research topics have included investigating risk factors for COVID-19 infection due to underlying health conditions or pharmacological risk factors, studying outcomes following COVID-19 infection, and understanding use of the health service as a result of the pandemic. These expedited protocols received feedback on overage only 4.5 days after submission, and all protocols relating to COVID-19 research received feedback in under 14 days.

This response would not be possible without the continued commitment of Committee Members, and I would like to thank all Members who extended their tenures in order to help address the significant increase in demand seen as a result of the pandemic. I would also like to pay particular thanks to Benjamin Cairns, Krishnan Bhaskaran, Iskandar Idris, Martin Gulliford and Richard Martin, who re-joined the Committee in June 2020.

I would like to thank Dr Ian Hudson, Professor Sir Michael Rawlins and Dr June Raine for their commitment to the work of ISAC during my time as Chair, and for the continuous support of CPRD Director Dr Janet Valentine. The work of ISAC is augmented by CPRD colleagues, and I am grateful to Dr Puja Myles, Head of Observational Research, Ms Tarita Murray-Thomas, Senior Researcher, and Mr Jonathan Lind, Mr Sam Speer, and Ms Claudia Hafford Tear, who have facilitated and managed the research applications process. I look forward to working with them in the new Research Data Governance Process.

**Professor Deborah Saltman AM**
**Chair, Independent Scientific Advisory Committee (ISAC)**

# 1. Introduction and background

## 1.1. Introduction to the report

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health and Social Care. Its role is to protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance, and effectiveness, and that they are used safely.

The Clinical Practice Research Datalink (CPRD) is a UK government, not-for-profit research service, jointly supported by the National Institute for Health Research (NIHR) and the MHRA, supplying anonymised health data for public health research.

The role of the Independent Scientific Advisory Committee (ISAC) is to assess the public health benefits and scientific merit of research proposals seeking to use CPRD data, including primary care data linked to other health-related data sets.

This Annual Report presents an overview of the CPRD database, research data governance, ISAC outputs and membership of the Committee, for the period 1 April 2020 to 31 March 2021. The report also contains data covering the period 1 April to 31 May 2021 before the introduction of the new Research Data Governance (RDG) process, which is covered in Annex 1.

## 1.2. Clinical Practice Research Datalink

### 1.2.1. The CPRD database

The CPRD database offers a quality-assured source of longitudinal, near real-time health data that is representative of the UK population. CPRD primary care data are sourced from a UK-wide network of over 2,000 GP practices across the UK. The CPRD database contains anonymised primary care electronic health records (EHR) on more than 60 million patients, of which 16 million are currently registered at contributing GP practices, encompassing 25% of the UK population. Patient records in the CPRD database have a median follow-up of 10 years, with 25% of the data having 20 years follow-up.

The CPRD database contains coded data from anonymised primary care EHR capturing information on:

- Demographic data
- Diagnoses and symptoms

- Drug exposures
- Vaccination history
- Laboratory tests
- Referrals to hospital and specialist care

CPRD data are used worldwide by regulators, academic researchers and the life science industry for observational and interventional public health and clinical studies. Over 2,800 peer-reviewed articles using CPRD data have been published to date. Studies using CPRD data have contributed to the development of best practice and clinical guidelines, such as demonstrating the safety and protective effect of the meningococcal vaccine in infants, and covered important issues such as adolescent mental health and the care needs of people with multiple health conditions.

### 1.2.2. Permissions and approvals to safeguard patient data

CPRD has NHS HRA REC approval to allow the collection and release of anonymised primary care data for observational research. [NHS HRA REC reference number: 05/MRE04/87]

Each year CPRD obtains Section 251 regulatory support through the HRA Confidentiality Advisory Group (CAG), to enable patient identifiers, without accompanying clinical data, to flow from CPRD contributing GP practices in England to NHS Digital, for the purposes of data linkage. [CAG reference number: 21/CAG/0008]. Linkage of secondary health related datasets to primary care data greatly enhances the capacity for public health research. The use of NHS Digital, the statutory body in England permitted to receive identifiable patient data, for data linkage ensures that CPRD itself never receives identifiable patient data.

As an organisation that has access to anonymised patient data, CPRD also completes an annual Data Security and Protection Toolkit to confirm that CPRD's data security standards align with the 10 National Data Guardian (NDG) data security standards.

CPRD operates a GP opt-in model, whereby a GP practice agrees to contribute their anonymised patient records to CPRD. GPs are provided with Fair Processing Notices to inform patients that their data is being collected by CPRD to support public health research and that they can opt-out of their data being shared with CPRD. CPRD does not collect data from patients who have opted out of sharing their data for research.

### 1.2.3. Data collection

CPRD manages the collection of data from GP practices that either use the Vision® Primary Care System software (contributing to the CPRD GOLD database) or the EMIS® GP Clinical System software (contributing to the CPRD Aurum database). Once a practice has agreed to contribute data to CPRD, de-identified data are transferred to CPRD in an encrypted form via the Health and Social Care Network (HSCN). On receipt, the data are verified for integrity and completeness before further processing and anonymisation.

### 1.2.4. Anonymisation process

CPRD data comprises anonymised coded patient-level data that have been anonymised in accordance with the Information Commissioner's Office Anonymisation Code of Practice. No data that can directly identify patients such as names, addresses, full date of birth and NHS number, are transmitted to or ever held by CPRD. The identity of individuals within the database is not known to anyone within CPRD or by researchers using CPRD data.

In order to update individual patient records on an ongoing basis, every patient and practice within the database must be uniquely distinguishable, to enable new information about a specific patient to be added to their longitudinal record. To achieve this, every patient is assigned an encrypted patient-level record code by the GP system software. To further protect patient identity, the identities of individual practices are also encrypted so that researchers are unable to determine which practices are contributing data to CPRD. The GP system software provider also anonymises records relating to doctors and practice staff who enter data into their system. As an additional privacy safeguard, the patient record code and practice number are encrypted again within CPRD before the anonymised data is supplied to researchers.

### 1.2.5. Data linkage

NHS Digital, legally known as Health and Social Care Information Centre (HSCIC), is the statutory body in England permitted to receive identifiable patient data. NHS Digital provides a linkage service for CPRD, enabling data from English GP practices sharing data with CPRD, to be linked to other health-related data sources, while upholding patient confidentiality.

The datasets routinely linked to CPRD primary care data during this reporting period are listed in Section 4.2.

# 2. Governance and Review of Research Applications

## 2.1. Role of ISAC including Terms of Reference

The Terms of Reference of ISAC are to:

- Consider and provide advice to the MHRA on the feasibility, quality and public health value of research studies proposing use of anonymised patient level data from the CPRD.
- Provide timely and high-quality peer reviews on the scientific (medical, epidemiological, methodological) merit of research protocols proposing access and use of CPRD data.
- Highlight important ethical or confidentiality issues that may arise during access and/or use of CPRD data in research studies, taking into consideration input from the Confidentiality Advisory Group or research ethics committees.
- Advise on, and contribute to, the scientific content of guidance relating to the development of research protocols proposing access and use of data from CPRD.
- Review internal workings of the Committee to ensure consistency, efficiency and high standards of peer-review are maintained.
- Advise on other specific issues as requested by the MHRA and/or CPRD.

## 2.2. Membership

The ISAC is comprised of scientific experts, who provide advice on the medical, statistical/epidemiological, and methodological aspects of protocols submitted to the Committee for review.

### 2.2.1. Membership between 1 April 2020 – 31 May 2021

During the period 1 April 2021 – 31 May 2021 the ISAC membership consisted of 18 members, including the Chair. Membership of ISAC between 1 April 2020 and 31 May 2021 is listed in Annex 2.

### 2.2.2. Appointment of members

ISAC members are appointed by the MHRA. New members are appointed for an initial two-year term, which may be extended for a further two years, to a maximum four-year appointment. The duties of ISAC members can be found in Annex 3.

Due to the COVID-19 pandemic, ISAC members who were reaching the end of their terms were asked to extend their terms until the implementation of the new Research Data Governance (RDG) process. More details of the RDG process can be found in Section 3.

### 2.2.3. Declarations of interest

Members of ISAC are required to declare any relevant interests or relationships with the pharmaceutical industry and any other interests that may affect their impartiality or be perceived as doing so. Declarations must include interests of their immediate family members (e.g. spouse). Declarations must be made on appointment and the MHRA must be notified immediately of any changes. Failure to comply may result in the removal of an individual from the Committee.

Members are also required to declare any potential conflicts of interest relevant to individual protocols at the time of protocol review. This allows interests to be taken into account during protocol evaluation, reducing potential bias in connection with these interests. ISAC members are excluded from participation in the review of protocols and applications arising from their own academic department. The Deputy Chair is responsible in cases where the Chair has a direct conflict of interest or is unavailable. A register of Committee member declared interests can be found in Annex 4.

## 2.3. Meetings of the Committee

### 2.3.1. Physical meetings

Due to the COVID-19 pandemic, the Committee did not meet physically during the reporting period.

### 2.3.2. Virtual working between meetings

Review of all CPRD research protocol submissions was performed virtually throughout the reporting period. Reviews were undertaken by ISAC members and CPRD staff as described in Section 2.5. All phases of protocol review were overseen and signed-off by the ISAC Chair.

## 2.4. Secretariat

The ISAC Secretariat, consisting of MHRA employees, manages the processing and review of research protocol requests for access to CPRD data, and provides administrative support for the Committee.

