

Danish registries (access/analysis)

First published: 01/02/2024

Last updated: 19/12/2025

Data source

Human

Administrative healthcare records (e.g., claims)

Biobank

Birth registry

Cancer registry

Death registry

Disease registry

Drug registry

Hospital discharge records

Other

Pharmacy dispensing records

Population registry

Registration with healthcare system

Specialist ambulatory care records

Vaccination registry

Administrative details

Administrative details

Data source ID

42187

Data source acronym

Danish Health and Administrative Registries

Data holder

[Danish Health Data Authority](#)

Data source type

Administrative healthcare records (e.g., claims)

Biobank

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Pharmacy dispensing records

Population registry

Registration with healthcare system

Specialist ambulatory care records

Vaccination registry

Data source type, other

Population based nationwide longitudinal registries, Prospective studies
database, Validation studies

Main financial support

National, regional, or municipal public funding

Care setting

Hospital inpatient care

Hospital outpatient care

Primary care – GP, community pharmacist level

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.

Yes

Description of the qualification

Registries undergo standard quality procedures at the data custodian

Data source website

<https://sundhedsdatastyrelsen.dk/data-og-registre/nationale-sundhedsregistre>

Contact details

Vera Ehrenstein ve@clin.au.dk

Main

ve@clin.au.dk

Data source regions and languages

Data source countries

Denmark

Data source languages

Danish

Data source establishment

Data source established

01/04/1968

Data source time span

First collection: 01/04/1968

The date when data started to be collected or extracted.

Publications

Data source publications

The Danish health care system and epidemiological research: from health care contacts to database records

Educational webinars

Data Resource Profile: The Danish National Hospital Medicine Register.
Pharmacoepidemiol Drug Saf 2024

Studies

List of studies that have been conducted using the data source

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

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

CAncer Risk and INsulin analogues (CARING) project

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.

Assessment of Utilisation of Pioglitazone in Denmark Post Label Change (July 2011)

Estimation of Off-Label Use of XGEVA® (denosumab) Using Population-Based Databases in Denmark (20101335)

ADVANCE POC I Risk pillar - Testing new approaches to monitoring benefit/risk with pertussis vaccines as test case: Incidence rates of safety outcomes of whole-cell pertussis and acellular pertussis vaccines in pre-school children

European Program of Post-Authorization Safety Studies for Protelos®/Osseor® through EU-ADR Alliance

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

A multinational active safety surveillance study of crizotinib in Europe and the United States

An observational cohort study to evaluate the risk of adverse pregnancy outcomes in patients treated with etanercept compared to those not treated with etanercept or other biologics using merged data from Sweden, Denmark and Finland

Exposure and coverage to routine schedule vaccines in different EU countries (ADVANCE-POC2)

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

Estimating prevalence and incidence of acute myocardial infarction in a set of heterogeneous sources of observational health data collaborating in the EMIF

Platform

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

Post-Authorization Safety Program—Validation of the Danish Data Resources for the Study of Cardiovascular and Neoplasm Events in Users of Treatments for Overactive Bladder

Post-Authorisation Safety Study (PASS) of the Utilisation Patterns of Apixaban in Denmark

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

Beyond Pooled – Part of the BEYOND study program (Benefit of NOACs study of non-valvular AF patients in nordic countries) (BEYOND Pooled (Denmark, Norway, Sweden))

Drug Utilisation Study for Olodaterol

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

Use of non-steroidal anti-inflammatory drugs and clinical outcome of COVID-19: a Danish nationwide cohort study (NSAID COVID-19)

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

A Population-based Cohort Study of Pregabalin to Characterize Pregnancy Outcomes

Survey on the collection of data on adverse events related to medicinal products through registries

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

Drug-drug interactions between dicloxacillin/flucloxacillin and DOACs

Multinational, multi-database cohort study to assess adverse cardiovascular and cerebrovascular outcomes and mortality in association with inhaled NVA237 in Europe (NVA237 PASS)

Multinational, multi-database drug utilization study of inhaled NVA237 in Europe (NVA237 DUS)

Incidence and Prevalence of Interstitial Lung Disease and their progressive fibrosing phenotypes in 6 European Countries (PERSEIDS)

Renin-angiotensin-aldosterone system inhibitors and adverse outcomes of COVID-19: a Danish nationwide cohort study (ACE-I/ARB and COVID-19)

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

Inhaled corticosteroids and COVID-19 morbidity: Nationwide cohort study

The effect of mental disorders and treatment with psychotropic agents on the course of COVID-19 (COVID-19 psychotropics)

