

Clinical Practice Research Datalink

First published: 01/02/2024

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Data source

Human

Birth registry

Hospital discharge records

Other

Primary care medical records

Administrative details

Administrative details

Data source ID

30008

Data source acronym

CPRD

Data holder

[Medicines and Healthcare products Regulatory Agency \(MHRA\)](#)

Data source type

Birth registry

Hospital discharge records

Other

Primary care medical records

Data source type, other

Variety of linked datasets are available.

Main financial support

Funding by own institution

Funding from industry or contract research

Care setting

Hospital inpatient care

Hospital outpatient care

Other

Primary care - GP, community pharmacist level

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

Yes

Description of the qualification

MHRA NIHR delivered database.

Data source website

<https://cprd.com/>

Contact details

Enquiries CPRD enquiries@cprd.com

Main

enquiries@cprd.com

Data source regions and languages

Data source countries

United Kingdom

Data source languages

English

Data source establishment

Data source established

01/01/1995

Data source time span

First collection: 01/01/1995

The date when data started to be collected or extracted.

Publications

Data source publications

[Approach to record linkage of primary care data from Clinical Practice Research Datalink to other health-related patient data: overview and implications](#)

[Data Resource Profile: Clinical Practice Research Datalink \(CPRD\)](#)

[Data resource profile: Clinical Practice Research Datalink \(CPRD\) Aurum](#)

[Utilisation and Safety of Polyethylene Glycol 3350 With Electrolytes in Children Under 2 Years: A Retrospective Cohort](#)

[Digital Object Identifiers \(DOIs\) for datasets](#)

Studies

List of studies that have been conducted using the data source

EUROmediCAT: Safety of Medication Use in Pregnancy in Relation to Risk of Congenital Malformations

Exposure to beta-blockers and survival in breast cancer patients: A cohort study using the UK General Practice Research Database.

Calcium channel blocker treatments and cancer risk. A methodological protocol to compare the results between databases, across designs: Evaluation of the impact of design/database/population differences on the outcome of the studied association

Isotretinoin and the effectiveness of the pregnancy prevention programmes in Europe

WP6 Replication Study: The risk of acute liver injury associated with the use of antibiotics: Population based case control study

A/H1N1 pandemic vaccines and pregnancy outcomes

Use of benzodiazepines and risk of hip/femur fracture. A methodological comparison across data sources and epidemiological design.

Use of inhaled long acting beta2 adrenoceptor agonists and the risk for Acute Myocardial Infarction (AMI). A methodological comparison across data sources and epidemiological design

Asthma treatment in pregnancy and the frequency of adverse pregnancy outcomes (WEUSRTP4850)

Metabolic effects associated with ICS (inhaled corticosteroid) use in COPD (chronic obstructive pulmonary disease) patients with type II diabetes

Increasing ICS Dose vs Add-on Therapy in Children with Asthma (Paediatric Asthma Step-up)

CAncer Risk and INsulin analogues (CARING) project

Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2016 Bi-annual assessment report. (B4Z-MC-B025)

Burden of severe uncontrolled eosinophilic asthma in the UK population

Use of antiepileptics and risk of suicidality. An exploratory study using the UK General Practice Research Database (GPRD) and data from the Danish registries with an evaluation of available data from further European data sources.

The Association between Long-Acting Beta-Agonists and Prescribing of Oral Steroids for Asthma Exacerbations

A study on the utilization of pioglitazone in clinical practice in the UK after the label change in July 2011

A Study on the Utilization of Pioglitazone in Clinical Practice With Regard to Diabetic Treatment Regimen and Comorbidities

Monitoring for proteinuria in patients with type 2 diabetes mellitus (Proteinuria monitoring in type 2 diabetes)

Benefits of high dose ICS in patients with asthma and high blood eosinophil counts

Characteristics and Treatment Patterns of Patients with Chronic Obstructive Pulmonary Disease (COPD), Initiating Tio+Olo or Other Maintenance Therapies in the US and the UK: A Retrospective Claims Database Study.

