Study approval

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Study application review

Researchers must submit a study application to access anonymised patient-level CPRD data. CPRD's Research Data Governance (RDG) process reviews study applications as part of the principles of Safe People and Safe Projects to ensure that researchers accessing CPRD data have viable plans that maintain public and professional trust, ensure the research is of public benefit, and are methodologically robust.

There are two types of study submission for access to anonymised patient-level CPRD data:

1. **Feasibility study** - where the intended purpose is to assess the feasibility of conducting a future study, using CPRD data or otherwise. More detail is available at Licence options (https://www.cprd.com/access-data/licence-options)
2. **Protocol** - to access CPRD data to explore a defined research question. Access can be via a Single Study Licence (/access-data/access-cprd-safe/single-study-licence) or Multi-Study Licence (/access-data/access-cprd-safe/multi-study-licence).

Documentation

- CPRD Research Data Governance (RDG) Operating Framework (https://www.cprd.com/sites/default/files/2022-02/CPRD%20Research%20Data%20Governance%20Operating%20Framework.pdf) (PDF, 178KB, 4 pages)
- Guidance on completion of a CPRD RDG application (https://www.cprd.com/guidance-completion-cprd-research-data-governance-rdg-application)
- Protocol application form in Word format (https://www.cprd.com/sites/default/files/2024-10/Template%20-%20CPRD%20RDG%20Protocol%20Application%20Form_v1.2.docx) (Word, 86KB, 5 pages)
- Guidance on requesting Linked Data (https://cprd.com/guidance-requesting-linked-data-cprd) for Multi-Study Licence (/access-data/access-cprd-safe/multi-study-licence) organisations

What information is requested

Research projects must demonstrate public health benefit and be reviewed and approved by CPRD. Information is requested about the following details:

- **A Chief Investigator (CI):** a named researcher who will be responsible for ensuring the study is undertaken with full adherence to CPRD terms and

conditions. The CI's organisational affiliation will be the study sponsor.

- **A Corresponding Applicant (CA):** a named researcher who will be the direct point of contact for the study. The CI and CA can be the same individual.
- **Collaborators:** all named researchers involved in the study, stating which individuals will require access to CPRD data.
- **Operational information:** to manage the data access licence agreement including the funding organisation, the licence options for access (either a Single Study or Multi-Study Licence), data processing locations, etc.
- **Data requested:** which CPRD data (https://www.cprd.com/data)are required to investigate the study objectives.
- **Any additional research services** (https://www.cprd.com/research-services)**:** such as GP or patient involvement (e.g. verification of CPRD observational data through GP questionnaires or request for supplementary information through the CPRD PROVE (https://www.cprd.com/research-services/cprd-prove) research service).
- **Study protocol:** concise descriptions about the research objectives, study design and methods, outcomes to be measured, how the study population will be defined, expected limitations of the study, plans to communicate the study results, etc. to justify the use of the requested data.

What researchers can expect

The process for research protocol submission and review is outlined below:

- **CPRD eRAP access** - all researchers must register an account on CPRD Gateway (https://gateway.cprd.com/) and be granted eRAP access under their organisational affiliation. CPRD will review account details and approve new registrations. All researchers must have approval to access CPRD eRAP before they can be listed on a protocol.
- **Pre-submission discussions** - the CI or CA can draft and complete feasibility studies or protocols on CPRD eRAP. Requests for certain types of data or services (e.g. linked NCRAS SACT or RTDS data (https://www.cprd.com/data/linked-data/ncras-cancer-datasets), or CPRD research services (https://www.cprd.com/research-services)) require contact with CPRD prior to research protocol submission.
- **Invite collaborators** - the CI or CA can invite collaborators to join their study, specifying if each individual will access CPRD data directly for the study. To locate any pending study invites collaborators should log into eRAP via their Gateway accounts and click "view all studies" in their studies dashboard. Then navigate to the "pending tasks" tab.
- **Research protocol submission** - once all requirements are met, the CI or CA can submit the study on CPRD eRAP.
- **Validation review** - the CPRD RDG Secretariat will conduct an initial

validation check to ensure all basic requirements are met (e.g. Client and Funder organisations are approved (https://www.cprd.com/access-data/organisation-approval), any pre-submission discussions have been completed, etc.).

