Medicines & Healthcare products Regulatory Agency

CPRD | UK data driving real-world evidence

CPRD Research Data Governance (RDG) Application Template

ALL APPLICATIONS MUST BE COMPLETED AND SUBMITTED VIA THE CPRD ELECTRONIC RESEARCH APPLICATION PORTAL (eRAP) www.erap.cprd.com

An eRAP guide for users can be found here www.cprd.com/cprd-erap-guide-users

Applicants may use this template offline to prepare their research application, prior to submission on eRAP. Applicants must also read CPRD's Research Data Governance (RDG) Guidance on how to complete their application found on the eRAP landing page under 'Related resources' (www.erap.cprd.com)

PART 1: APPLICATION FORM

GENERAL INFORMATION ABOUT THE PROPOSED RESEARCH STUDY
1. Study Title (max. 255 characters)
2. Research Area (place '**X**' in all boxes that apply)

Drug Safety		Economics	
Drug Utilisation		Pharmacoeconomics	
Drug Effectiveness		Pharmacoepidemiology	
Disease Epidemiology		Methodological	
Health Services Delivery			

3. Does this protocol describe an observational study using purely CPRD data?

Yes		No	

4. Does this protocol involve requesting any additional information from GPs, or contact with patients?

Yes		No	

If **yes, provide the reference number**:

5. Chief Investigator

Title:	
Full name:	
Job title:	
Affiliation/organisation:	
Email address:	
CV Number (if applicable):	
Will this person be analysing the data? (Y/N)	

6. Corresponding Applicant

Title:	
Full name:	
Job title:	
Affiliation/organisation:	
Email address:	
CV Number (if applicable):	
Will this person be analysing the data? (Y/N)	

7. List of all investigators/collaborators

Title:	
Full name:	
Job title:	
Affiliation/organisation:	
Email address:	
CV Number (if applicable):	
Will this person be analysing the data? (Y/N)	

ACCESS TO THE DATA

8. Sponsor of the study

Institution/Organisation:	
Address:	

9. Funding source for the study

Same as Sponsor?	Yes		No	
Institution/Organisation:				
Address:				

10. Institution conducting the research

Same as Sponsor?	Yes		No	
Institution/Organisation:				
Address:				

11. Data Access Arrangements

Indicate with an '**X**' the method that will be used to access the data for this study:

Study-specific Dataset Agreement	

Institutional Multi-study Licence	
Institution Name	
Institution Address	

Will the dataset be extracted by CPRD?

Yes		No	

If **yes, provide the reference number**:

Are multiple data deliveries required for this research?

Yes		No	

If **yes, provide the reference number:**

12. Data Processor(s):

Processing	
Accessing	
Storing	
Processing area (UK/EEA/Worldwide)	
Organisation name	
Organisation address	

Processing	
Accessing	
Storing	
Processing area (UK/EEA/Worldwide)	
Organisation name	
Organisation address	

INFORMATION ON DATA

13. Primary care data (place '**X**' in all boxes that apply)

CPRD GOLD		CPRD Aurum	

Reference number (if applicable):

14. Please select any linked data or data products being requested

Patient Level Data (place '**X**' in all boxes that apply)

ONS Death Registration Data		NCRAS Tumour/ Treatment data	
HES Admitted Patient Care		NCRAS Systemic Anti-Cancer Treatment (SACT) data	
HES Outpatient		NCRAS National Radiotherapy Dataset (RTDS) data	
HES Accident and Emergency		Second Generation Surveillance System (SGSS, COVID-19)	
HES Diagnostic Imaging Dataset		COVID-19 Hospitalisations in England Surveillance System (CHESS)	
CPRD Mother Baby Link		CPRD Ethnicity Record	
Pregnancy Register			

Area Level Data (place '**X**' in <u>one</u> Practice / Patient level box that may apply)

Practice level (UK)		**Patient level (England only)**	
Practice Level Index of Multiple Deprivation		Patient Level Index of Multiple Deprivation	
Practice Level Index of Multiple Deprivation Domains		Patient Level Index of Multiple Deprivation Domains	
Practice Level Carstairs Index for 2011 Census (Excluding Northern Ireland)		Patient Level Carstairs Index for 2011 Census	
2011 Rural-Urban Classification at LSOA level		2011 Rural-Urban Classification at LSOA level	
		Patient Level Townsend Score	

Reference / Protocol number (where applicable):

15. Are you requesting linkage to a dataset not listed above?

Yes		No	

If **yes, provide the Non-Standard Linkage reference number**:

16. Does any person named in this application already have access to any of these data in a patient identifiable form, or associated with an identifiable patient index?

Yes		No	

If **yes, provide further details**:

PART 2: PROTOCOL INFORMATION

Applicants must complete all sections
Study Title *(max. 255 characters)*
Lay Summary *(max. 250 words)*
Technical Summary *(max. 300 words)*
Outcomes to be Measured *(max. 100 words)*
Objectives, Specific Aims and Rationale *(max. 250 words)*
Study Background *(max. 250 words)*
Study Type *(max. 50 words)*
Study Design *(max. 100 words)*
Feasibility counts *(max. 200 words)*
Sample size considerations *(max. 200 words)*
Planned use of linked data (if applicable) *(max. 200 words)*
Definition of the Study population *(max. 250 words)*
Selection of comparison group(s) or controls *(max. 250 words)*
Exposures, Outcomes and Covariates *(max. 1000 words)*
Data/ Statistical Analysis *(max. 1000 words)*
Plan for addressing confounding *(max. 200 words)*
Plans for addressing missing data *(max. 200 words)*
Patient or user group involvement *(max. 150 words)*
Plans for disseminating and communicating study results *(max.150 words)*
Conflict of interest statement *(max.150 words)*
Limitations of the study design, data sources, and analytic methods *(max. 200 words)*
References *(max. 20 references)*
List of Appendices *(max. of 5 files)*
Grant ID *(optional)* *(max. 255 characters)*