Use of Nalmefene (Selincro®) in European databases: Cohort design using longitudinal electronic medical records or claims databases

Burden of disease in patients with COPD and high blood eosinophil counts (High eosinophils and COPD)

A multi-database cohort study to assess the incidence rates of colorectal hyperplasia among hypertensive patients

Prevalence and Incidence of Problematic Prescription Opioid Use and Abuse in the United Kingdom and Germany (OXY9504)

Intended and unintended effects of Z-drug use for sleep disturbance in people with dementia - 'Z-drug Evaluation in Dementia' (ZED)

Usage Patterns of Selected Systemic NSAIDs (Including Diclofenac): A Retrospective Cohort Study

A Postmarketing Observational Evaluation of the Safety of FLUENZ in Children and Adolescents With High-risk Conditions

EMR200084_512: Risk of lactic acidosis with metformin use in type 2 diabetes mellitus with renal impairment: retrospective cohort study

A Nested Case-control Post-authorization Safety Study of Etoricoxib and Other Non-steroidal Anti-inflammatory Therapies in a Cohort of Patients with Ankylosing Spondylitis (AS) in the UK, France and Germany (MK-0663-163)

Incidence of Thyroid Neoplasm and Pancreatic Cancer in Type 2 Diabetes Mellitus Patients who Initiate Once Weekly Exenatide Compared with Other Antihyperglycemic Drugs

Effectiveness of triple therapy vs. dual bronchodilation in COPD (Effectiveness of triple therapy in COPD)

Combined bronchodilators in COPD and the risk of adverse cardio-pulmonary events: A population-based observational study (Comb Bronchodil in COPD and CardPulm AEs)

Pan European Multi-Database Bladder Cancer Risk Characterisation Study

Decline In lung-function Among Patients with chronic obstructive Lung disease
On maintenance therapy (DIAPLO)

Association between anxiolytic or hypnotic drugs and total mortality

Prasugrel Treatment Patterns in Outpatient Settings in Germany, the United
Kingdom, and France (H7T-MC-B011)

Strattera patient exposures and adherence in the United Kingdom, Germany,
the Netherlands, and Sweden: 2014 Bi-annual assessment report

Safety Evaluation of Adverse Reactions in Diabetes - Drug utilisation studies
(SAFEGUARD)

Safety Evaluation of Adverse Reactions in Diabetes - Comparative studies
(SAFEGUARD)

Characteristics of patients initiating empagliflozin or other non-insulin glucose
lowering drugs in the United Kingdom (Empa DUS in UK)

Stress Urinary Incontinence and Suicidality Seen in the United Kingdom General
Practice Research Database (F1J-MC-B056)

A Drug Utilisation Study of Domperidone in Europe Using Databases

EMR200101_502: Incidence and pattern description of gastrointestinal, skin,
genital, corneal, and mucosal erosions, ulcerations, perforations,
haemorrhages, fistulas, abscesses, delayed wound healing and death among
patients treated with nicorandil with and without diverticular disease

Longitudinal Analyses of Body Mass Index and Risk of Parkinson's Disease in 2
million people over 2 decades (BMI and Parkinson´s disease)

Longitudinal Analyses of Blood Pressure and Risk of Alzheimer's disease and Vascular Dementia in 2.6 million people over 2 decades (BP and Dementia)

Multinational Observational Database Study on Imminent Osteoporotic Fracture Risk: Stage 1 (IFRISK)

Post-authorisation Safety Study: Risk of Out-of-Hospital Sudden Cardiac Death in Users of Domperidone, Users of Proton Pump Inhibitors, and Users of Metoclopramide

An Observational Drug Utilization Study of SYCREST® (asenapine) in the United Kingdom (P08308)

An Observational Post-Authorization Safety Surveillance (PASS) Study of SYCREST® (asenapine) among Patients aged 18 and older Diagnosed with Bipolar Disorder (P08307)

Asthma and Type 2 Comorbidities - Real-life Characterisation of Patients with Active Asthma and Type 2 Asthma Comorbidities

The use of a spacer in the delivery of large (Fluticasone Propionate) and small particle (Qvar®) inhaled corticosteroid (ICS) in asthma (FP and Qvar Spacer vs Non-Spacer in Asthma)

Persistence and compliance to anti-osteoporosis medications in the United Kingdom using the Clinical Practice Research Datalink (CPRD) (20160192)