## 2.5. Review of research protocols

Researchers request access to CPRD data by submitting a protocol application form to the ISAC Secretariat. The ISAC Secretariat assesses each submission for completeness and once validated,

each application is sent on to CPRD researchers, who perform an initial assessment of the application's feasibility and a screening for risks relating to the proposed research. CPRD researchers will carry out a scientific review of protocols deemed to be routine research and the Committee carry out a scientific review of protocols which are considered non-routine. Non-routine research applications propose research of major public health importance/implications, high public health or reputational risks or use of novel methodology to address important health questions.

When reviewing CPRD protocols, the Committee and CPRD researchers considers whether:

- the CPRD database is a suitable data source for the proposed research;
- there are any major scientific concerns with the medical, statistical, epidemiological, or methodological aspects of the study:
    - the methodology is considered appropriate, including consideration of possible bias and confounding;
    - there is a well-defined hypothesis or clear question to be addressed where appropriate;
- the proposed study is relevant to public health
- there is compliance with the requirement to ensure practice and patient confidentiality is protected.

The ISAC Chair receives the reviews of each protocol and makes an assessment to approve, reject or request a resubmission of the protocol. The decision is communicated to the applicant, along with appropriate feedback and comments where necessary. In cases where a resubmission is required, the applicant must respond to reviewer feedback in their re-submitted application. All resubmissions are reassessed by the ISAC Chair and the final decision is communicated to the applicant.

During the course of some studies, it may become necessary to deviate from an ISAC approved protocol. Any deviations from an approved protocol should be reported to the ISAC Secretariat, and significant deviations from an approved protocol, such as to the study design or analysis plan, require ISAC approval.

### 2.5.1. Review of COVID-19 protocols

In response to the coronavirus outbreak, CPRD expedited the processing of protocols relating to COVID-19 research. Applicants were asked to contact the ISAC secretariat in advance of submitting their protocol and include a clear impact statement in terms of public health, safety, or policy, in order to determine eligibility for expedited processing. All expedited COVID-19 studies were reviewed by CPRD researchers and Committee members, before receiving a final assessment by the ISAC Chair.

Metrics relating to the processing of COVID-19 protocols are presented in Section 4.3 and additionally in Annex 1.

During the reporting period, there have been 12 peer-reviewed papers published from 9 different COVID-19 protocols, and 7 pre-prints from 6 different protocols. In total, there have been 19 published or pre-print papers from 13 different COVID-19 protocols.

### 2.5.2. CPRD's Electronic Research Applications Portal (eRAP)

On 10 August 2021, CPRD launched the Electronic Research Applications Portal (eRAP), bringing the application and review process onto a single online platform, replacing the previous document-based application method. The platform allows users to create a personal profile, prepare and submit research protocols, and monitor the progress of their protocols through the review process.

After submission, the triage and review process on eRAP follows that of the previous document-based process, with applications first validated before being sent for initial assessment by CPRD researchers. CPRD researchers will carry out a scientific review of protocols deemed to be routine research, and the Committee carry out a scientific review of protocols which are considered non-routine. This is followed in all instances by a final assessment by the ISAC Chair. Feedback is issued via eRAP.

Since the launch of eRAP, researchers have been able to create and submit protocols via eRAP, and resubmit protocols responding to reviewer feedback. The ability to amend approved protocols, including protocols originally submitted via the previous system, will be available when Phase II of eRAP is delivered in mid 2021/22. Enhanced features will continue to be delivered in 2022/23, including submission of feasibility studies and linkage request information.

## 2.6. Transparency of approved research protocols

Summary information about each approved research protocol is published on the CPRD website. Information is published a minimum of three months after applicants receive the approved data for their research. The summary information on approved studies can be found at https://cprd.com/protocol-list.

In response to the coronavirus outbreak, CPRD expedited publication of summary information on approved COVID-19 studies. Summary information was published on the CPRD website within 72 hours of approval to ensure transparency and to help avoid unnecessary duplication.

## 2.7. Publication of ISAC approved studies

The findings of many studies approved by ISAC are published in peer-reviewed scientific journals. A comprehensive list of all publications using or referencing CPRD data can be found on the CPRD website: https://www.cprd.com/bibliography/. The introduction of Digital Object Identifiers (DOIs) for CPRD database releases in late 2020/21, has made it easier for researchers to reference specific database releases in their publications and to link approved studies to these publications.

## 2.8. Publication of ISAC activities

Although no meetings were held during the reporting period, summary minutes of ISAC meetings are published as standard on the CPRD website, once the Committee has agreed the full minutes. The summary ISAC minutes are available at https://cprd.com/ISAC-minutes-annual-reports. The annual reports of ISAC are made available on the CPRD website, at https://cprd.com/ISAC-minutes-annual-reports.

# 3. Independent Review of CPRD Internal Data Governance Framework

The data governance framework for CPRD, underpinned by ISAC, has evolved over time since 2006 when ISAC was instated. Since then, the external information governance environment, public views on data sharing and the volumes of data and requests to access these data held by CPRD have changed substantially.

To ensure that CPRD's data governance processes remain proportionate, fit for purpose and sustainable, the former MHRA Chief Executive, Dr Ian Hudson, commissioned the former Director of Public Health at NICE, Professor Mike Kelly, to undertake a review of CPRD's internal data governance framework. The terms of reference for the review included making recommendations to the MHRA to address any issues arising from the review findings.

Professor Kelly concluded that, while the current CPRD data governance process worked well, there was a need to redesign some of the processes to create a more resilient internal data governance system for the future. The Report of the independent review is available on the CPRD website.

The MHRA Board and NIHR accepted the Review recommendations in full. The resulting new Research Data Governance (RDG) process was approved to go live on 01 June 2021. The RDG process, which replaces the ISAC, provides a transparent and robust mechanism for reviewing research applications to access CPRD data. Outputs from the RDG process will be regularly reported on the CPRD Website. More details of the new RDG process are provided in the CPRD Research Data Governance Operating Framework, available on the CPRD website.

# 4. Activities and Outputs

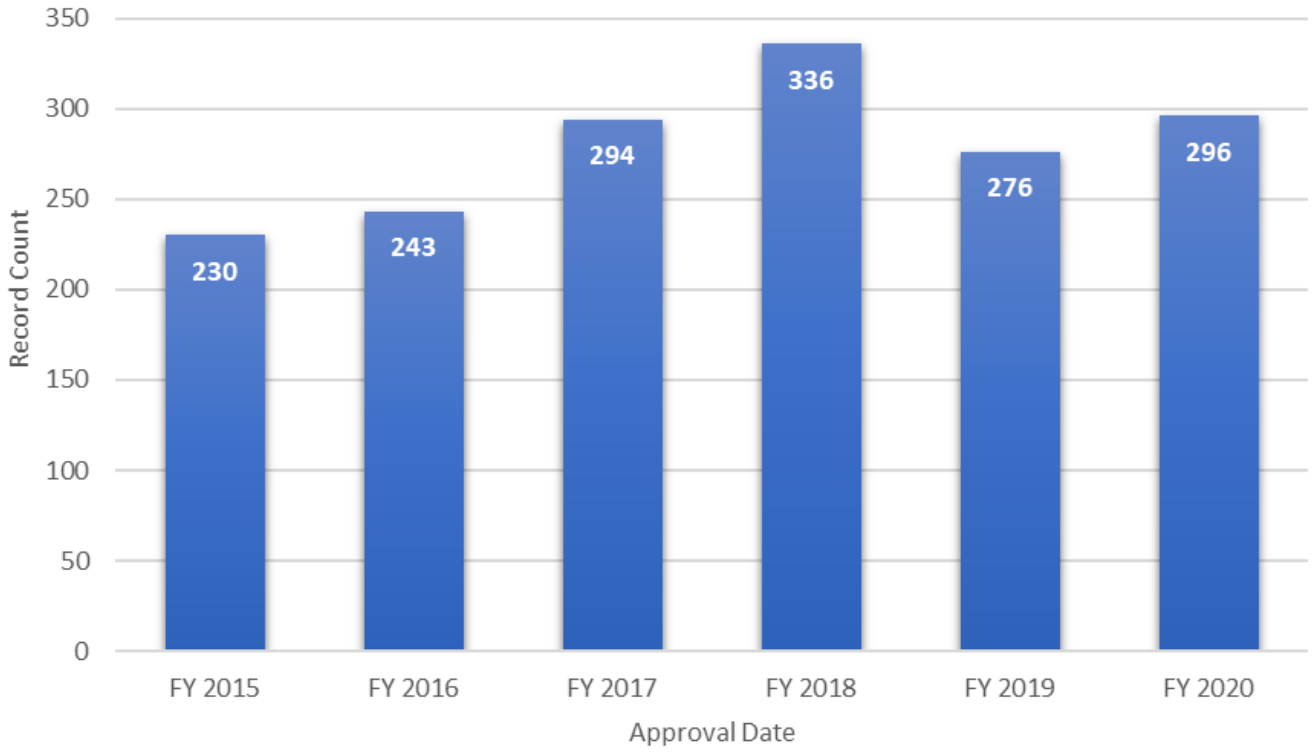
## 4.1. Summary of applications and approvals for use of CPRD data

During this reporting period 1 April 2020 – 31 March 2021, ISAC reviewed a combination of newly received research applications, as well as protocol resubmissions and amendments from applications submitted in the current and previous reporting periods.

Data for the period 1 April to 31 May 2021 are included in Annex 1, which covers the time between the annual reporting period and the introduction of the new RDG process.

ISAC approved 296 applications in the reporting period. Figure. 1 which illustrates the number of research applications approved over the past 6 years, shows only a small 7% increase in approved protocols in 2020/21 compared with the previous year. Protocols approved in one financial year may have been submitted in a previous financial year, and therefore the figures differ from those for newly received applications. No protocols were rejected during this reporting period.

