Medicines & Healthcare products Regulatory Agency

CPRD More Dimensions to Data

CLINICAL PRACTICE RESEARCH DATALINK (CPRD)

RESEARCH DATA GOVERNANCE OPERATING FRAMEWORK

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1. Introduction

1.1. The Clinical Practice Research Datalink (CPRD) is a research data service supporting retrospective and prospective public health and clinical studies. CPRD is jointly sponsored by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR), as part of the Department of Health and Social Care (DHSC).

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.

Access to CPRD data is subject to protocol approval via CPRD's Research Data Governance (RDG) Process. CPRD is ultimately responsible for granting protocol approval, considering independent advice provided by Expert Review Committees (ERCs) and the Central Advisory Committee (CAC), as relevant.

2. Principles

2.1. The RDG process ensures that the three broad principles which underpin access to CPRD data are adhered to:

- **Public and Professional Trust:** The data CPRD holds are provided through the trust of GPs who choose to contribute their GP practice anonymised patient data to CPRD. This trust is predicated on the wider public accepting the use of data derived from their medical records for the purpose of research to improve patient care and public health - this public and healthcare professional trust, and CPRD's reputation as a trustworthy organisation, must not be compromised.
- **Patient and Public Health Benefit:** The supply of data through CPRD is governed by regulatory permissions and approvals for the purposes of public health research only.
- **Maintaining Integrity of the CPRD Database Asset:** The proposed use of the data must not undermine the integrity or utility of the data held - this includes a requirement that the proposed use of the data should not in any way limit its use for statutory public health purposes or undermine the cohort through a breach of public trust.

3. CPRD RDG Process

The RDG Process is outlined in the flow diagram in 3.8. The steps are:

3.1. **Screening of applicants and funders:**
CPRD undertakes a rigorous assessment of prospective applicants and due diligence of funding/research organisations, to ensure that CPRD data are only accessed by *bona fide* researchers for public health research which is funded by trustworthy organisations.

3.2. **Application triage:**
Each application is checked for completeness and an assessment is performed by CPRD Researchers to determine whether the proposed study is routine or non-routine research.

3.3. **Routine research review:**
Routine research protocols are reviewed by CPRD Researchers.

3.4. **Non-routine research review:**
Protocols categorised as non-routine research are reviewed by an Expert Review Committee (ERC). Advice on the scientific merit of protocols is provided to CPRD by the ERCs. The role of the ERCs is described in section 4.

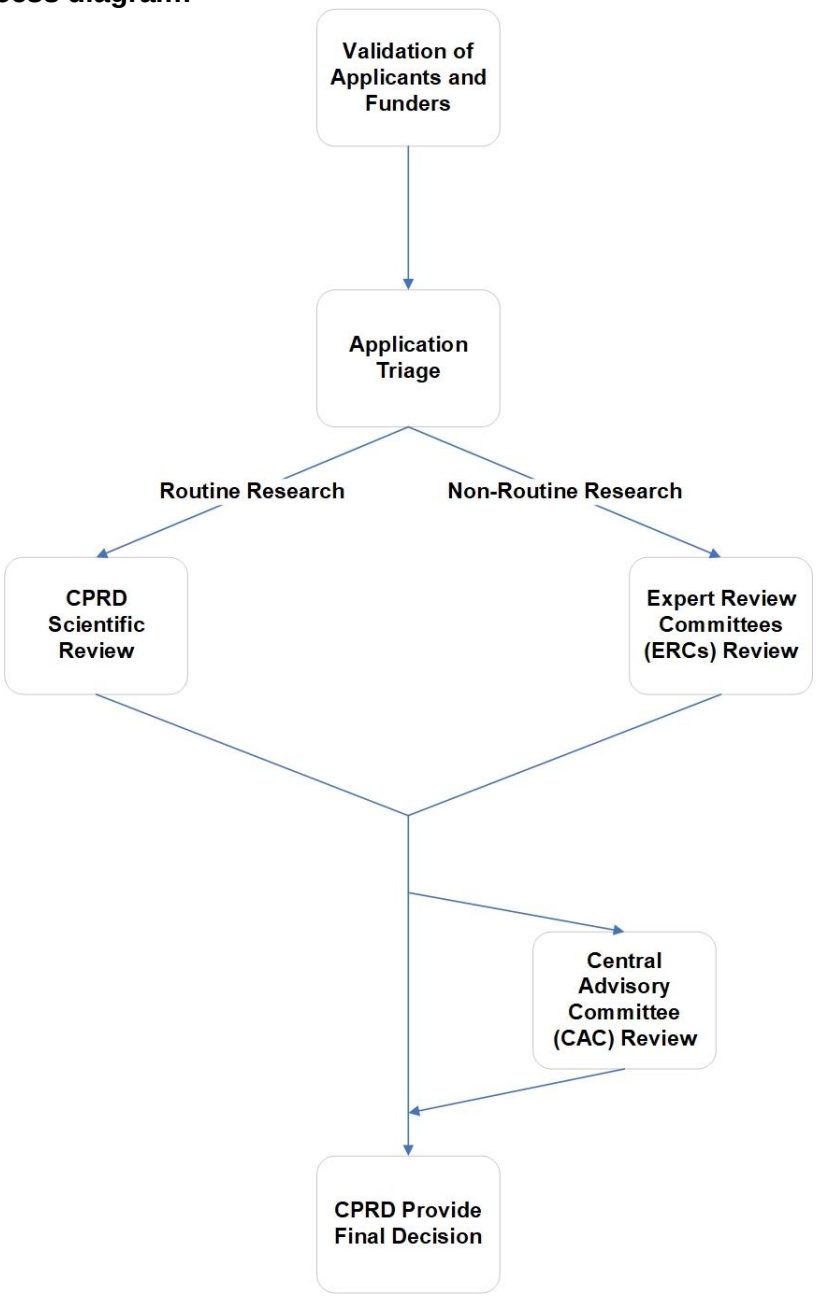
Routine and non-routine research studies may also undergo additional review by lay reviewers, subject matter experts, or information governance experts.