Evaluation of potential off-label use of dabigatran etexilate in Europe

Utilisation of antiepileptic medicines in girls and women of childbearing potential - a study in three European countries

Investigating the possible role of Blood eosinophil counts in guiding ANti-inflammatory treatment of COPD exAcerbations (BLANCA)

Real-world effectiveness of extra-fine formulations in Denmark

Benzodiazepine and anticholinergic use and incident dementia (ABCD study)

Evaluation of the undertreatment and disease outcomes for patients with coexisting Heart Failure and Chronic Obstructive Pulmonary Disease

An observational historical cohort study to evaluate chronic disease onset associated with long-term oral corticosteroid and its cost impact on patients in the OPCR / CPRD databases

Dose response curves for patients prescribed small & large particle ICS formulation: an observational evaluation of the comparative effect of ICS dose on asthma control achieved in real-life UK patients managed on extrafine hydrofluoroalkane beclomethasone, ciclesonide, fluticasone propionate, or Clenil

Historical matched-cohort study assessing whether the use of inhaled corticosteroids shortens time to first diagnosis or accelerates the progression of side effects compared to non-ICS therapies in patients with Chronic Obstructive Pulmonary Disease. (ICS use in COPD patients and risk of side effects)

A non-interventional study of LAIV utilization to identify and characterize medication errors due to expired vaccine use in individuals 2-17 years of age in the CPRD

Risks and benefits of bisphosphonate use in patients with chronic kidney disease: a population-based cohort study

A RETROSPECTIVE, REAL-LIFE EVALUATION OF THE CARDIOVASCULAR DISEASE RISK ASSOCIATED WITH EXPOSURE TO PHARMACOLOGICAL SMOKING CESSATION INTERVENTIONS IN A REPRESENTATIVE UK PRIMARY CARE PATIENT POPULATION

Comparative effectiveness of combination therapies in COPD

A drug utilisation study of Rifaxamin- α 550mg

Comparative effectiveness of triple therapy in COPD: A new-user cohort study

The risk of acute liver injury associated with the use of antibiotics. A methodological comparison across epidemiological data sources

Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2018 Bi-annual assessment report (B4Z-MC-B026)

Drug utilization study of mirabegron (Betmiga®) using real-world healthcare databases from the Netherlands, Spain, United Kingdom and Finland (Mirabegron DUS)

Association between the Prevalence of cardiovascular risk factors and new use of testosterone

Health outcomes of patients with acute coronary syndromes prescribed ticagrelor in UK primary care: a retrospective cohort study (Outcomes in UK ACS patients prescribed ticagrelor)

Excess risk and predictors of fracture/s following bariatric surgery for obese patients in the NHS: a real-world self-controlled case series and cohort study

A prediction model for future exacerbation risk in children

Eosinophilic asthma phenotypes and associated clinical outcomes

205639 - Meta-analysis of the risk of autoimmune thyroiditis diseases, Guillain-Barré Syndrome, and Inflammatory Bowel Disease with Cervarix Vaccination

An observational evaluation of prescribing of fixed-dose combination inhaled corticosteroid / long-acting beta2-agonist (ICS/LABA): fluticasone propionate / formoterol (FP/FOR) and adverse events in routine primary care at 18-months and 36-months post launch

Comparative Assessment of VTE and Other Risks among Patients with Rheumatoid Arthritis treated with Baricitinib versus Tumor Necrosis Factor Inhibitors: A Multi-database Observational Cohort Study

Post-authorization Safety Study Evaluation of Neoplasm Events in Users of Mirabegron and Other Treatments for Overactive Bladder : Core Common Protocol

The Impact of Exacerbation Burden on Lung Function Trajectory in a Broad Asthma Population and Severe Asthma Population (Exacerbation and lung function trajectory)

A Joint Drug Utilisation Study (DUS) of valproate and related substances, in Europe, using databases

Risk of angiotensin converting enzyme inhibitor intolerance in asthma compared to the general population

Impact of EU label changes for systemic diclofenac products: post-referral prescribing trends

Ability of primary care health databases to assess medicinal products discussed by the European Union Pharmacovigilance Risk Assessment Committee (CAPs and NAPs in primary EHDs)

Linaclotide Utilisation Study in Selected European Populations

Bendroflumethiazide versus Indapamide for Primary Hypertension: Observational (BISON) study within CPRD