**Fig. 1 – Research applications approved between financial years 2015/16 and 2020/21**




A total of 345 new research protocols requesting access to CPRD data were received in 2020/21. As demonstrated in Figure 2 which shows the number of protocols received over the past 6 years, this represents the highest number of protocols ever submitted to CPRD during a financial year and is

27% higher than the 271 protocols received in the previous financial year. The increase in number of new applications for CPRD data may be a consequence of the demand for data during the COVID-19 pandemic. The figure is obtained by counting protocols that have a 'submission received' date within the given financial year.

**Fig. 2 – New research applications received between financial years 2015/16 and 2020/21[1]**

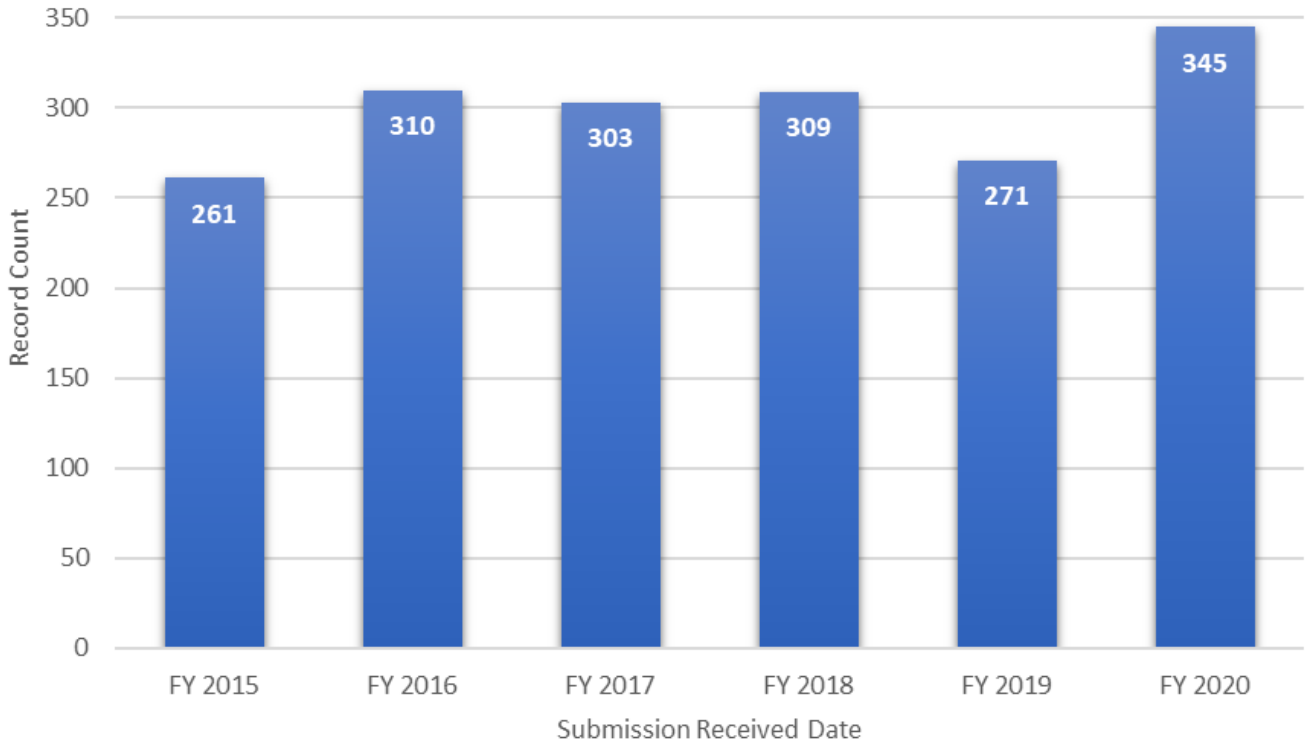



Figure 3 presents a breakdown of the 296 protocols approved by ISAC in the reporting period, categorised by the Chief Investigator's organisational affiliation. The Chief Investigator can only be assigned a single organisational affiliation. The chart shows that nearly half of all approved protocols were led by researchers based in UK academic organisations.

[1] The ISAC Report published in 2016 covered a 15-month period from 1 January 2015 to 31 March 2016. The figures given in this report refer only to the 2015/16 financial year and may therefore differ from figures provided in the 15-month Committee Report.

**Fig. 3 – Number of approved protocols by Chief Investigator's organisational affiliation, 2020/21**

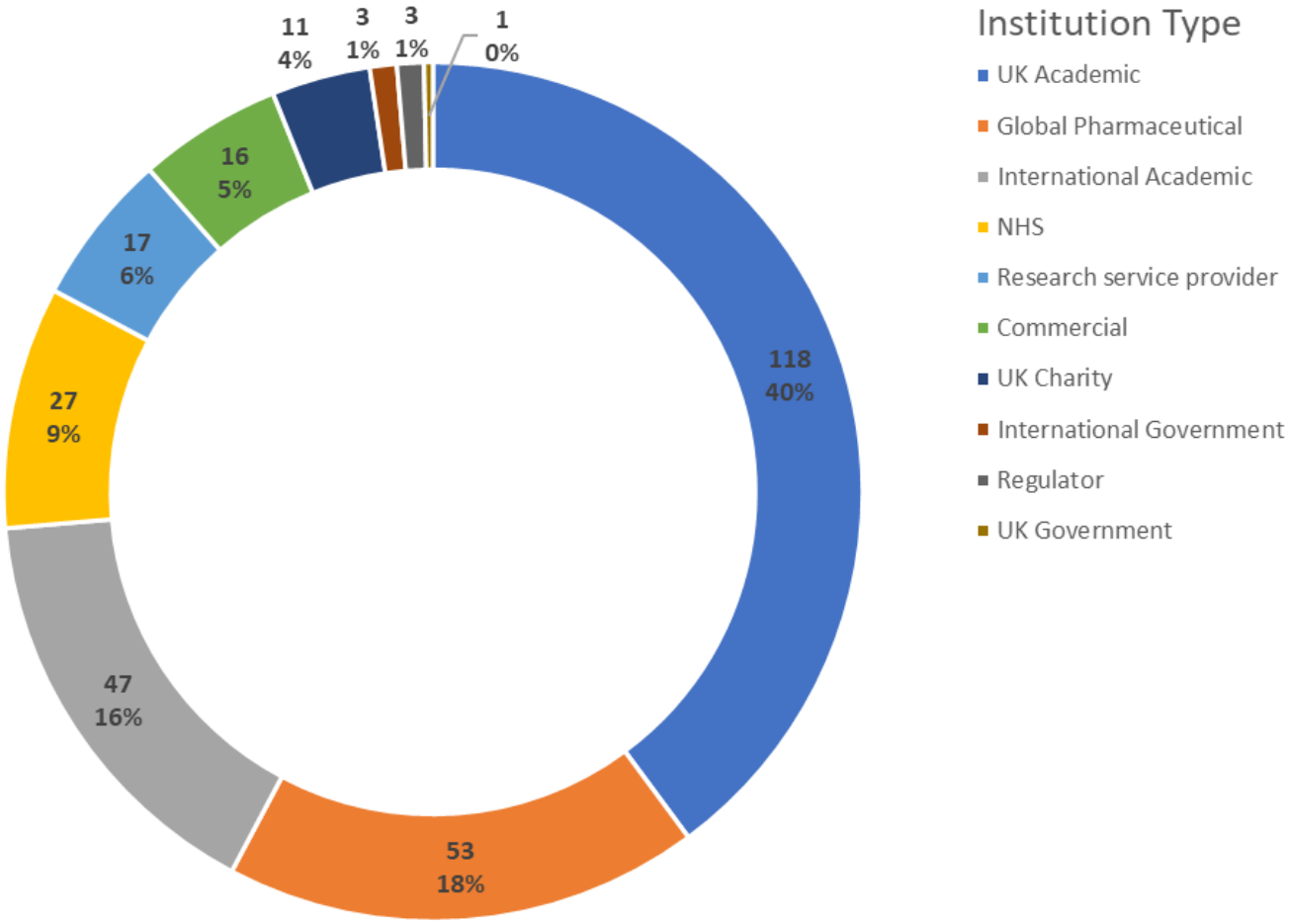
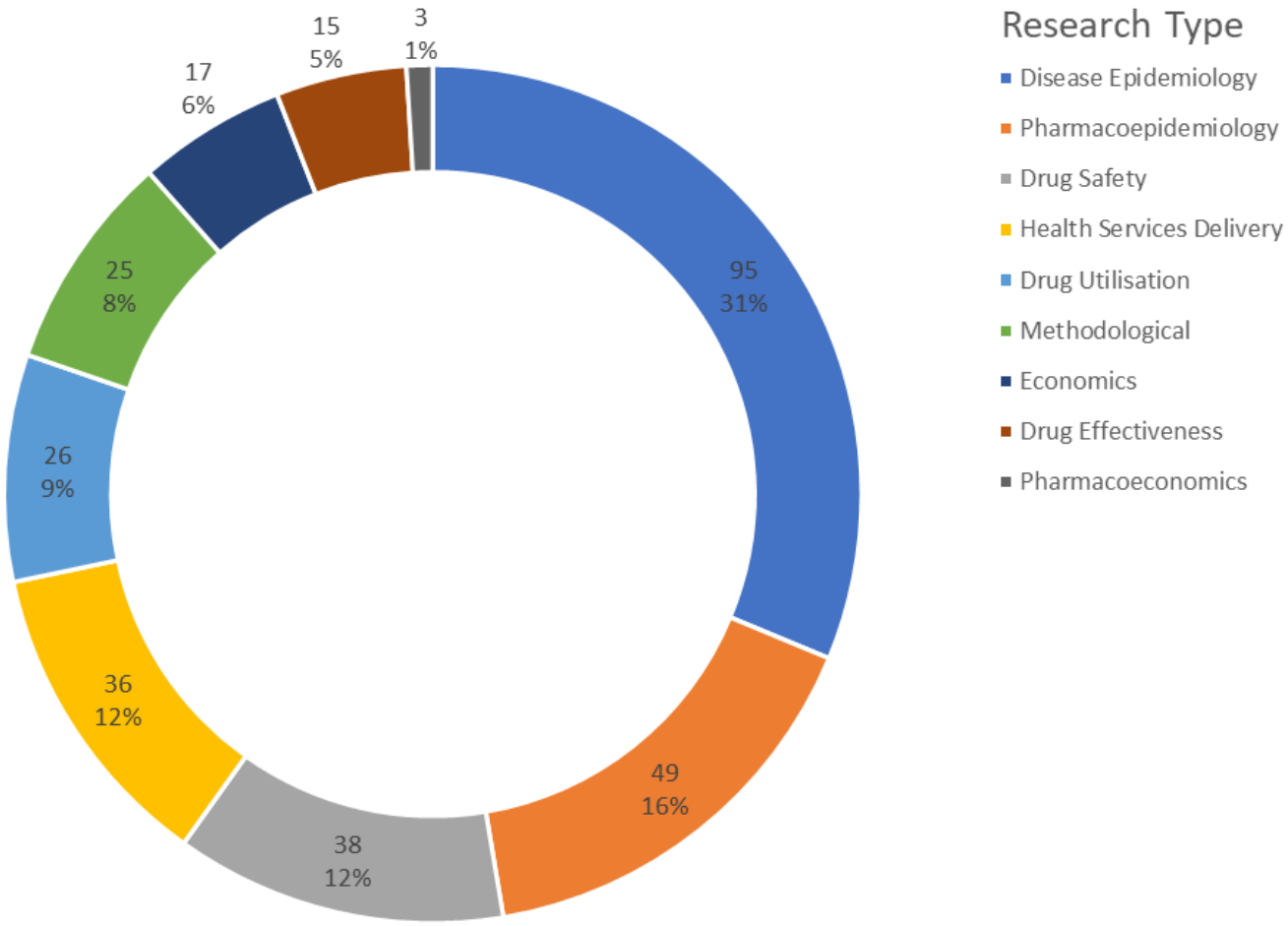



