Medicines & Healthcare products Regulatory Agency

Information Pack
CPRD Research Data Governance Expert Review Committee (ERC) Chair or Member

1. Background Information

Clinical Practice Research Datalink (CPRD) is a research service supporting retrospective and prospective public health and clinical studies. CPRD research data services are delivered by the Medicines and Healthcare products Regulatory Agency (MHRA) with support from the National Institute for Health and Care Research (NIHR), as part of the Department of Health and Social Care.

CPRD collects anonymised patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health-related data to provide a comprehensive longitudinal, representative UK population health dataset. For details on the specific datasets that CPRD holds and processes, see our web pages on linked data and how CPRD safeguards patient data.

CPRD data has been used for more than 30 years to safeguard and improve patient and public health. It supports vital research into health care delivery in the UK, safety and effectiveness of medicines and risk factors for disease. More than 3,000 medical and public health research studies have been published using CPRD data. These have informed drug safety and clinical best practice guidance.

CPRD data are used by medicines regulators such as the MHRA, other government organisations such as NHS England and/or UK Health Security Agency, the National Health Service (NHS), academic researchers and pharmaceutical companies. Information on the approved studies web page shows the types of studies conducted and which organisations are carrying out these studies.

2. Accessing CPRD Data

Access to CPRD data is subject to research protocol approval via the CPRD Research Data Governance (RDG) process. The RDG process is outlined in the flow diagram in **Annex 1,** and is supported by teams of Expert reviewers, Lay reviewers, a Central Advisory Committee (CAC), CPRD Researchers and the CPRD Information Governance team.

The review of research applications is conducted via two main routes based on the perceived public health risks of the research. Research triaged as higher risk is reviewed via the 'non-routine' route by at least one Expert Review Committee (ERC) team comprising a Chair, two external reviewers and one CPRD Researcher, with input from Lay reviewers and/or the CPRD Information Governance team, where required. Research triaged as low risk is reviewed via the 'routine' route led by CPRD Researchers, with input from the CPRD Information Governance team and/or Lay reviewers, where needed. Routine applications may be referred for ERC or CAC review, if required.

All reviewers advise CPRD on the feasibility of the proposed research, its public health benefits/risks, and potential information governance risks.

The CAC comprise all ERC Chairs and Lay reviewers in the RDG process. It advises CPRD on specific issues relating to access to CPRD data for public health research purposes, including advice

on scientific, ethical, patient confidentiality, or reputational issues, and other issues as required by the CPRD. The CAC also reviews research applications escalated to the CAC either via CPRD (applications from the routine route) or on the recommendations of an ERC (applications from the non-routine route). The Committee also provides oversight of the CPRD research application triage process and supports calibration and quality assurance across the review process.

CPRD is ultimately responsible for granting protocol approval, considering the advice provided by CPRD Researchers, ERCs and the CAC, as relevant.

3. Role of Expert Review Committees (ERC)

ERCs provide expert scientific and clinical advice to CPRD on individual applications requesting access to CPRD data for public health research purposes. This advice may also include ethical considerations and guidance on potential reputational issues posed by the research.

Roles and responsibility of ERC Members

ERC Members independently review CPRD research applications and make recommendations to their ERC Chair about the research feasibility (including research team experience), the public health benefits/risks of the research and potential information governance risks.

Research Application Review

- Provide independent expert advice on the merit of research proposing access to and use of CPRD data, including consideration of ethical and reputational issues.
- Able to review research in a range of disease or therapeutic areas, and not just own areas of specialism.
- Ensure reviews are completed in a timely manner, and in accordance with the latest CPRD review guidelines.
- Act in the interests of the MHRA, irrespective of any commitments to other organisations or groups or any personal interests (and making appropriate declarations where any potential conflicts arise).

Eligibility Criteria for ERC Members

To be considered for the role of ERC Member, you must have the qualities, skills, and experience outlined below for appointment.

- Academic and/or professional qualification establishing expertise in general or specialist clinical practice, public health research, data science in health care environment e.g., public health, statistics, epidemiology.
- Previous experience on expert committees and/or in peer review.
- Experience of either using electronic health record (EHR) systems within clinical practice and/or conducting research using data from such sources.
- Ability to readily assimilate complex information with high attention to detail.
- Proven ability to work both independently and as part of a multidisciplinary team.
- Excellent verbal and non-verbal communication skills.
- Proven ability to work to tight deadlines and targets.

Role and responsibility of an ERC Chair

ERC Chairs moderate the reviews and recommendations of their ERC team Members and provide clear recommendations to the CPRD in accordance with CPRD scientific review and moderator guidance. ERC chairs also serve on the CPRD CAC as described above.

Research Application Review

- Provide final recommendations to CPRD about the public health benefits and risks of research using CPRD data, including ethical, confidentiality, or reputational risks, based on ERC members review and own advice.
- Ensure that the full range of opinions arising from scientific reviews conducted by ERC Members are duly considered when making recommendations to CPRD.
- Ensure timely advice and recommendations to CPRD on research seeking access to CPRD data sources.
- Act in the interests of the MHRA, irrespective of any commitments to other organisations or groups or any personal interests (and making appropriate declarations where any potential conflicts arise).

Advisory Functions

- Advise CPRD on existing or emerging public issues that may impact its ability to support and/or promote public health research.
- Contribute to review calibration and quality assurance activities to strengthen and/or streamline the CPRD RDG process.
- Make considered contributions to the work of the CAC and its decision-making processes.
- Contribute between meetings on matters of CPRD business, such as reading meeting papers, completing calibration exercises and participate in reviewer training.
- Cascade learning from CAC to ERCs and provide ERC leadership to achieve consistency in reviews.
- Chair quarterly CAC meetings as a rotating Chair.
- Support the CPRD RDG Appeals process, where needed.