Risk of switching to angiotensin-II receptor blocker therapy in people with asthma who initiate ACE inhibitor therapy compared to the general population: a retrospective cohort study

Pattern of use of Direct Oral Anticoagulants in Non-valvular Atrial Fibrillation patients in UK general practices

Post-authorization Safety Study Evaluation of Cardiovascular Events in Users of Mirabegron and Other Treatments for Overactive Bladder

Pharmacological risk factors for COVID-19 infection: a matched prospective cohort study of patients in primary care

NN304-4528: Retrospective Cohort study of all-Cause and Cardiovascular Mortality in type 2 diabetes patients using basal insulin Detemir and Glargine

Hydroxychloroquine safety and potential efficacy as an antiviral prophylaxis in light of potential wide-spread use in COVID-19: a multinational, large-scale network cohort and self-controlled case series study

Diagnosis and management of infectious disease in primary care during the COVID-19 lockdown: changes in antibacterial and antiviral use

A Retrospective Cohort Study to Assess Drug Utilisation and Long-Term Safety of Galcanezumab in European Patients in the Course of Routine Clinical Care (I5Q-MC-B002)

An Observational Study of the Risk of Malignant Neoplasms and Malignant Neoplasms of Special Interest (Thyroid and Pancreatic Cancer) in Subjects Treated with Albiglutide Compared to Those Treated with Other Antidiabetic Agents (201805)

European non-interventional post-authorization safety study related to serious cardiovascular events of myocardial infarction and stroke, and all-cause mortality for romosozumab by the EU-ADR Alliance

EUROPEAN NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY RELATED TO ADHERENCE TO THE RISK MINIMIZATION MEASURES FOR ROMOSUZUMAB BY THE EU-ADR ALLIANCE

EUROPEAN NON-INTERVENTIONAL POST AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS INFECTIONS FOR ROMOSUZUMAB BY THE EU ADR

ALLIANCE

Utilisation of dulaglutide in European countries: A cross-sectional, multi-country and multi-source drug utilisation study using electronic health record databases (H9X-MC-B010)

An Observational/Non-interventional Evaluation of Subject Outcomes for Type 2 Diabetes Mellitus (T2DM) Subjects Prescribed Dipeptidyl Peptidase-4 Inhibitors (DPP4i), Sodium-glucose Cotransporter-2 Inhibitors (SGLT2i) or Sulphonylureas (SUs) at First Intensification

Impact of EU label changes for hydroxyzine products: post-referral prescribing trends

Post-Authorization Safety Program—Validation of the Clinical Practice Research Datalink for the Study of Cardiovascular and Neoplasm Events in Users of Treatments for Overactive Bladder

A longitudinal study of 4 cohorts of patients with psoriasis and psoriatic arthritis: one treated with Otezla (apremilast), one with an injectable comparator drug, one with an oral comparator drug and one with an oral and an injectable comparator drug (Otezla-CPRD-001)

Acridinium Bromide Drug Utilisation Post-Authorisation Safety Studies (DUS): Common Protocol for Acridinium (DUS1) and Acridinium/Formoterol Fixed-Dose Combination (DUS2)

Project Sc(y)lla: SARS-Cov-2 Large-scale Longitudinal Analyses on the comparative safety and effectiveness of treatments under evaluation for COVID-19 across an international observational data network

Utilisation of oral anticoagulants in older people with atrial fibrillation in UK general practice

The risk of musculoskeletal adverse outcomes after treatment with endocrine blocking treatments for breast cancer (MSKAI)

A comparison of the effectiveness and safety of direct oral anticoagulants versus warfarin in older patients with atrial fibrillation using the Clinical Practice Research Datalink

Linaclotide Safety Study for the Assessment of Diarrhoea—Complications and Associated Risk Factors in Selected European Populations with IBS-C

Post-marketing study of ropinirole prolonged release tablets in Parkinson's disease: Evaluation outcomes associated with long term use of Ropinirole-PR using the clinical practice research datalink (CPRD) (111981)

Longitudinal Analyses of Blood Lipids and Future Risk of Dementia in CPRD (Lipids and dementia)

Impact of risk minimisation in patients treated with rosiglitazone-containing products