Figure 4 provides an overview of the 296 approved protocols, categorised by research type. A protocol may be assigned to more than one study type by the applicant. The Figure shows that most applicants describe their research as disease epidemiology.

**Fig. 4 – Approved protocols by research type 2020/21**




## 4.2. Protocol applications including requests for linkage to other datasets

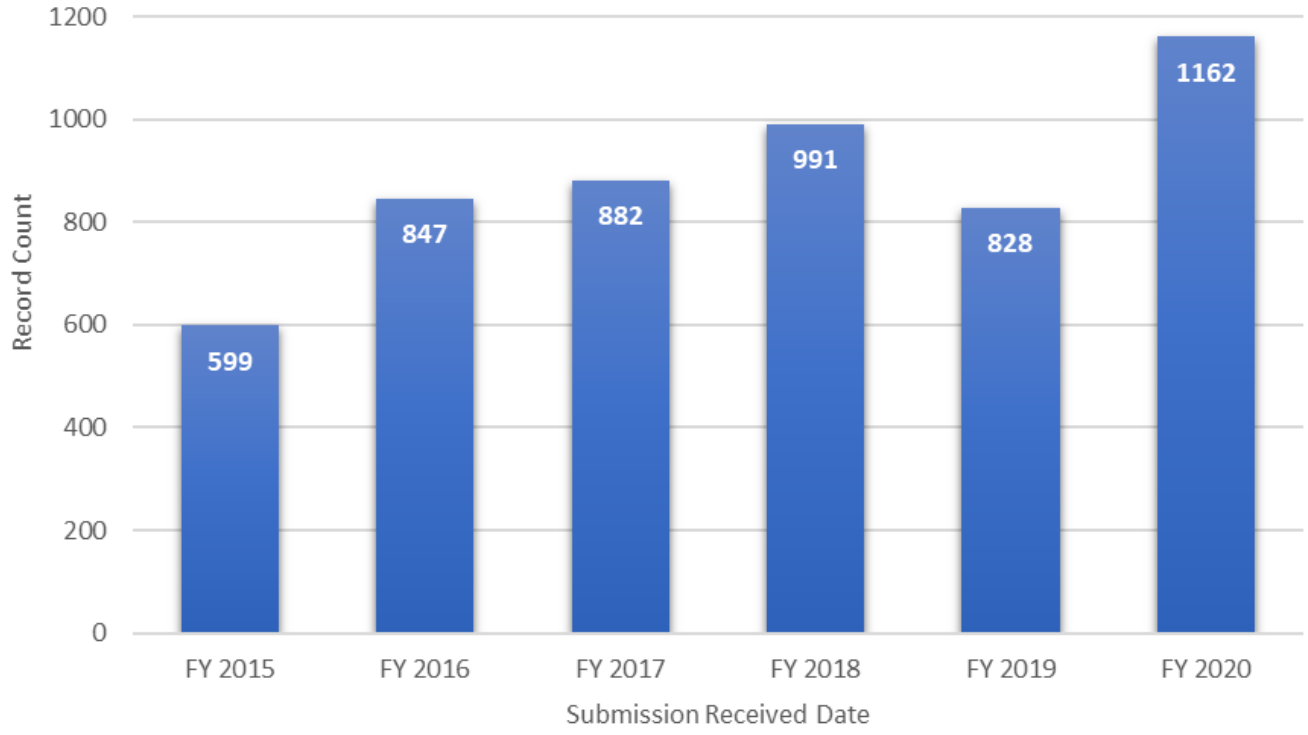
The value of research using primary care data can be significantly augmented by linkage to other data sources. Primary care data collected by CPRD can be linked to a number of other patient level and area level datasets, including but not limited to: Hospital Episode Statistics, Office for National Statistics mortality data, National Cancer Registration and Analysis Service data, Mental Health Services Data Set, and Practice Level Index of Multiple Deprivation.

A significant proportion of protocols submitted to ISAC request linkage to other datasets. Figure 6 shows the number of applications requesting data linkage over the years. A total of 345 new applications submitted to ISAC in the 2020/21 requested data linkage over the reporting period, represented 1162 linked datasets being requested[2]. The significant increase in data linkage requestions, which is the highest number on record, reflects the increase seen in the overall number

[2] Figures correct at the time of writing. Linkages requested are categorised by the financial year in which the original protocol was submitted to ISAC. Amendments received in subsequent reporting periods will cause these figures to change slightly.

of new research applications received during the financial year. The data show that, on average, around three linkages are requested for each protocol submitted, and continues to highlight the importance of CPRD's data linkage service.

**Fig. 6 – Linkages requested in ISAC applications submitted between financial years 2015/16 and 2020/21**

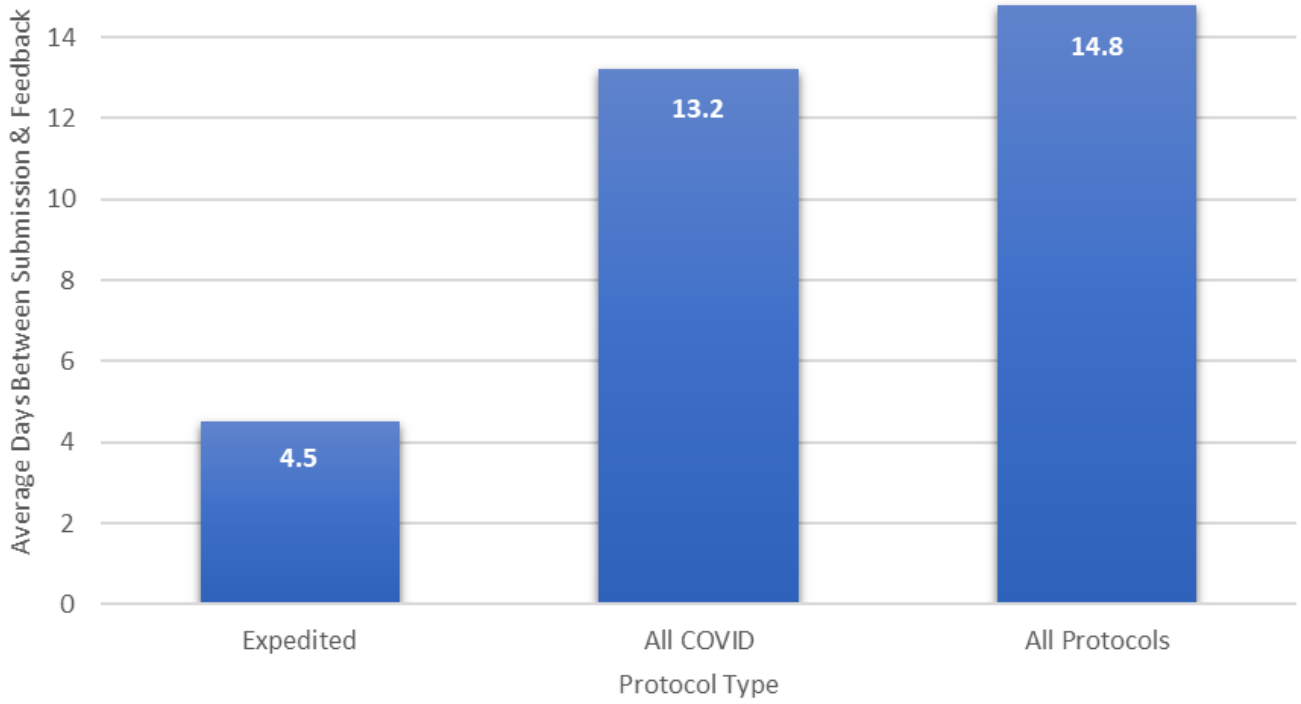



## 4.3. COVID-19 Protocols

During the COVID-19 pandemic, CPRD expedited processing of certain protocols relating to COVID-19 research. During the reporting period, 42 applications were made relating to COVID-19 research of which 9 were eligible for expedited processing. The COVID-19 applications account for the vast majority of increase in new applications received by CPRD in 2020/21.