Eligibility Criteria for ERC Chair

To be considered for the role of ERC Chair, you must have the qualities, skills, and experience outlined below for appointment.

- Demonstrate that you have a first-class reputation through relevant academic and/or professional qualifications and work at the interface between science and public health policy making.
- Have extensive experience of working successfully chairing scientific review, ethics, or governance committees or working as an Editor.
- Have considerable knowledge and/or experience of research using electronic health record (EHR) systems and/or conducting research using such data, including CPRD data.
- Have strong leadership skills, and a commitment to accountability and probity.
- Have excellent interpersonal and communication skills.
- Proven ability to work to tight deadlines and targets.

Virtual Working and Workload

Research protocols are reviewed across a virtual working environment. ERC Members should expect to review 1-2 applications per month. Members will be notified when a research application has been allocated to them and must accept or decline the review request. Members are expected to accept at least one application per month for review. Individual reviews typically take up to 45 minutes to complete. Members will have 10 working days to complete the review.

All ERC Members will receive training and will be provided with learning materials prior to commencing reviews. To ensure quality and consistency, CPRD may invite ERC Members to attend further training or calibration sessions. Such sessions will be conducted remotely.

For ERC Chairs, the CAC will convene virtually at least quarterly but may additionally meet on an *ad hoc* basis.

Duration of Appointment

ERC Members will be appointed for the period set out in the appointment letter, which is usually a 4-year term, with a review after 2 years unless membership is terminated before that date. Members' tenure may be further extended by a maximum of 1 year.

All ERC members will have their names published on the CPRD website for the duration of their appointment.

ERC Chairs and Members contribute to the CPRD RDG process on a **voluntary** basis.

Expertise Required

We are seeking to appoint **two** ERC Chairs and **six** ERC Members to the CPRD RDG process.

Expertise is being sought in the following broad areas, as related to public health research:

- General Practice
- Statistics and Epidemiology
- Pharmacoepidemiology and Pharmacovigilance
- Data science, modelling, and machine learning
- Clinical Medicine - secondary care, cancer, infectious diseases and other specialties
- Public health policy, particularly health outcomes research

We welcome UK and international applicants. PhD and Masters' students are not eligible to apply.

If you are unsure whether or not you are eligible to apply, please contact the RDG secretariat at rdg@cprd.com.

4. Equality and Diversity

The MHRA values and promotes diversity and is committed to equality of opportunity for all.

5. Data Protection

Your personal information is held and used in accordance with the General Data Protection Regulation 2016 (GDPR) EU 2016/679 and the Data Protection Act 2018. The DHSC is the legal 'controller' under GDPR.

CPRD respects the privacy of individuals who share their data and process it in a manner that meets the requirement of the GDPR. More details, including information about your rights, can be found in the CPRD's Privacy Policy.

Please see the section on 'General Data Protection Regulation 2016' below for more information.

6. How to apply

All applicants are required to complete an application form for the relevant role which are available here

The deadline for applications: **24 February 2025**

Completed application forms should be returned by email to the RDG at rdg@cprd.com.

We will notify all applicants of the outcome of their application **within 4 weeks** of receipt of a completed application form.

Successful applicants will be invited to attend one of the training sessions on Tuesday 29 April 2025, 15:00-16:30 and Friday 2 May 2025, 15:00-16:30. Additional sessions will be run as required.

7. Contact details

If you would like any more information before making an application, please contact the RDG Secretariat (rdg@cprd.com)

General Data Protection Regulation 2016

What happens to your data?

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Who has access to your data?

All information shared with us is kept appropriately and only shared with key decision makers in the recruitment process.

Your data may also be processed for statistical analysis purposes. We may share non-identifiable summarised data with the DHSC. We do not share your data with any other third parties.

How long do we retain your data?

On completion of the recruitment process, unsuccessful applications are kept for 6 months. After 6 months they will be destroyed. Successful applications will be stored securely and in accordance with MHRA policy. The DHSC is the legal 'controller' under GDPR.

Subject Access Request

The Data Protection Act allows you to find out what information we hold about you on computer and in some paper records. This is known as a subject access request (SAR).

To find out if we hold your personal data, or to access it please email:
enquiries@cprd.com

We will need evidence of your identity before searching our records; and will respond within one month of receiving your request. If we need extra time, we will inform you within the month.

How can you ask for your data to be removed?

You can ask for your details to be removed at any time by emailing us at enquiries@cprd.com.

CPRD research data services are delivered by the MHRA, an executive agency of the Department of Health & Social Care (DHSC), with responsibility for regulating medicines, medical devices and blood components for transfusion in the UK. The DHSC is the legal 'controller' of all the data that MHRA hold. You may contact the Data Protection Officer at:

Data Protection Officer
DHSC
1st Floor North
39 Victoria Street
London
SW1H 0EU

or at data_protection@dhsc.gov.uk

In common with most organisations, CPRD holds administrative personal data such as information on staff, customers, GP practices, partners and third-party suppliers. The legal basis for processing the administrative personal data that we hold is detailed on the CPRD Privacy Notice page and is covered under the privacy notices of MHRA and DHSC.

The Information Commissioner's Office

For independent advice about data protection, privacy and data sharing issues you can contact the independent Information Commissioner's Office at:

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Tel: 0303 123 1113

Annex 1. Clinical Practice Research Datalink Research Data Governance (RDG) Process