Metformin use in renal impairment

Influence of safety advisories on drug utilization: an international interrupted time series study

Post-authorization safety Electronic Medical Records database retrospective cohort study of new users of inhaled UMEC/VI or new users of inhaled UMEC in the primary care setting

Pancreatic Cancer and Thyroid Cancer Risks with Dulaglutide Treatment

WEUSKOP6416: Evaluating severe events in patients with Chronic Obstructive Pulmonary Disease (COPD) to inform risk minimization: A Retrospective Observational Study (116952)

A cohort study to investigate the prescribing of albiglutide among women of child-bearing age who have type 2 diabetes (201795)

Acidinium Bromide Post-Authorisation Safety Study to Evaluate the Risk of Cardiovascular Endpoints

Drug utilisation studies using data mapped to the OMOP Common Data Model: a proof of concept study assessing respiratory drug use in patients with asthma or COPD

Cohort Study of the Relative Incidence of Major Cardiovascular Events Among Patients Initiating Prucalopride Versus a Matched Comparator Cohort

Methods for controlling by indication for prescriptions: application to medications for neuropathic pain

Demonstrating solutions for studying intermittent medication exposures in diseases with episodic manifestations during pregnancy: application to medication for migraine in pregnancy

Overactive bladder anticholinergics and risk of incident dementia: a cohort study design using a triangulation approach

EUMAEUS: Evaluating Use of Methods for Adverse Event Under Surveillance (for vaccines)

Assessment of off-label use of baricitinib in the paediatric population (Paediatric use of baricitinib)

Drug utilization study for Elvanse® / Tyvense® / Elvanse® Adult in Europe

Effectiveness of Indapamide SR on top of Perindopril on blood pressure change: a methodological study to validate effect of anti-hypertensive drugs in CPRD Aurum.

Natural history of coagulopathy and use of anti-thrombotic agents in COVID-19 patients and persons vaccinated against SARS-CoV-2

Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries (COVID-19)

Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of Spikevax in Europe (COVID-19)

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Risk of Skin Cancer and Lymphoma in Users of Topical Tacrolimus, Pimecrolimus, and Corticosteroids (JOELLE)

ASSOCIATION BETWEEN THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME (TTS) OR THROMBOEMBOLIC EVENTS, AND COVID-19 VACCINES

Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

An Observational Post-Authorisation Safety Study (PASS) of Patients with Chronic Opioid Use for Non-Cancer Pain and Cancer Pain who have Opioid-Induced Constipation (OIC) (Naldemedine PASS)

Burden and consequences of the use of COPD-related systemic corticosteroids (OCS COPD study)

Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

PCSCVM003617/ A Real-World Database Study of Canagliflozin Utilization in Type 1 Diabetes Patients Over Time among European Countries

An observational cohort study to describe intermittent OCS utilisation and its association with adverse outcomes and healthcare resource use and costs in asthma using the OPCR and CPRD databases. (The burden of intermittent OCS use in asthma)

Investigating biases in observational studies of inhaled corticosteroids and the risk of COVID-19-related outcomes

Utilisation of low-dose rivaroxaban in patients with atherosclerotic cardiovascular disease in the United Kingdom and the Netherlands

Drug utilisation study of new users of fluticasone furoate / vilanterol (FF/VI) in the primary care setting: UK Clinical Practice Research Datalink (CPRD) study (205052)

PRJ2282/201491: CHES: CPRD-COPD Hawthorne Effect Study in Salford: A UK cohort study to characterise patients enrolled in the Salford Lung Study and to evaluate a potential Hawthorne effect

Exposure to pioglitazone and the risk of prostate cancer: a nested case-control study

Post-authorisation safety study to assess the risk of urinary tract malignancies in relation to empagliflozin exposure in patients with type 2 diabetes: a multi-database European study (PASS DiabCancer)

A post-authorisation/post-marketing observational study to evaluate the association between exposure to AZD1222 and safety concerns using existing secondary health data sources (COVID-19)

Non-interventional post-authorization multi-database safety study to characterize the risk of angioedema and other specific safety events of interest in association with use of Entresto® (sacubitril/valsartan) in adult patients with heart failure