Expedited processes were implemented to manage data requests relating to the pandemic. Figure 5 shows that the average time from submission to feedback for expedited protocols was 4.5 days, a near 70% reduction in feedback time compared to the average for all submissions in the reporting period. On average, all COVID-19 applications received feedback in 13.2 days, 11% faster than the average for the reporting period.

**Fig. 5 – Average working days between protocol submission and feedback for expedited COVID-19 protocols compared to all COVID-19 protocols and all protocols**

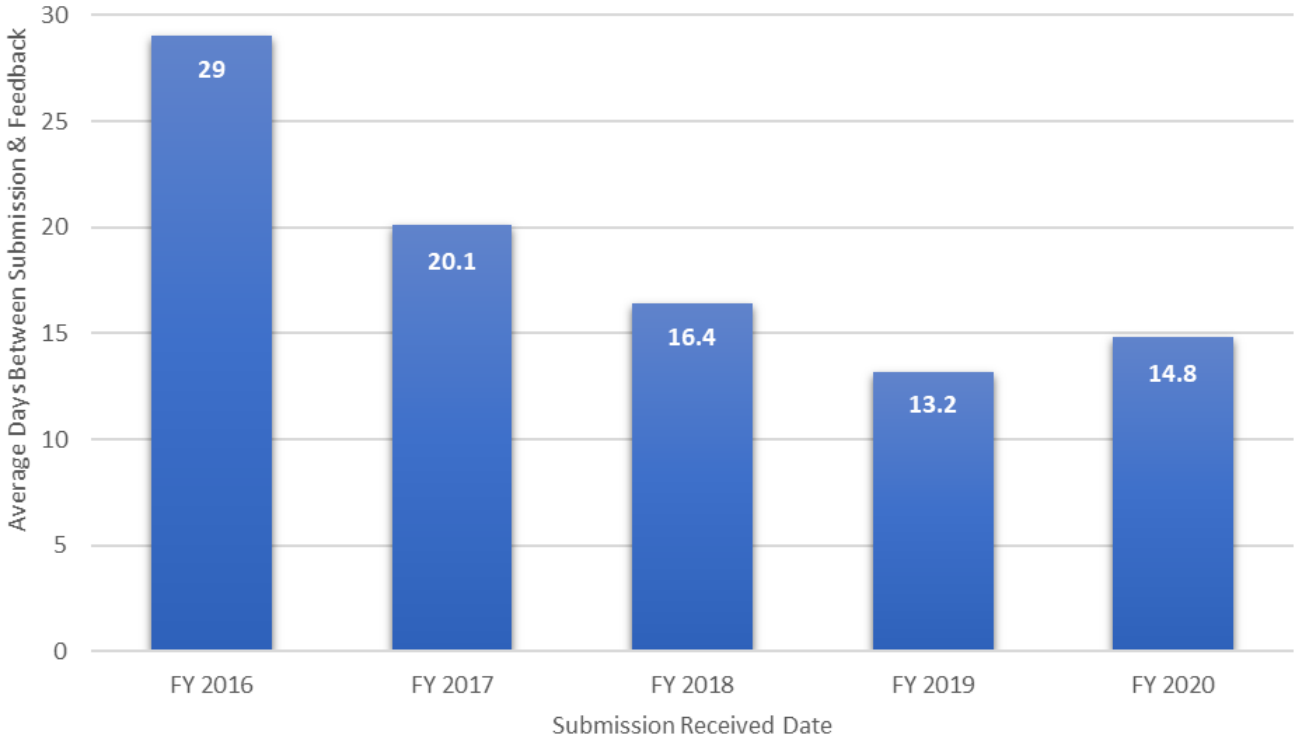



## 4.4. ISAC update

ISAC aims to make a decision on submitted applications within 28 working days. This target is defined as the time between an application being successfully submitted to ISAC and the decision on that protocol being communicated to the applicant. During the 2020/21 reporting period, the ISAC transitioned to reviewing all protocols on eRAP. However, for a period of time the Committee was continuing to review resubmissions and amendments via the previous system. This has contributed to a small increase in feedback time during the reporting period, although the figure of 14.8 days is still almost half of the target time.

Figure 7 shows the time taken between protocol submission and feedback sent to the applicant since 2016/17. The average time taken to communicate a decision on submitted applications in 2020/21 increased by 12% to just under 15 working days. This figure was just over a day more than for 2019/20, which was prior to the increased workload experienced during the pandemic and implementation of the new eRAP systems but still almost 2 days less than timeframes experience prior to 2018/19

**Fig. 7 – Average working days between protocol submission and feedback sent date between financial years 2016/17 and 2020/21**




## 4.5. Summary

In summary, the number of new ISAC applications increased significantly from the previous reporting year, up 27%. The majority of this increase was due to the additional 42 applications received in the reporting period which related to COVID-19 research.

There was a slight increase in the average feedback time during the reporting period to just under 15 days, which can largely be explained by the launch of the eRAP platform in August 2020 and additional workload responding to the demand for data at the outbreak of the global pandemic. Despite this, and the changes to working methods created by the pandemic, CPRD was able to provide feedback to expedited COVID-19 protocols in just 4.5 working days. On average, expedited COVID-19 protocols were approved in only 11 working days.

Of the 296 protocols approved in the reporting period, over 50% were led by UK academic institutions, with disease epidemiology research remaining the most prevalent research type. Data linkage remains an important CPRD service, with 309 of the 345 protocols submitted in the reporting period requesting linkage to one or more other data sources.[3]

[3] Figure correct at time of writing

# Annex 1 – Key metrics for 1 April – 31 May 2021

This annex presents key metrics covering the period from the end of the Annual Report period 2020/21 to the implementation of the new RDG process. Collectively the report captures all activities of the ISAC from 1 April 2020 to the end of ISAC operations on 31 May 2021 after which time ISAC was superseded by the CPRD's new Research Data Governance Process.

In this intervening period, the ISAC received 54 new research applications. The ISAC also approved 54 research applications between 1 April and 31 May.

Figure 8 provides a breakdown of the 54 protocols approved in the additional period by the Chief Investigator's organisational affiliation. UK Academia remained the primary affiliation during this period.

**Fig. 8 – Number of approved protocols by Chief Investigator's organisational affiliation between 01/04/2021 and 31/05/2021**