- **Scientific review** - research protocols that pass the validation check will progress to RDG review by CPRD researchers for routine applications, or may include review by an Expert Review Committee (ERC) (https://www.cprd.com/access-data/study-approval/review-committees), lay reviewers, subject matter experts, or information governance experts if required. The Central Advisory Committee (CAC) (https://www.cprd.com/access-data/study-approval/review-committees) provides quality assurance of the RDG process and further review for escalated research protocols.
- **Feedback** - CPRD aims to review and provide feedback on all research protocols within 4 weeks of submission. Research protocols that are incomplete or do not meet the required standards will not be approved, and may require amendments to be made and re-submitted within 6 months. Resubmissions not made within 6 months of initial feedback will be recorded as withdrawn and applicants will need to submit a new protocol.
- **Contract agreement** - once a research protocol is approved, CPRD will prepare the licence agreement (https://www.cprd.com/access-data/licence-options)for the study sponsor to sign, to enable access to CPRD data.
- **Amending research applications** - researchers may submit post-approval amendments to an approved research protocol on CPRD eRAP. CPRD will review these amendments through the RDG process.
- **Summary publication** - after 3 months from the initial protocol approval date, the study summary (including health outcomes to be measured, the researchers and their organisations) will be published at Approved studies (https://www.cprd.com/approved-studies).
- **Application lifespan** - after 4 years from the initial protocol approval date, all approved studies will be archived on eRAP and no further amendments can be made (except to the CI, CA, or collaborators).

Eligibility for expedited review

Expedited review of research protocols may be requested from CPRD. This process provides rapid review of research applications seeking access to CPRD data.

Research must meet the criteria below to be considered for expedited review:

1. Serious public health concerns e.g., COVID-19, drug safety or other

regulatory concerns
2. Urgent health policy research
3. Ministerial Requests i.e., research in support of security, intelligence, prosecution, international relations
4. Research requested by law or court order

To ascertain if a research protocol is eligible for expedited review, a statement should be prepared that demonstrates how the research meets at least one of the criteria listed above, and the expected impact of the work. The impact statement must be emailed to rdg@cprd.com for consideration.

The CPRD research data governance team will confirm whether a protocol is eligible for expedited review within 2 working days of receipt of a request.

Following confirmation by CPRD that the research is eligible for expedited review, a valid application must be submitted via CPRD eRAP within 5 working days. Failure to do so may result in withdrawal of approval for expedited review.

Please note that the review of expedited research protocols is based on the same scientific review criteria used in the review of CPRD research protocols that have not been expedited for review.

RDG Exempt Activity

The following uses of CPRD data are exempt from submission of a research application to the CPRD Research Data Governance (RDG) process. These exemptions are supported by CPRD's NHS Database Research Ethics Committee Approval (21/EM/0265). The use of CPRD data under these exemptions remain subject to the terms of CPRD's Study Licence Agreements.

1. Simple feasibility counts

These are limited to counts of events or patients as specified below:

Counts conducted by CPRD

- Counts may be conducted by CPRD on behalf of licence or non-licence holders via the CPRD Simple Feasibility Count service.
- Counts may include CPRD primary care data (CPRD Aurum and/or CPRD Gold) and/or Link Data sources.
- Counts provided by CPRD are subject to a fee and can be requested by downloading the CPRD feasibility count form

(https://www.cprd.com/sites/default/files/2025-06/Feasibility%20count%20form%20v2.5.docx).
- Further information about the CPRD Simple Feasibility Count service can be requested from enquiries@cprd.com.

Counts conducted by Customers under a CPRD Multi-Study Licence Agreement

- Counts may be conducted by Researchers from an organisation that holds a CPRD Multi-Study Licence (https://www.cprd.com/access-data/access-cprd-safe/multi-study-licence) (MSL), hereafter referred to as the Customer.
- Counts must be conducted by Nominated Users from the Customer organisation and for the Customer directly.
- Counts must be based on the CPRD primary care databases only, that is, CPRD Aurum and/or CPRD Gold.

Examples of simple feasibility counts include:

- Counts of patients with a particular clinical condition, stratified by year, gender or age group.
- Counts of patients receiving prescriptions for a certain substance, stratified by year, gender or age group.
- Counts of prescriptions for a substance/substances, stratified by year, gender or age-group.

All simple feasibility counts conducted by CPRD or the Customer must meet CPRD's statistical disclosure controls (https://www.cprd.com/sites/default/files/2024-10/CPRD%20Safe%20Outputs%20Guidance.pdf).

Publications of simple feasibility counts

Simple feasibility counts may be used to support CPRD RDG or Interventional research applications, be included in grant applications, published in internal reports, included in conference presentations, shared with medicines regulatory bodies or public health agencies (see the section below on 'Exemptions and analyses for medicines regulatory bodies and public health agencies'), or peer-reviewed academic journals.

All findings must be presented in the context of a feasibility count within a given data source and/or database (e.g. CPRD Aurum). For example, it would not be appropriate to present the findings in a publication as an incidence or prevalence count.