Non-Interventional retrospective longitudinal study in the United Kingdom and France to investigate the therapeutic strategies after discontinuation of valproate and related substances in clinical practice (VALSE study - VALNAC09344)

Observational Studies in Cancer Associated Thrombosis for Rivaroxaban – United Kingdom Cohort (OSCAR—UK)

A Drug Utilisation Study extension (DUS ext.) of valproate and related substances, in Europe, using databases (VALNAC09343)

Non-interventional post-authorization multi-database safety study to assess the risk of myotoxicity, hepatotoxicity and acute pancreatitis in statin-exposed heart failure patients with or without concomitant use of sacubitril/valsartan (Entresto®)

FINERone druG Utilization Study and assessment of Temporal changes following availability of different treatment options in patients with chronic kidney disease and type 2 diabetes (FINEGUST)

E2090-E044-501: A Retrospective database Study of the Prescribing of Zonisamide in UK General Practice: A Drug Utilisation Study as Part of Post-Marketing Safety Surveillance

A Pan-European Post-Authorisation Safety Study: Risk of Pancreatic Cancer Among Type 2 Diabetes Patients who Initiated Exenatide as Compared with those who Initiated Other non-Glucagon-Like Peptide 1 Receptor Agonists based Glucose Lowering Drugs (EXCEED)

Strengthening Use of Real-World Data in Medicines Development: Metadata for Data Discoverability and Study Replicability (MINERVA)

Comparison of the Risk of Cancer Between Patients With Type 2 Diabetes Exposed to Dapagliflozin and Those Exposed to Other Antidiabetic Treatments

Concordance between primary and secondary electronic healthcare databases:
A multi-database self-controlled case series study

Hearing loss and risk of major osteoporotic fracture: a population-based cohort
study in the United Kingdom (20200418)

Impact of EU label changes and revised pregnancy prevention programme for
medicinal products containing valproate: utilisation and prescribing trends

Safety of Paxlovid During Pregnancy

Safety of Paxlovid Among Patients with Moderate or Severe Hepatic or Renal
Impairment

Association between COVID-19 vaccines and paediatric safety outcomes in
children and adolescents aged 5-19 years in the Nordic countries: Myocarditis,
pericarditis and thromboembolic events

Effectiveness of heterologous and booster Covid-19 vaccination in 5 European
countries, using a cohort approach in children and adults with a full primary
Covid-19 vaccination regimen (Covid Vaccines Effectiveness (CoVE))

NN8022-4246 In market utilisation of liraglutide used for weight management in
the UK: a study in the CPRD primary care database

Reproducible Evidence: Practices to Enhance and Achieve Transparency
(REPEAT)

Cohort monitoring of Adverse Events of Special Interest and COVID-19
diagnoses prior to and after COVID-19 vaccination (ECVM)

Rapid Safety Assessment of SARS-CoV-2 vaccines in EU Member States using
electronic health care datasources (CVM Covid19-Vaccine-Monitor-EHR)

Background rates of Adverse Events of Special Interest for monitoring COVID-19
vaccines (ACCESS-BGR)

Comparison of the Risk of Acute Kidney Injury Between Patients With Type 2 Diabetes Exposed to Dapagliflozin and Those Exposed to Other Antidiabetic Treatments

Comparison of the Risk of Acute Liver Injury Between Patients With Type 2 Diabetes Exposed to Dapagliflozin and Those Exposed to Other Antidiabetic Treatments

Comparison of the Risk of Severe Complications of Urinary Tract Infections (UTI) Between Patients With Type 2 Diabetes Exposed to Dapagliflozin and Those Exposed to Other Antidiabetic Treatments

Post-authorisation safety study in patients with type 2 diabetes mellitus to assess the risk of acute liver injury, acute kidney injury and chronic kidney disease, severe complications of urinary tract infection, genital infections, and diabetic ketoacidosis among patients treated with empagliflozin compared to patients treated with DPP-4 inhibitors (PASS renal, liver injury, infection, ketoacidosis)

Multi-country non-interventional study on the effectiveness and safety of Empagliflozin in adult patients with type 2 diabetes in Europe and Asia

DARWIN EU® Prevalence of rare blood cancers in Europe

DARWIN EU® Drug utilisation of valproate-containing medicinal products in women of childbearing potential