3.5. **Quality assurance:**
The Central Advisory Committee (CAC) will review any routine research or non-routine research applications which have been escalated to the CAC either by CPRD or on recommendation of an ERC. Quality assurance of the Research Data Governance Process is also provided by the CAC. The role of the CAC is described in section 5.

3.6. **Final decision and feedback:**
As the legal entity acting as the data controller on behalf of the Department of Health and Social Care (DHSC), CPRD is ultimately responsible for decisions on all applications for access to CPRD data. Advice from the ERCs and CAC, where applicable, is taken into account when making the final decision. CPRD will communicate the final decision to the applicant.

3.7. Applicants may appeal via the Appeals Process if an application is rejected.

3.8. **RDG Process diagram:**



4. Expert Review Committees (ERCs)

4.1. The role of the ERCs is to provide expert scientific advice to CPRD on individual applications requesting access to CPRD data for public health research purposes, including consideration of ethical and reputational issues.

4.2. The ERCs must provide advice in line with the Terms of Reference and Members' Terms and Conditions of Appointment to the ERC, and in accordance with Review Guidelines.

4.3. Each ERC comprises:

- One CPRD Researcher
- Two external Expert Review Committee Reviewers
- One external Expert Review Committee Chair

4.4. Other CPRD staff, lay representatives and subject matter experts may be invited to provide advice at the request of CPRD or the ERC Chair.

5. Central Advisory Committee (CAC)

5.1. The role of the CAC is to provide advice to CPRD on specific issues relating to access to CPRD data for public health research purposes, including advice relating to scientific, ethical, patient confidentiality, or reputational issues; and to ensure consistency of reviews across the ERCs.

5.2. The CAC provides quality assurance for the Research Data Governance Process.

5.3. Membership of the CAC includes the Chairs of the ERCs and Lay Members. CAC meetings will be attended by the CPRD Director and CPRD Head of Observational Research. The Chair of the CAC will rotate amongst the ERC Chairs on a quarterly basis.

5.4. Subject matter experts, further lay members, additional CPRD staff, and others, may be requested to attend as invited guests on an *ad hoc* basis.

6. Methods of working

6.1. The work of the ERCs and CAC is conducted virtually.

6.2. The CAC will convene at least quarterly, but may additionally meet on an *ad hoc* basis.

7. Secretariat

7.1. The CPRD RDG secretariat will provide all secretarial and administrative functions for the Research Data Governance Process.

8. Code of conduct

8.1. The ERCs and CAC will operate broadly under the Principles of Scientific Advice to Government as detailed in Annex A of the *Code of Practice for Scientific Advisory Committees (CoPSAC).*

8.2. A copy of the CoPSAC guidance can be found at https://www.gov.uk/government/publications/scientific-advisory-committees-code-of-practice

9. Transparency

9.1. The names and affiliations of CAC and ERC members will be published on the CPRD website.

9.2. Summary information of all approved studies is published at https://cprd.com/protocol-list.

9.3. Summary minutes of CAC meetings will be published on the CPRD website following any necessary redactions agreed by the CPRD Director and CAC meeting Chair.

10. Accountability

10.1. CPRD's Research Data Governance Process, including the CAC and ERCs, is accountable to CPRD via the CPRD Director.