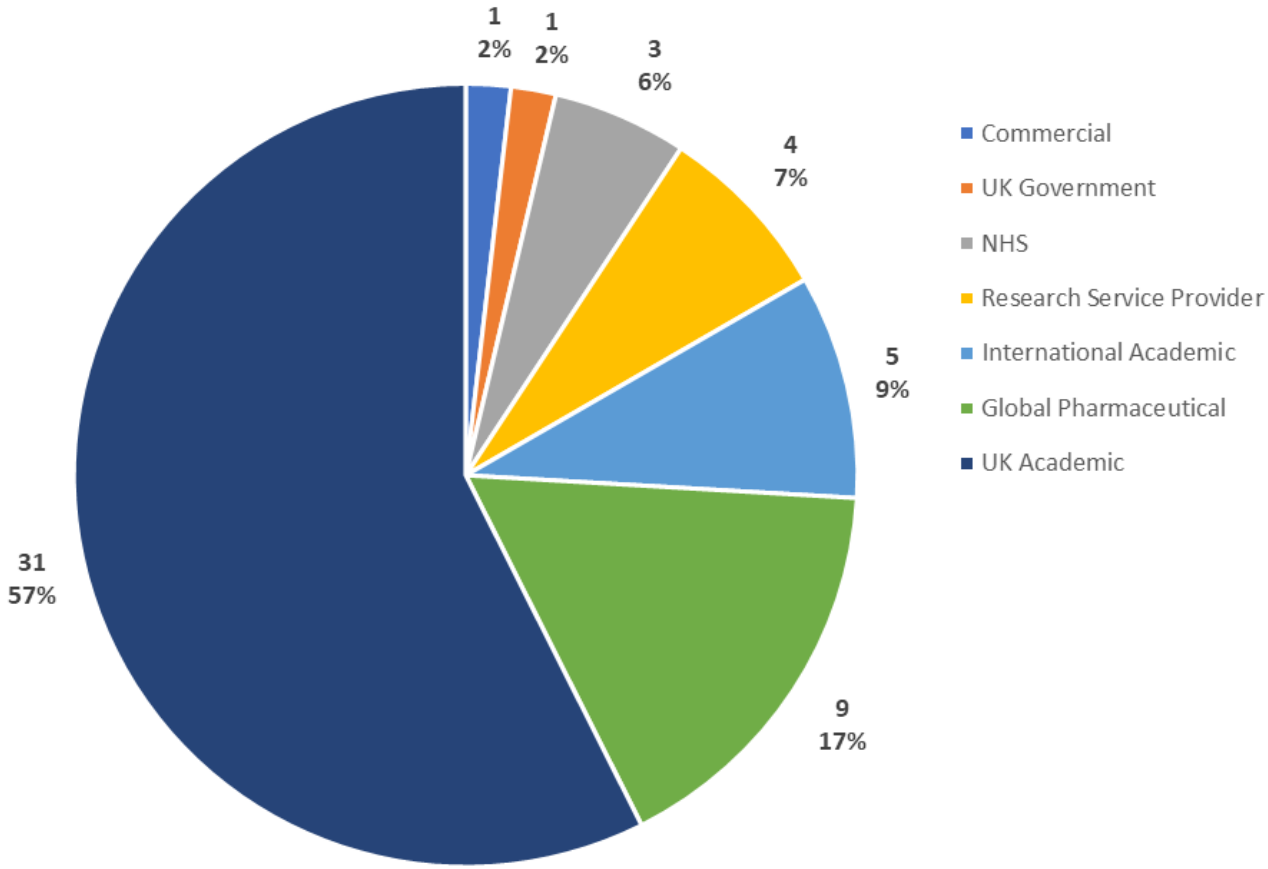
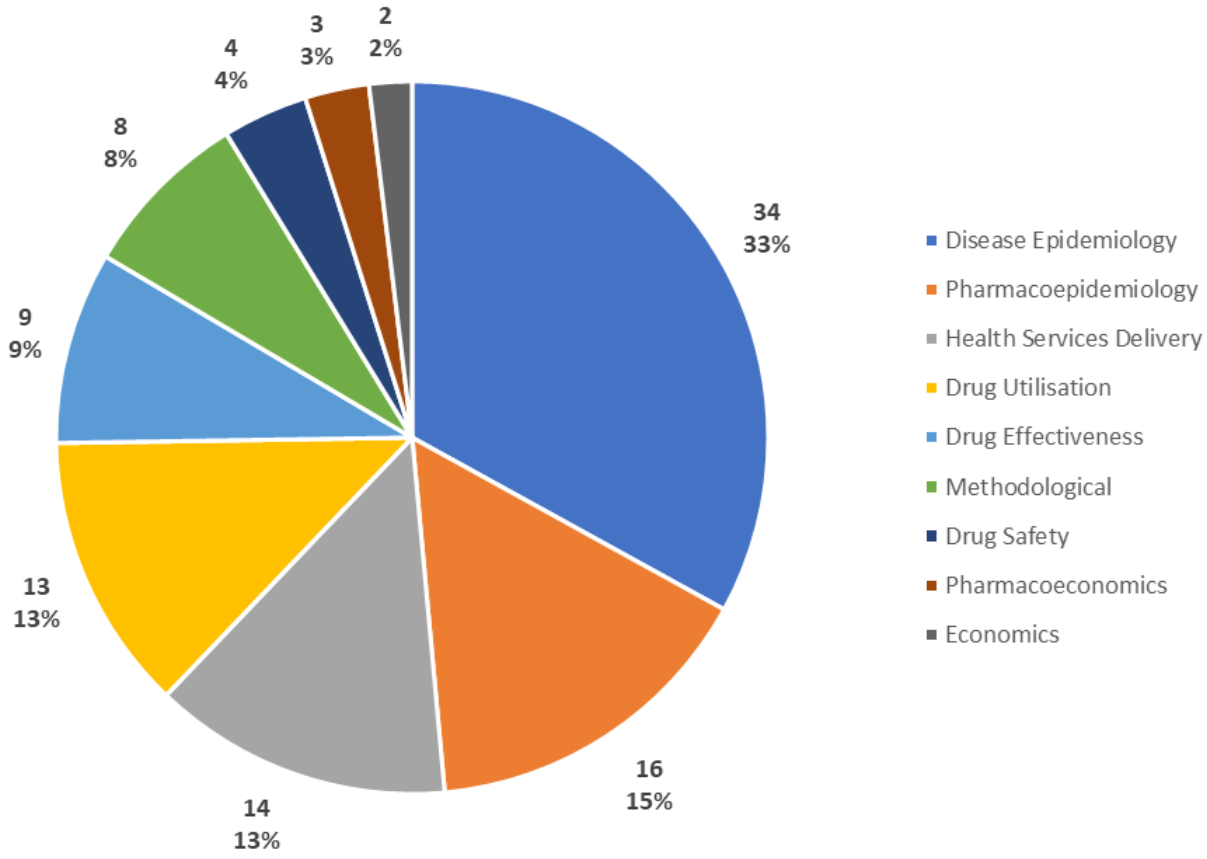


Figure 9 provides an overview of the 54 protocols approved in the additional period, categorised by research type. During the additional period, one third of protocols were self-reported as relating to disease epidemiology.

**Fig. 9 – Approved protocols by research type, between 01/04/2021 and 31/05/2021**




During the additional period there were 6 protocols submitted relating to COVID-19 research, 1 of which was expedited. Feedback for the expedited protocol was provided in 6 working days, with feedback for the other COVID-19 protocols submitted within the additional period provided in 15.4 working days.

During the additional period, the average working days between protocol submission and feedback increased marginally to 15.6 working days. The slight increase may be due to the additional period incorporating the Easter holiday.

# Annex 2 – Membership over 1 April 2020 – 31 May 2021 and member biographies

**Professor Deborah Saltman AM (Chair) MBBS MD MRCGP FRACGP FAFPHM GAICD. (Appointed as Chair on 18 January 2016)**

**Professor Richard Stevens (Deputy Chair) BA MSc PhD (Reappointed as Deputy Chair in April 2018)**
Associate Professor, Medical Statistics Group, Nuffield Dept of Primary Care Health Sciences, University of Oxford

**Professor Krishnan Bhaskaran MSc PhD (Reappointed 17 June 2020)**
Professor of Statistical Epidemiology and Wellcome Senior Research Fellow, London School of Hygiene and Tropical Medicine

**Professor Sinead Brophy BSc PhD (Reappointed 1 January 2018)**
Professor of CIPHER, College of Medicines, Swansea University

**Dr Benjamin Cairns (Reappointed 17 June 2020)**
Senior Research Fellow and University Research Lecturer in the Nuffield Department of Population Health, University of Oxford

**Dr Iain Carey (Appointed 13 November 2017)**
Senior Lecturer in Epidemiology, St George's, University of London

**Dr Rosie Cornish (Appointed 17 January 2017)**
Research Fellow, Population Health Sciences, Bristol Medical School, University of Bristol

**Dr Duncan Edwards BSc, MB BS, MRCGP (Reappointed 1 March 2018)**
NIHR Doctoral Research Fellow and GP, Department of Public Health and Primary Care, The School of Clinical Medicine, University of Cambridge

**Professor David Fishwick MBChB FRCP (Glasgow and London) AFOM MD (Appointed 13 November 2017**
Honorary Professor of Occupational and Environmental Respiratory Disease, University of Sheffield

**Dr Kate Fleming MA Cantab MSc PhD PGCHE (Appointed fPROMS1 January 2018)**

Senior Lecturer in Social Epidemiology, University of Liverpool

**Professor Martin Gulliford (Reappointed 17 June 2020)**
Professor of Public Health, King's College London

**Dr Iskandar Idris (Reappointed 17 June 2020)**
Clinical Associate Professor & Honorary Consultant Physician, Faculty of Medicine & Health Sciences, University of Nottingham

**Professor Umesh Kadam MB ChB MRCGP MPhil PhD FFPH (Reappointed 26 February 2020)**
Professor of Primary Care & Public Health Research, Diabetes Research Centre, University of Leicester

**Dr Evangelos Kontopantelis PhD (Appointed 1 January 2017)**
Professor and Data Sciences Health Services Researcher, Division of Informatics, Imaging and Data Sciences, University of Manchester

**Professor Richard Martin PhD (Reappointed 17 June 2020)**
Professor of Clinical Epidemiology, University of Bristol

**Dr Emily McFadden MA (Cantab) MSc PhD (Reappointed 5 November 2018)**
Senior Statistical Epidemiologist & Departmental Lecturer, Nuffield Department of Primary Care Health Sciences, University of Oxford

**Professor Andrew Morris BSc MSc PhD (Appointed 15 December 2017)**
Professor of Statistical Genetics. Division of Musculoskeletal & Dermatological Sciences, University of Manchester.

**Professor Keith Neal (Reappointed 30 September 2017)**
Emeritus Professor in the Epidemiology of Infectious Diseases, University of Nottingham and Consultant in Health Protection, for the Programmed Delivery Unit, Public Health England

**Dr Grace Okoli PhD, MBChB, MRCGP (Appointed 13 November 2017)**
NIHR Clinical Lecturer, Centre for Primary Care and Public Health, Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

**Professor Jennifer Quint PhD (Reappointed 1 January 2018)**

Professor of Respiratory Epidemiology, National Heart and Lung Institute, Imperial College London

**Professor Martin Tobin (Appointed 15 December 2017)**

Director of Leicester Precision Medicine Institute and Professor of Genetic Epidemiology and Public Health, University of Leicester

**Dr Hester Ward BSc, MBBS, MRCP, FRCPE, MPH, FFPH (Reappointed 1 January 2018)**

Consultant in Public Health Medicine, NHS National Services Scotland

**Dr Paul Welsh (Appointed 13 November 2017)**

Senior Lecturer, Institute of Cardiovascular and Medical Sciences, University of Glasgow

**Dr Stephen Weng (Appointed 13 November 2017)**

NIHR Research Fellow, Division of Primary Care, Faculty of Medicine & Health Sciences, University of Nottingham

**Professor Ian Wong (Reappointed 1 January 2018)**

Chair in Pharmacy Practice, UCL School of Pharmacy & Lo Shiu Kwan Kan Po Ling Professor in Pharmacy, The University of Hong Kong

**Member biographies**

**Professor Deborah Saltman AM** is the Chair of ISAC. Previously she was a clinical and scientific advisor and consultant within the medical communications and pharmacoeconomics arena. She holds positions as Honorary Professor in the Faculty of Medicine at Imperial College and the University of Sydney and is Visiting Professor at the University of Technology, Sydney. She has extensive experience in databases and database research, HTA assessments, health research, postgraduate medical education and medical publishing.

