German Pharmacoepidemiological Research Database

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Data source | Human | Administrative healthcare records (e.g., claims)

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26534

Data source ID

26534

Data source acronym

GePaRD

Data holder

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Data source type

Administrative healthcare records (e.g., claims)

Main financial support

Funding by own institution

Care setting

Hospital inpatient care

Hospital outpatient care

Primary care – GP, community pharmacist level

Primary care – specialist level (e.g. paediatricians)

Secondary care – specialist level (ambulatory)

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.

No

Data source website

https://www.bips-institut.de/en/research/research-infrastructures/gepard.html

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Data source regions and languages

Data source countries

Germany

Data source languages

English

German

Data source establishment

Data source established

01/01/2004

Data source time span

First collection: 01/01/2004

The date when data started to be collected or extracted.

Publications

Data source publications

Ohlmeier C, Langner I, Garbe E, Riedel O (2016) Validating mortality in the German Pharmacoepidemiological Research Database (GePaRD) against a mortality registry. Pharmacoepidemiol Drug Saf 25:778-784

Wentzell N, Schink T, Haug U, Ulrich S, Niemeyer M, Mikolajczyk R (2018) Optimizing an algorithm for the identification and classification of pregnancy outcomes in German claims data. Pharmacoepidemiol Drug Saf 27:1005-1010

Haug U, Schink T. German Pharmacoepidemiological Research Database (GePaRD). In: Sturkenboom MCJM, Schink T, editors. Databases for pharmacoepidemiological research. Cham: Springer. 2021. S. 119-124. https://doi.org/10.1007/978-3-030-51455-6_8

Schink T, Princk C, Braitmaier M, Haug U. Use of combined oral contraceptives and risk of venous thromboembolism in young women: A nested case-control analysis using German claims data. BJOG: An International Journal of Obstetrics & Gynaecology. 2022;129(13):2107-2116. https://doi.org/10.1111/1471-0528.17268

Schwarz S, Hornschuch M, Pox C, Haug U. Colorectal cancer after screening colonoscopy: 10-year incidence by site and detection rate at first repeat colonoscopy. Clinical and Translational Gastroenterology. 2023;14(1):e00535. https://doi.org/10.14309/ctg.0000000000000535

Studies

List of studies that have been conducted using the data source

Database Study of Thalidomide (Thalidomide Celgene®) in Germany: Monitoring Off-Label Use

Burden of Herpes Zoster in selected immunocompromised populations in the German Pharmacoepidemiological Research Database (GePaRD)

Off-label use of neuroleptics and antidepressants and risks of psychostimulant use in ADHD patients during childhood and adolescents (OLUNAR)

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

An Observational Post-Authorization Safety Study (PASS) of MOVENTIG® (Naloxegol) Among Patients Aged 18 Years and Older Treated with Opioids Chronically

Database study of lenalidomide (Revlimid®) in Germany: Monitoring off-label use

Cilostazol Drug Utilisation Study

Second primary cancers in patients with castration resistant prostate cancer (BOCARP)

A post-authorisation safety study (PASS) to evaluate cardiovascular events in adult patients with obstructive sleep apnoea (OSA) treated with solriamfetol (JZP865-401)

Risk of Febrile Convulsions after 1st dose MMRV vaccination in comparison to MMR and MMR+V vaccination (MMRV 1st dose)

Pharmacoepidemiological Safety Study of Neuroleptics and Antidepressants in the Area of Geriatric Psychiatrics (PhaSiNAg)

Risk of Venous Thromboembolism and All-Cause Mortality in Cancer Patients Treated with Epoetins either with or without Transfusions versus Cancer Patients Treated with Transfusions alone

Thromboembolic Risk in Patients with Chronic Kidney Disease Treated receiving Epoetin zeta or other Erythropoietin Stimulating Agents – the BIPS study

Risk of Febrile Convulsions after a Second Immunization against Measles, Mumps and Rubella with MMRV as compared to MMR or MMR+V (MMRV 2nd dose)

Estimation of Background Incidence Rates of Guillain-Barré Syndrome in Germany in the years 2007-2009 (BIGS)

The risk of ischemic cardiovascular events associated with oxycodone/naloxone use

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

Adherence, persistence and switching patterns – once- and twice-daily direct oral anticoagulants (QD versus BID DOACs)

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)

Extrapyramidal symptoms in patients treated with Abilify Maintena®: Cohort study with a 2-year follow-up using European automated healthcare databases

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 ROMOSOZUMAB BY THE EU-ADR ALLIANCE

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

VALIDATION STUDY PROTOCOL (OP0007) FOR THE 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 (OP0004) AND EUROPEAN NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS INFECTIONS FOR ROMOSOZUMAB BY THE EU-ADR ALLIANCE (OP0006)

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

Post-Authorisation Safety Study of Agomelatine and the Risk of Hospitalisation for Acute Liver Injury

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

Intravenous Iron Postauthorisation Safety Study (PASS): Evaluation of the Risk of Severe Hypersensitivity Reactions