Risk and course of COVID-19 infection in patients with hypo- or hyperthyroidism. A Danish population-based cohort study (Thyroid dysfunction and COVID-19 infection)

Multisource Surveillance Study of Pregnancy and Infant Outcomes in Ocrelizumab-Exposed Women With Multiple Sclerosis (MELODIC Study)

Impact of use of newer glucose lowering drugs on outcomes in patients with COVID-19

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

Metformin use in renal impairment

Anti-microbial resistance: choice of therapeutic interventions and outcomes for the treatment of infections caused by MDR Gram-negative pathogens

Study of utilisation of combined hormonal contraceptives in Europe

Effectiveness and safety of non-vitamin K anticoagulants (NOACs) versus warfarin in frail patients with nonvalvular atrial fibrillation (AF): a nationwide cohort study

Impact of use of proton pump inhibitors on susceptibility to infection and risk of hospitalisation in patients with COVID-19

Dynamics of prescription drug use, diagnoses and health care utilization after community managed SARS-CoV-2 infection

The prognosis of coronavirus disease (COVID-19) in patients recently treated with immunosuppressant medications.

A Retrospective Cohort Study to Assess the Safety of Baricitinib Compared with Other Therapies Used in the Treatment of Rheumatoid Arthritis in Nordic Countries (I4V-MC-B011)

Treatment patterns and outcomes of Crohn's disease and ulcerative colitis patients initiated with biologic therapies in Denmark (IBDBIODK)

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

Drug utilization study of dexamfetamine in European countries (DUS of dexamfetamine)

Cohort Study of the Incidence of Major Cardiovascular Events in New Adult Users of Lisdexamfetamine and Remote Adult Users of Other ADHD Treatments

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

Prospective Cohort Study of Long-Term Safety of Teriflunomide in Multiple Sclerosis Patients in Europe (OBS12753)

Use of Low-dose Quetiapine and the Risk of Major Adverse Cardiovascular Events

A national register based study examining the prevalence, comorbidities, healthcare resource utilisation and burden of illness of hereditary hypophosphatemia in Denmark

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

Cardiovascular and renal outcomes, and mortality in Danish patients with type 2 diabetes who initiate empagliflozin versus GLP1-RA: A Danish nationwide comparative effectiveness study (EMPLACE)

Hip fracture information profiling, surveillance and treatment across epidemiological registries (HIPSTAR)

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)

Real-world evidence for non-valvular atrial fibrillation patients treated with oral anticoagulation in the Nordics (REATTAIN)

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

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

A post-authorisation safety study (PASS) to evaluate the long-term cardiovascular and psychiatric safety profile of methylphenidate (MPH) in adult patients with attention deficit/hyperactivity disorder (ADHD) in European Countries (PASS on methylphenidate in adults)

A post-authorisation, non-interventional, retrospective, drug-utilisation study to describe the pattern of use of lenalidomide in patients with myelodysplastic syndromes (MDS) (CC-5013-MDS-012)

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)

A post-marketing registry-based prospective cohort study of long-term safety of risankizumab in Denmark and Sweden

Drug Utilisation Study of Intuniv® (guanfacine extended release) in European Countries, Study protocol I: Database study (Intuniv data base study Europe)

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

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®)

Cohort study of cardiovascular events in patients with chronic obstructive pulmonary disease initiating olodaterol or other long-acting beta2-agonists

A non-interventional register-based comparative effectiveness study of rhFSH-alfa reference product vs. highly purified human menopausal gonadotropin or rhFSH-alfa biosimilar products for ovarian stimulation in in vitro fertilization or intracytoplasmic sperm injection treatment in Denmark and Sweden – The Nordic Follitropin Alfa Comparative Effectiveness Study (NORD-FACE)

NN9535-4447 Epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes- A cohort study based on Nordic registry data

Establish an EU catalogue of sources of real-world data, characterised by a common set of metadata and data quality measurements

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

Impact of EU label changes and revised pregnancy prevention programme for oral retinoid containing medicinal products: utilization and prescribing trends

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

A Population-based Study of the Safety of Gabapentin Use During Pregnancy

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

VAG-4602: Vaginal estradiol tablets (Vagifem®) and endometrial cancer risk in the treatment of postmenopausal vaginal atrophy: A register-based cohort study in postmenopausal women

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

A Non-interventional Observational Longitudinal Post-Authorization Safety Study (PASS) of SIMPONI® in Treatment of Ulcerative Colitis using Nordic National Health Registries (MK-8259-013)

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)

DRUG UTILISATION AND SAFETY STUDY OF MYSIMBA/CONTRACE IN EUROPE AND THE UNITED STATES (NB-451 DUS)