DARWIN EU® DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

Safety of the Novavax COVID-19 vaccine in England using a self-controlled case series design: A post-authorisation safety study using data from the Clinical Practice Research Datalink (CPRD) Aurum and linked databases

DARWIN EU® - Background rates of serious adverse events to contextualise safety assessments in clinical trials and non-interventional studies in adolescent and adult patients with severe asthma

Association between opioid use and the development of diverticulitis (Opioids Diverticulitis)

Post-authorisation Safety Study of Rimegepant in Patients with Migraine and History of Cardiovascular Disease in European Countries

Comparing Database Harmonisation Methods Applied to Real-World Electronic Healthcare Data

Utilization of antimentia treatments: a large multinational-network population-based study.

The Impact of COVID-19 Pandemic on Drug Use: Implications for Regulatory Intervention Impact Studies

mRNA-1273-P910: Clinical course, outcomes and risk factors of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2.

Comparing the risk of metoprolol-related adverse drug reactions between women and men with heart failure using effectiveness outcomes as a proxy: a population-based cohort study using CPRD

Characterization of the epidemiology, treatment patterns and burden of Pulmonary Hypertension Group 1 and 3 in France, Germany and the UK: a real-world evidence study (PHILD_RWE_FR_DE_UK)

Characterization of neurodevelopmental disorders in children exposed in utero to valproate and/or other antiepileptic drugs with long-term follow-up: retrospective study of multiple European data sources (AVALON)

DARWIN EU® Use of take-home naloxone for opioid overdose treatment

EHDS2 Pilot Use Case: Natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV-2 during the Omicron period.

Incidence, prevalence, and characterisation of medicines with suggested drug shortages in Europe

Dipeptidyl Peptidase-4 Inhibitors and Inflammatory Bowel Disease Risk: Impact of Study Design Differences on Comparative Safety Results

Predicting the risk for first COPD severe exacerbation (PRECISE-X)

Post-Authorisation Safety Study of Comirnaty Original/Omicron BA.1 and Comirnaty Original/Omicron BA.4-5 in Europe

Monitoring the effectiveness of risk minimisation in patients treated with pioglitazone-containing products

Comparing the Estimated Risk of Hip Fracture Among Subjects Exposed to Tramadol as Compared to Subjects Exposed to Codeine (Tramadol vs Codeine)

Long-term real-world safety of ozanimod – A post-authorisation safety study (PASS) in patients diagnosed with ulcerative colitis

Cardiovascular outcomes of treat-to-target vs fire-and-forget urate-lowering therapy in patients with gout starting urate-lowering therapy. An emulated multicentre open-label two-parallel arm superiority trial carried out in primary care

A Post-Authorisation Safety Study (PASS) of ABRYSV0 (Respiratory Syncytial Virus Stabilised Prefusion Subunit Vaccine) in Pregnant Women and their Offspring in a Real World Setting in Europe and UK (C3671026)

Post-Authorization Safety Study to Assess the Effectiveness of the Newly Implemented Risk Minimization Measures for Topiramate: Drug Utilization Study

TARGET EU: Comparative effectiveness and safety studies using the target trial emulation and estimand frameworks

Comparative effectiveness and safety in patients with prostate cancer who received radical prostatectomy vs. radiotherapy: target trial emulation

TARGET-EU: Dapagliflozin and major adverse cardiovascular events in type 2 diabetes

Montelukast and Neuropsychiatric Events: A Target Trial Emulation to Quantify Adverse Reactions

Evaluating the utilisation of Urospir® (spironolactone) in paediatric and adult patients in the United Kingdom: A drug utilisation study using the Clinical Practice Research Datalink (CPRD) database

TARGET-EU: Comparison of single-device vilanterol/fluticasone furoate with other single-device inhaled corticosteroid and long-acting beta agonist combinations in the risk of pneumonia in adolescents with asthma

TARGET-EU: Effectiveness of BNT162b2 mRNA COVID-19 vaccine in healthy individuals or with stable pre-existing medical conditions against SARS-CoV-2 infection

TARGET EU: The risk of angioedema and other safety events in heart failure patients treated with sacubitril/valsartan compared to angiotensin-converting enzyme inhibitors

TARGET-EU: Tolvaptan and risk associated to hepatotoxicity in autosomal dominant polycystic kidney disease

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

No

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

Yes

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

ICD-10

Other

Cause of death vocabulary, other

Medcode ID's

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

Prodcod ID's

Dispensing of medicines

Not Captured

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

Yes

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

Yes

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

Indication vocabulary

ICD-10

Other

Indication vocabulary, other

Medcode ID's

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

Yes

Administration of vaccines

Yes

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

Procedures vocabulary

OPCS

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available?