A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical pratice in Germany

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

Studying drug exposure when disease is measured through accurate identification of an incident case: application to breast cancer in pregnancy (ConcePTION breast cancer demo)

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

Exposure to SSRI/SNRI and depression in pregnancy and long-term childhood outcomes: the effect of modifying factors

Novel statistics to handle rare diseases and small sample sizes using Bayesian techniques: Application to Multiple Sclerosis (MS) and Systemic Lupus Erythematosus (SLE) in pregnancy

The BRodalumab Assessment of Hazards: A Multinational Safety (BRAHMS) study in electronic healthcare databases

Dulaglutide Modified-Prescription-Event Monitoring Study and network database study: a multi-database collaborative research program of observational studies to monitor the utilisation and safety of dulaglutide in the EU

Drug utilisation study of Radium 223 under routine clinical practice in Europe (DIRECT)

Post-authorisation safety study of NOCDURNA for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria: A multi-country cohort study using secondary data. (NOCDURNA PASS)

CONSIGN study: COVID-19 infection and medicines in pregnancy - a multinational registry based study

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

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®)

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

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

A non-interventional post-authorisation safety study to investigate the risk of mortality in multiple sclerosis patients treated with alemtuzumab (LEMTRADA®) relative to comparable multiple sclerosis patients using other disease modifying therapies: a cohort study

Long-Term Post-Marketing Observational Study of the Safety of Roflumilast

Baricitinib Drug Utilisation Study: Assessment of Effectiveness of New Recommendations for Use Based on Secondary Data Sources in France, Germany, The Netherlands, and Sweden (I4V-MC-B038)

Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data

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

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

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.

Yes

Disease details

Amyotrophic lateral sclerosis

Guillain-Barre syndrome

Disease details (other)

All rare diseases if coded, examples: autio-immune thyroiditis (Morbus Basedow), juvenile rheumatiod arthritis

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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?

No

Cause of death

Not Captured

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

Dispensing of medicines

Captured

Dispensing vocabulary

ATC

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?

Not Captured

Medical devices

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

No

Administration of vaccines

Yes

Procedures

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

Captured

Procedures vocabulary

Other

Procedures vocabulary, other

OPS

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?

No

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

Diagnosis / medical event vocabulary, other

ICD-10-GM

Medicinal product information

Captured

Medicinal product information collected

Brand name

Formulation

Package size

Route of administration

Strength

Medicinal product vocabulary

ATC

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Deprivation index

Education level

Gender

Living in rural area

Pharmaceutical copayment

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 (≥ 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% of the German population (not restricted to people insured by statutory health insurances).

While GePaRD captures preterm and term newborn infants with 0-27 days of age in our database (as indicated in question 19), it is not possible to evaluate the population of babies based on age in days because the exact date of birth is not available in our database (only the year of birth). However, due to the possibility of linking the majority of mothers and their pregnancies to babies, the data source can distinguish babies at the age of 0 who were term-births and or pre-term, and confirm that it captures babies within the age-range of 0-27 days in the database. Over all years, there are 1140417 term-births and 96438 pre-termbirths in GePaRD. For 80% of these births there is information on the respective baby in GePaRD.

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)

Nation-wide

Family linkage

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

Ad hoc

Population

Population size

27781432

Active population size

17056963

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	3666904	2891324
Infants and toddlers (28 days – 23 months)	349344	505034
Children (2 to < 12 years)	1989237	1532739
Adolescents (12 to < 18 years)	1328323	853551
Adults (18 to < 46 years)	10784312	5572310

Age group	Population size	Active population size
Adults (46 to < 65 years)	7123499	4939026
Elderly (≥ 65 years)	6206717	3654303
Adults (65 to < 75 years)	2488595	1760050
Adults (75 to < 85 years)	2124868	1424267
Adults (85 years and over)	1593254	469986

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://www.bips-institut.de/en/research/research-infrastructures/gepard.html

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?

No

Description of data collection

Reimbursement

Event triggering registration

Event triggering registration of a person in the data source

Insurance coverage start

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

Death

Emigration

Insurance coverage end

Other

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

Lost to follow-up

Event triggering creation of a record in the data source

Healthcare service utilization

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?

No

Data management specifications that apply for the data source

Data source refresh

Yearly

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)?

Yes

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

Project approval is based on the authorization by the SHI providers and the respective governing authorities (e.g., the Federal Office for Social Security for national SHI providers). For this purpose, BIPS applies for project-specific permits from the SHI providers. Upon approval, the SHI provider requests official project approval from the governing authority. This may be issued in accordance with Section 75 of the German Social Code (SGB) X if the interest warranting protection of the person concerned is not affected or if the public interest in the research or planning significantly outweighs the interest in personal privacy.

Data source last refresh

28/02/2023

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

ConcepTION CDM

CDM website

https://www.imi-conception.eu/

CDM release frequency

6 months

Data source ETL frequency

12,00 months

Data source ETL status

Not ETL-ed