2. Feasibility studies conducted by Customers under a CPRD Multi-Study

Licence Agreement

Feasibility studies may be conducted under a CPRD Multi-Study Licence (https://www.cprd.com/access-data/access-cprd-safe/multi-study-licence) (MSL) held by the Customer organisation and according to CPRD feasibility study guidance (https://www.cprd.com/sites/default/files/2024-06/Guidance%20-%20CPRD%20RDG%20Feasibility%20Study%20Application_v1.1.pdf).

- Feasibility studies conducted by Customers must use CPRD primary care data only, that is, CPRD Aurum and/or CPRD Gold.
- The work undertaken must have a direct focus on informing public health research, health care planning or economic evaluation of health technologies in a future study. Other types of research such as marketing research are not permitted.
- Analysis of feasibility studies must be descriptive only, that is, this must not include hypothesis testing or tests of significance.
- Feasibility studies must be conducted by Nominated Users from the Customer organisation and for the Customer directly.
- Outputs from feasibility studies undertaken as RDG exempt activity must be for internal Customer use only and must not be disseminated to parties outside of the Customer organisation, except where outputs are pre-approved by CPRD for sharing with medicines regulatory bodies or public health agencies (see the section below on 'Exemptions and analyses for medicines regulatory bodies and public health agencies').
- Organisations must maintain an up-to-date log of all feasibility studies undertaken as RDG exempt activity. This must include the following details below. This log may be audited by CPRD at any time.
    - Data sources used
    - Summary of use (no more than 250 words)
    - User at the Customer organisation
    - Date of data access

All outputs derived from feasibility studies exempted from RDG review must meet CPRD's statistical disclosure controls (https://www.cprd.com/sites/default/files/2024-10/CPRD%20Safe%20Outputs%20Guidance.pdf).

Publication of findings from feasibility studies

Only outputs that are pre-approved exemptions for medicines regulators or public health agencies (see the section below) may be published from feasibility studies conducted as RDG exempt activity,

Feasibility studies intended for publication, with a potential for publication, or which will be disseminated outside of the Customer organisation (excluding

pre-approved exemptions), require CPRD RDG approval. Please contact CPRD for further information about feasibility studies that may require RDG approval (enquiries@cprd.com).

Exemptions and analyses for medicines regulatory bodies and/or public health agencies

Some uses of CPRD data for submission to medicines regulatory bodies or public health agencies have been pre-approved by CPRD and do not require a research protocol. The conditions of such use are as follows:

- Only the use of CPRD primary care data (CPRD Aurum and/or CPRD Gold) is permitted under this exemption.
- Only organisations that hold a current CPRD Multi-Study Licence (MSL), hereafter referred to as Customers, are permitted to use the data above under this exemption.
- Analyses permitted under this exemption are limited to numerator or denominator counts only as outlined below. Rate estimation and other analysis including hypothesis testing are not permitted.

  Examples of counts that are pre-approved by CPRD include:
  - Counts of patients receiving prescriptions for a certain substance
  - Counts of prescriptions for a certain substance / substances
  - Distribution of number of prescriptions per patient (mean, median, minimum, maximum, interquartile range etc…)
  - Distribution of prescription duration
  - Distribution of patient time at risk
  - Counts of patients with a particular clinical event.

- The sharing of counts for medicines regulatory bodies and/or public health agencies, as outlined above, remain subject to all other controls detailed within CPRD's Multi-Study Licence, and must meet CPRD's statistical disclosure controls (https://www.cprd.com/sites/default/files/2024-10/CPRD%20Safe%20Outputs%20Guidance.pdf).
- Customers must maintain an up-to-date log of the counts shared that include the following details below. This log may be audited by CPRD at any time.
  - The date that the counts were shared.
  - The name of the medicines regulators/public health agencies that the counts have been shared with.
  - A short description of the counts shared.
  - Measures implemented to ensure that CPRD's statistical disclosure controls have been met.

Where the counts required for submission to medicines regulatory bodies or

public health agencies do not meet CPRD's statistical disclosure controls (https://www.cprd.com/sites/default/files/2024-10/CPRD%20Safe%20Outputs%20Guidance.pdf), or will otherwise not meet CPRD's controls as outlined within the CPRD Multi-Study Licence (MSL), please contact enquiries@cprd.com to seek approval for the use of these data. Please note that approval **must** be sought prior to sharing/publication of the counts, that is, retrospective approval will not be granted.

If the above analyses require access to linked data sources, a research protocol must be submitted to obtain data access. Please contact rdg@cprd.com for further advice.

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