The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

Yes

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

Genetic data

Are data related to genotyping, genome sequencing available?

Not Captured

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Not Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

No

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

No

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

Yes

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-10

Other

Read

SNOMED CT

Diagnosis / medical event vocabulary, other

Medcode ID's

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dose

Formulation

Package size

Strength

Medicinal product vocabulary

dm+d

Other

If 'other,' what vocabulary is used?

Prodcod ID's

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Diet

Frequency of exercise

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Ethnicity

Gender

Marital status

Socioeconomic status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (\geq 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated percentage of the population covered by the data source in the catchment area

20%

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are registered only for private care)

GP practices that do not contribute data to CPRD and patients who opt-out of data sharing for research purposes.

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Permanently

Family linkage available between the following persons

Mother-child

Population

Population size

67026300

Active population size

16227262

Population by age group

| Age group | Active population size |
|------------------------------------|------------------------|
| Paediatric Population (< 18 years) | 3260000 |
| Elderly (≥ 65 years) | 2819900 |

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

5.21

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt

9.62

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

<https://cprd.com/data-quality>

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

No

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

Yes

Description of data collection

Based on data from the EMIS (CPRD Aurum) or VISION (CPRD GOLD) software systems used by GPs in the UK primary care NHS.

Event triggering registration

Event triggering registration of a person in the data source

Practice registration

Event triggering de-registration of a person in the data source

Death

Emigration

Practice deregistration

Event triggering creation of a record in the data source

Patient consultation, hospital correspondence

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

Yes

Linkage description, possible linkage

Anonymised primary care patient data can be individually linked to secondary care and other health and area-based datasets. This linkage enables CPRD to provide a fuller picture of the patient care record to support vital public health research, informing advances in patient safety and delivery of care. CPRD is expanding its healthcare data and research services to increase both the cover of primary care data and the number of datasets that are linked and made available on a routine basis to the research community. CPRD Aurum are linked to patient-level health data by a trusted third party, NHS Digital, using NHS number, exact date of birth, sex and patient residence postcode. CPRD does not receive or hold patient identifiers including name, full date of birth, postcode and NHS number. Identifiers are removed prior to transfer of data to CPRD to protect patient confidentiality.

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Cancer data from NHS England National Disease Registration Service (NDRS) (formerly Public Health England (PHE))

Linkage variable

The variables patid and pracid can be used for linkage purposes.

Linkage completeness

Completeness of linkages and timelag with CPRD Aurum/GOLD primary care data varies across the linked datasets.

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

COVID-19 data

Linkage variable

The variables patid and pracid can be used for linkage purposes.

Linkage completeness

Completeness of linkages and timelag with CPRD Aurum/GOLD primary care data varies across the linked datasets.

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Data from NHS England (Hospital Episode Statistics, ONS Death registration data)

Linkage variable

The variables patid and pracid can be used for linkage purposes.

Linkage completeness

Completeness of linkages and timelag with CPRD Aurum/GOLD primary care data varies across the linked datasets.

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Small area level data

Linkage variable

The variables patid and pracid can be used for linkage purposes.

Linkage completeness

Completeness of linkages and timelag with CPRD Aurum/GOLD primary care data varies across the linked datasets.

Data management specifications that apply for the data source

Data source refresh

Quarterly

Informed consent for use of data for research

Other

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

No

Data source preservation

Are records preserved in the data source indefinitely?

Yes

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

Yes

Informed consent, other

opt-out

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

Yes

CDM Mappings**CDM name (other)**

Other

Data source ETL CDM version

Study specific

CDM name

OMOP

CDM website

<https://www.ohdsi.org/Data-standardization/>

Data source ETL CDM version

OMOP version 5.3.2,