Deborah was made a member of the Order of Australia in 2004 and is a recipient of the Rose Hunt Medal from the RCGP (UK 2006). She is also a Notable Australian Doctor and has a doctorate in general practice as well as Fellowships of the RACGP, RCGP, RACP (Public Health Faculty). She is also a graduate of the Australian Institute of Company Directors. An active member of several professional organisations, Deborah has worked with the UK Council of Psychotherapists to develop a new Code of Ethics.

**Professor Richard Stevens** is deputy director of the statistics group at the Nuffield Department of Primary Care Health Sciences (NDPCHS) in Oxford, and a fellow of Kellogg College, Oxford. His previous experience includes eight years at the Oxford Centre for Diabetes, Endocrinology and Metabolism, where he worked with the UK Prospective Diabetes Study group on the epidemiology and computer modelling of the cardiovascular complications of type 2 diabetes, and three years with the Cancer Research UK Epidemiology unit, where he studied pancreatic cancer in the Million Women Study cohort. He is course director of the M.Sc. course in Evidence Based Health Care Medical Statistics at the University of Oxford.

**Professor Krishnan Bhaskaran** is Professor of Statistical Epidemiology and Wellcome Senior Research Fellow in the Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine. He leads the Beyond Cancer research group and co-leads the Electronic Health Records research group at LSHTM. His research interests include investigating the long-term health of cancer survivors, the health effects of obesity, and methodological issues in electronic health records research. He is also one of the statistical leads for the OpenSAFELY initiative for COVID-19 research. He is a module leader on the LSHTM MSc in Epidemiology and teaches extensively on the course. He also holds a number of external roles including MSc external examiner for Imperial College London, funding panel member for Yorkshire Cancer Research, and data safety monitoring board member for a number of COVID-19 vaccine trials.

**Professor Sinead Brophy** is Professor of Public Health Informatics at Swansea University. She has over 20 years of experience working with large data sets and linkage of routine data for digital epidemiology, and longer-term follow-up of interventions and natural experiments. She is Deputy Director of the National Centre of Population Health and Wellbeing and Lead of Early Years in the Administrative Data Research Partnership, PI on Growing up in Wales program. She is also Deputy Director in the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement a reviewer for the Health Research Board for Ireland and training lead in HDRUK Wales, as well as being the Associate Editor in BMC Public Health and previously the Pharmacoepidemiology lead (CIPHER –Centre for the Improvement of Population Health through E-records Research) within the FARR Institute and Co-Director of the Welsh Arthritis Research Network. She also has expertise in developing electronic cohort studies.

**Dr Benjamin Cairns** is a Senior Research Fellow and University Research Lecturer in the Nuffield Department of Population Health, University of Oxford. His expertise is in epidemiology and statistical methods for large-scale studies of chronic diseases, with particular experience working on obesity, cancer and cardiovascular diseases in the Million Women Study, the UK Biobank and other cohort studies. He is a University Lead for the HDR UK/Turing Wellcome PhD Programme in Health Data Science, and Director of the linked DPhil course at Oxford.

**Dr Iain Carey** is Senior Lecturer in Epidemiology at St George's, University of London. He has been involved in research projects utilising primary care databases since 2001, including DIN, THIN and CPRD. His research interests have focused on issues pertinent to older people, such as polypharmacy and inappropriate prescribing, the quality of care in elderly care homes and the impact of bereavement in the elderly.

**Dr Rosie Cornish** is a statistical epidemiologist. She has worked at the University of Bristol since 2007 - in the Department of Population Health Sciences, Bristol Medical School. She works on both applied and methodological projects, with a particular focus on analyses in the presence of missing data and the use of administrative and routine health data in research.

**Dr Duncan Edwards** is an NIHR Doctoral Research Fellow at the University of Cambridge and GP in South Norfolk. He graduated from Royal Free and University College London Medical School in 2005. After working as a junior doctor in London and East Anglia, he undertook general practice training combined with an academic clinical fellowship at the University of Cambridge between 2007 and 2011 before he joined Grove Surgery, Thetford as a GP partner in 2011. From 2013-5 he was a board member of South Norfolk CCG. His own research is focused on the prevention and treatment of stroke and cardiovascular disease in the primary care setting.

**Professor David Fishwick** is currently a Consultant Respiratory Physician with a major clinical and research interest in occupational lung disease, holding the following roles; Consultant Respiratory Physician, STH Foundation NHS Trust, Co-Director of the Centre for Workplace Health (CWH), and the Chief Medical Adviser of the Health and Safety Executive of Great Britain. In addition, he is an Honorary Professor of Occupational and Environmental Respiratory Medicine, University of Sheffield, awarded in 2010.

**Dr Kate Fleming** is a Senior Lecturer in Social Epidemiology at the University of Liverpool. Her research focuses on the epidemiology of alcohol use, of pregnancy and child health, and on the use of linked electronic health records for epidemiological research. At the intersection of this she is particularly interested in how we might measure the harms caused by alcohol exposure in pregnancy. Following a primary degree in Natural Sciences (Pharmacology) from University of Cambridge and an MSc in Epidemiology from LSHTM, Kate previously worked at the University of Nottingham focussing on studies using the CPRD, including her own PhD on liver disease.
In addition to her research activity, Kate has substantial commitments to the teaching of public health for the undergraduate MBChB programme at the University of Liverpool.

**Professor Martin Gulliford** is Professor of Public Health in the School of Population Health and Environmental Sciences at King's College London. His research focuses on the use of electronic health records to evaluate public health interventions including public health trials with either cluster or individual level randomisation, as well as health economic modelling studies. The main areas of application are in obesity, chronic disease prevention, ageing and antimicrobial utilisation. He recently edited ‘Healthcare Public Health: Improving health services through population science’, OUP 2020.

**Dr Iskandar Idris** is Clinical Associate Professor & Honorary Consultant Physician at the University of Nottingham. He is the Principal Investigator within the MRC Arthritis UK for Musculoskeletal Research and Ageing and the Vascular Medicine Research group.

**Professor Umesh Kadam** is Professor of Primary Care and Public Health Research (University of Leicester), a GP and clinical epidemiologist with 25 years of experience in coding and using GP data. He has led a clinical linkage (general practice, hospital data and specialist registries) epidemiology programme using CPRD and international datasets in the US, Sweden and the Netherlands. His research programme focuses on multimorbidity, cardio-metabolic and common chronic diseases in primary care.

**Professor Evangelos Kontopantelis** is a Professor and Data Sciences Health Services Researcher, mainly working with large-scale primary care databases (PCDs) to investigate important health care issues: the effect of monetary incentives on quality of care, predictors of cancer, cancer screening utilisation, care for people with severe mental illnesses. From a methodological perspective, he is primarily interested in computational statistics, meta-analysis, time series analysis and the validity issues around large databases in health care.

**Professor Richard Martin** is Professor of Clinical Epidemiology at the University of Bristol, Honorary Consultant in Public Health and NIHR Senior Investigator. He is Lead PI of CRUK's Integrative Cancer Epidemiology Programme (2015-2025), which has provided robust evidence on metabolic pathways in cancer. He leads the world's largest randomised trial of prostate cancer screening (CAP trial; n=413,000, JAMA 2018) that updated UK (2020) and USA (2018) screening policy, and he co-leads the long-term follow-up of the world's largest randomised controlled trial of breastfeeding promotion (n=17,000), that has led to robust evidence about the effects of breastfeeding on obesity (JAMA 2017), eczema (JAMA Pediatr 2018), IQ (PLOS Medicine 2018) and childhood eating attitudes (IJE 2014).

**Dr Emily McFadden** is a Senior Statistical Epidemiologist and Departmental Lecturer in the Nuffield Department of Primary Care Health Sciences at the University of Oxford, and a member of the Centre for Evidence Based Medicine. Her research interests include the use of large routine databases in medical research and research design. As part of the postgraduate Evidence Based Health Care programme, she coordinates the Big Data Epidemiology module and lectures in Study Design and Research Methods. She graduated from the University of Cambridge with an MA in Natural Sciences and Biological Anthropology, and from the London School of Hygiene and Tropical Medicine with an MSc in Epidemiology. She completed her PhD in 2009 at the University of Cambridge in the Department of Public Health and Primary Care. From 2009 to 2012 she worked as a Research Fellow in Epidemiology and Medical Statistics at the Institute of Cancer Research.

**Professor Andrew Morris** is a Professor of Statistical Genetics in the Centre for Genetics and Genomics Versus Arthritis at the University of Manchester, and has visiting appointments at the Estonian Genome Centre, University of Oxford, University of Liverpool, and Helmholtz Centre Munich. He obtained a BSc in Statistics (1994) and an MSc in Biometry (1995), before undertaking a PhD in Statistical Genetics. He has worked as part of major international collaborations, including the International HapMap Consortium and the Wellcome Trust Case Control Consortium, and was awarded a Wellcome Trust Senior Research Fellowship in 2007 (renewed in 2012). His research has focused on the development of methodology for the analysis of genome-wide association and re-sequencing studies, recently considering rare variants and trans-ethnic analyses, and complex clinical

outcomes in pharmacogenetics. He is currently a leading analyst in international collaborative efforts to understand the genetic basis of a wide range of complex human traits and diseases, including type 2 diabetes and glycaemic traits, kidney function, and blood pressure.