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

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

Use cases for development, optimisation and implementation of artificial intelligence methods for real world data analyses in regulatory decision-making

and health technology assessment along the product lifecycle (Real4Reg)

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)

Kesimpta (ofatumumab) pregnancy and infant safety study using real world data

Cohort Study of Long-term Safety of Upadacitinib in the Treatment of Atopic Dermatitis in Denmark and Sweden

Exposure to ACEi, ARB and statin drugs among women of child-bearing age in Denmark

A Non-Interventional Multi-Country Post-Authorisation Safety Study (PASS) to Assess the Incidence of Serious Infections & Malignancies in Systemic Lupus Erythematosus (SLE) Patients Exposed to Anifrolumab (SIMA PASS)

Cohort Study of Long-term Safety of Upadacitinib for the Treatment of Ulcerative Colitis and Crohn's Disease in a Real-world Setting in Europe

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

Drug Utilization Study Evaluating Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Ulcerative Colitis in Europe

A Non-Interventional Multi-Database Post-Authorisation Study to Assess PregnancyRelated Safety Data from Women with SLE Exposed to Anifrolumab (ROSE PASS)

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

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

Comparative Cohort Study of Long-term Safety Outcomes of Risankizumab Compared to Biologic Treatments for Ulcerative Colitis and Crohn's Disease in a Real-world Setting in Sweden and Denmark

Drug Utilization Study Evaluating Additional Risk Minimization Measures for Upadacitinib in the Treatment of Atopic Dermatitis in Europe

An Active Surveillance Study to Monitor the Safety of Abrocitinib Among Real-World Patients with Atopic Dermatitis (AD) in the European Union (EU) (B7451084)

Postauthorisation Safety Study (PASS) of Avatrombopag and Haematological Malignancies in Patients With Primary Immune Thrombocytopaenia

A Drug Utilization Study to Evaluate the Effectiveness of Risk Minimization Measures (RMMs) for Abrocitinib in the EU Using Electronic Healthcare Data (B7451085)

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

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

Prescriptions of medicines

Not Captured

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)].

No

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

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

Other

Procedures vocabulary, other

NOMESCO, NSCP, standard vocabulary in all Nordic countries

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?

Captured

Genetic data vocabulary

Other

Genetic data vocabulary, other

Nguyen-Nielsen M, et al. Existing data sources for clinical epidemiology: Danish registries for studies of medical genetic diseases. Clin Epidemiol 2013.
<https://www.ncbi.nlm.nih.gov/pubmed/23966801>

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.

Captured

Biomarker data vocabulary

Other

Biomarker vocabulary, other

NPU for lab data

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

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Package size

Route of administration

Strength

Medicinal product vocabulary

ATC

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Diet

Frequency of exercise

Other

Tobacco use

Lifestyle factors included other

Available via linkage to national survey

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Living in rural area

Marital status

Sex

Socioeconomic status

Type of residency

Quantitative descriptors

Population Qualitative Data

Population age groups

All

In utero

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)
Adult and elderly population (≥ 18 years)
Adults (18 to < 65 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

100%

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)

So far no diagnoses from primary care, but data on referrals to specialist and some services as well. Socioeconomic data can be obtained by accessing data at a different data custodian (Statistics Denmark). However, these data are updated less frequently than those of Danish Health Data Authority.

<https://www.vejledningsfunktionen.dk/en/videos-of-webinars/>

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

Father-child

Household

Mother-child

Sibling

Population

Population size

6000000

Active population size

9000000

Median observation time

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

30.00

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

30.00

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://sundhedsdatastyrelsen.dk/data-og-registre/forskerservice/forskermaskinen>

Biospecimen access

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

Yes

Biospecimen access conditions

Lab data and pathology data are available in a routine dataset in silico

Access to subject details

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

No

Description of data collection

Routine registration of triggering events.

Event triggering registration

Event triggering registration of a person in the data source

Birth

Immigration

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

Death

Event triggering creation of a record in the data source

Danish registries is a set of tables with different events triggering a record in each table depending on the purpose of the registry

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, pre-linked

Exact linkage. All researchers access data via Danish Health Data board, which links the data.

Linkage description, possible linkage

Data custodian enables linkage based on protocol

Linked data sources

Pre linked

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

No

Data source, other

All data sources are linkable

Linkage strategy

Deterministic

Linkage variable

Unique personal identifier

Linkage completeness

100%

Data management specifications that apply for the data source

Data source refresh

Yearly

Informed consent for use of data for research

Required for intervention studies

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?

No

Data source last refresh

30/08/2023

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 status

Completed

CDM name

OMOP

CDM website

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

Data source ETL status

Completed