Medicines & Healthcare products Regulatory Agency

CPRD

THIS DOCUMENT IS FOR REFERENCE ONLY. ALL APPLICATIONS SHOULD BE SUBMITTED VIA eRAP AT www.erap.cprd.com

PART 1: APPLICATION FORM

GENERAL INFORMATION ABOUT THE PROPOSED RESEARCH STUDY

1. Study Title (Max. 255 characters including spaces)

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)	

[Add more investigators/collaborators as necessary by copy and pasting a new table for each investigator/collaborator]

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:

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		

[Add more processors as necessary by copy and pasting a new table for each processor]

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			
HES Admitted Patient Care			
HES Outpatient			
HES Accident and Emergency		NCRAS Cancer Registration Data	
HES Diagnostic Imaging Dataset		NCRAS Cancer Patient Experience Survey (CPES) data	
HES PROMS (Patient Reported Outcomes Measure)		NCRAS Systemic Anti-Cancer Treatment (SACT) data	
CPRD Mother Baby Link		NCRAS National Radiotherapy Dataset (RTDS) data	
Pregnancy Register		NCRAS Quality of Life Cancer Survivors Pilot (QOLP)	
Mental Health Data Set (MHDS)		NCRAS Quality of Life Colorectal Cancer Survivors (QOLC)	

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 (index other than the most recent)		Patient Level Index of Multiple Deprivation Domains	
Practice Level Index of Multiple Deprivation Domains		Patient Level Carstairs Index for 2011 Census	

Practice Level Carstairs Index for 2011 Census (Excluding Northern Ireland)		Patient Level Townsend Score	
2011 Rural-Urban Classification at LSOA level		2011 Rural-Urban Classification at LSOA level	

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:

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PART 2: PROTOCOL INFORMATION

Applicants must complete all sections
A. Lay Summary (Max. 250 words)
B. Technical Summary (Max. 300 words)
C. Outcomes to be Measured
D. Objectives, Specific Aims and Rationale
E. Study Background
F. Study Type
G. Study Design
H. Feasibility counts
I. Sample size considerations
J. Planned use of linked data (if applicable):
K. Definition of the Study population
L. Selection of comparison group(s) or controls
M. Exposures, Outcomes and Covariates
N. Data/ Statistical Analysis
O. Plan for addressing confounding
P. Plans for addressing missing data
Q. Patient or user group involvement
R. Plans for disseminating and communicating study results
S. Conflict of interest statement
T. Limitations of the study design, data sources, and analytic methods
U. References
List of Appendices
Grant ID *(optional)*