**Professor Keith Neal** trained in infectious diseases and public health. After training worked as a senior academic in the epidemiology of infectious diseases and as a consultant for the UK public health services (Health authorities, Health Protection Agency and Public Health England) as a consultant epidemiologist for over 30 years. His research interests included hepatitis C, meningococcal disease, food poisoning risks and sequelae particularly campylobacter and making surgery safer. He was involved in vaccine trials for HPV and meningitis. He delivered undergraduate and post graduate teaching on epidemiology, infectious diseases, public health and also ran the student elective project module His public health work including outbreak investigation and management, vaccine and travel advice, assessing clinical services and delivery epidemiological services of a region (5-8 million people). He represented his colleagues on the national infected health care workers advisory panel, hepatitis, meningitis and food poisoning national groups. He also contributed to the Ebola response with three visits; for the European Union, WHO and finally PHE to act as locum for the national lead. He has been working for PHE as part of the COVID-19 response.

**Dr Grace Okoli** is a general practitioner who lives and works in south London. She works as a clinical lecturer in the department on a part-time basis. With a background in molecular and cellular biology, she completed her PhD at Imperial College London. On completion of her doctorate, she became a post-doctoral researcher at Johns Hopkins School of Medicine in the United States, where she worked on developing an oral gene delivery system for the management of haemophilia – the protocol is currently under patent. At present, she is interested in the use of biomarkers in primary care to aid the early diagnosis of disease.

**Professor Jennifer Quint** received her BSc MBBS degrees from the University of London, UK before going on to gain a PhD from University College London and an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine, University of London. More recently, she became a Fellow of the Higher Education Academy and Royal College of Physicians. She is currently a Professor of Respiratory Epidemiology at the National Heart and Lung Institute (NHLI), Imperial College London and an Honorary Consultant at the Royal Brompton Hospital. Furthermore, she leads a clinical epidemiology research group covering various areas of respiratory and cardiovascular disease. Her work centres largely on the use of electronic health records to study COPD and other chronic respiratory diseases, including bronchiectasis and asthma. The majority of this work has been on exploring both the effect of COPD exacerbations on vascular outcomes and the relationship between environmental factors and exacerbations of COPD. She partners with the Royal College of Physicians and is responsible for the

analysis for the National COPD Audit and Pilot Asthma Audit. Professor Quint was awarded a COPD Rising Star award at COPD10 in 2016 as well as being “Highly Commended” at the BMA Medical Book Awards for co-authoring the Eureka Respiratory Medicine textbook. She currently serves as educational editor and associate editor for *Thorax*, is secretary of the Epidemiology group of the European Respiratory Society and the Information Governance Trustee for the British Thoracic Society.

**Professor Martin Tobin** is a Fellow of the Academy of Medical Sciences, Professor of Genetic Epidemiology and Public Health at the University of Leicester, and Chair of the Leicester Precision Medicine Institute. He leads a programme of research on the genomics of common, complex diseases and traits with particular emphasis on the genetics of lung health and COPD. He leads one of the major clinical partnerships for Genomics England (Quantitative Methods, Machine Learning and Functional Genomics), the SpiroMeta consortium, and the EXCEED study. Key interests including early career research training, public engagement and genomic-driven precision medicine in non-European ancestries. He contributes to panels and advisory committees for the Medical Research Council and the Academy of Medical Sciences.

**Dr Hester Ward** is a Consultant in Public Health Medicine for NHS National Services Scotland and Honorary Reader, University of Edinburgh School of Molecular, Genetic & Population Health Sciences. She has expertise in health informatics and is interested in improving population outcomes through use of health information.

**Dr Paul Welsh** is a senior lecturer at University of Glasgow. Following completion of his PhD in 2008, he obtained two separate British Heart Foundation Fellowships and completed an MSc in Epidemiology at London School of Hygiene and Tropical Medicine (Distinction, 150th Anniversary Prize). He has a wide range of research interests including the epidemiology of cardiovascular disease, diabetes, and inflammatory diseases, and he has a specific interest in biomarkers of disease.

**Dr Stephen Weng** is an Assistant Professor of Integrated Epidemiology and Data Science who leads the data science research within the Primary Care Stratified Medicine Research Group. Dr Weng integrates traditional epidemiological methods and study design with new informatics-based approaches, harnessing and interrogating "big health care data" from electronic medical records for the purpose of risk prediction modelling, phenotyping chronic diseases, data science methods research, and translation of stratified medicine into primary care.

**Professor Ian Wong** is jointly appointed by the UCL School of Pharmacy in London and the University of Hong Kong. Professor Wong is currently the Head of Research Department of Practice and Policy at

UCL School of Pharmacy and the Co-Director of the Centre for Safe Medication Practice and Research at the University of Hong Kong. He served as a board member of Pharmacy and Poisons Board of Hong Kong (the regulatory agency). Professor Wong was the founding director of the Centre for Paediatrics Pharmacy Research at UCL and Great Ormond Street Hospital for Children (2002 to 2011). Prof Wong has extensive experience in using clinical research databases for pharmacoepidemiology research.

# Annex 3 – Duties of ISAC members

1. Provide formal and informal advice to MHRA between meetings. Applications will be circulated electronically to ensure they are reviewed within 14 days and most CPRD applications will have to be decided without committee members meeting in person.
2. Attend all scheduled and unscheduled meetings of the Committee.
3. Consider, comment and contribute by their individual expertise and judgement as appropriate on all agenda items and to assist the Committee to frame clear and unequivocal advice to MHRA in accordance with the Committee's terms of reference.
4. Be able and be prepared to speak on a range of relevant issues and not just their own areas of specialism.
5. Develop an understanding of the types and uses of CPRD data and understand how and when release of data could lead to patients being identified if applications are not robust scientifically.

# Annex 4 – ISAC Members Declaration of Interests (2020/21)

| | Personal Interests | | Non-Personal Interests | | Current Interest |
|---|---|---|---|---|---|
| **Member** | **Name of Company** | **Nature of Interest** | **Name of Company** | **Nature of Interest** | |
| **Prof Deborah Saltman AM (Chair)** | None | N/A | None | N/A | |
| **Prof Richard Stevens (Deputy Chair)** | Novartis | Member of Data Monitoring Committee for a trial. | None | N/A | Yes |
| **Dr Krishnan Bhaskaran** | None | N/A | None | N/A | |
| **Prof Sinead Brophy** | None | N/A | UCB | Grant funding | |
| **Prof Benjamin Cairns** | Oxford BioTherapeutics | Spouse is VP & Head of Human Resources | None | N/A | Yes |
| **Dr Iain Carey** | None | N/A | None | N/A | |
| **Mrs Rosie Cornish** | None | N/A | None | N/A | |
| **Dr Duncan Edwards** | None | N/A | None | N/A | No |
| **Prof David Fishwick** | None | N/A | None | N/A | |
| **Dr Kate Fleming** | None | N/A | None | N/A | No |
| **Prof Martin Gulliford** | None | N/A | None | N/A | |
| **Dr Iskandar Idris** | None | N/A | None | N/A | |
| **Prof Umesh Kadam** | None | N/A | None | N/A | |
| **Prof Evangelos Kontopantelis** | None | N/A | None | N/A | |
| **Prof Richard Martin** | None | N/A | None | N/A | |
| **Dr Emily McFadden** | None | N/A | None | N/A | |
| **Prof Andrew Morris** | None | N/A | None | N/A | No |
| **Prof Keith Neal** | None | N/A | None | N/A | |
| **Dr Grace Okoli** | None | N/A | None | N/A | |

| | Personal Interests | | Non-Personal Interests | | Current Interest |
|---|---|---|---|---|---|
| **Member** | **Name of Company** | **Nature of Interest** | **Name of Company** | **Nature of Interest** | |
| **Dr Jennifer Quint** | AstraZeneca | Consultancy | AstraZeneca | Grants | Yes |
| | GlaxoSmithKline | Consultancy | GlaxoSmithKline | Grants | Yes |
| | Bayer | Consultancy | Bayer | Grants | Yes |
| | Insmed | Consultancy | Insmed | Grants | Yes |
| | Boehringer Ingelheim | Consultancy | Boehringer Ingelheim | Consultancy | Yes |
| | | | IQVIA | Consultancy | Yes |
| **Prof Martin Tobin** | None | N/A | GSK | BBSRC CASE studentship to Alex Williams (joint supervisor with GSK)<br><br>Respiratory Genomic Collaboration with University of Leicester (co-investigator) | Yes |
| **Dr Hester Ward** | Raptor Pharmaceuticals | Spouse: One off Advisory Board meeting attendance in 2016 (fee paid) | None | N/A | Yes |
| | Lamellar Biomedical Ltd | Spouse is medical advisor to the Board | | | Yes |
| | Elsevier | Spouse is editor on three medical text books (co-editor on 1) | | | Yes |
| **Dr Paul Welsh** | None | N/A | Boehringer Ingelheim | Grant | Yes |
| | | | Roche | Contract/grant for cohort phenotyping | Yes |
| **Dr Stephen Weng** | Road to Health Ltd. | Consultancy | | | Yes |
| | | | Amgen | Grant | Yes |

| | Personal Interests | | Non-Personal Interests | | Current Interest |
|---|---|---|---|---|---|
| **Member** | **Name of Company** | **Nature of Interest** | **Name of Company** | **Nature of Interest** | |
| **Prof Ian Wong** | Therakind | Director and shareholder | | | Yes |
| | Healthcare Innovation Technology Service (UK) | Director | | | Yes |
| | Jacobson Pharmaceutical (Hong Kong) | Consultancy | | | Yes |