

BIG-PAC

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Data source

Human

Administrative healthcare records (e.g., claims)

Hospital discharge records

Hospital inpatient records

Hospital outpatient visit records

Pharmacy dispensing records

Primary care medical records

Registration with healthcare system

Specialist ambulatory care records

Administrative details

Administrative details

Data source ID

1000000235

Data source acronym

BIG-PAC

Data holder

[Atrys Health S.A.](#)

Data source type

Administrative healthcare records (e.g., claims)

Hospital discharge records

Hospital inpatient records

Hospital outpatient visit records

Pharmacy dispensing records

Primary care medical records

Registration with healthcare system

Specialist ambulatory care records

Main financial support

Funding by own institution

Funding from industry or contract research

Funding from public-private partnership

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.

Yes

Description of the qualification

BIG-PAC has not undergone any qualification process. However, all the information gathered in it comes from anonymized electronic medical records whose origin is the public health care system

Data source website

[Atrys Health - Smart Data Unit - BIG-PAC database](#)

Contact details

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Main

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Data source regions and languages

Data source countries

Spain

Data source languages

Spanish

Data source establishment

Data source established

01/06/2018

Data source time span

First collection: 01/01/2012

The date when data started to be collected or extracted.

Publications

Data source publications

Resource use and costs in patients with poorly controlled type 2 diabetes mellitus and obesity in routine clinical practice in Spain

Costs and healthcare utilisation of patients with heart failure in Spain

Clinical Inertia in Poorly Controlled Type 2 Diabetes Mellitus Patients with Obesity: An Observational Retrospective Study

Clinical and Economic Consequences of Inhaled Corticosteroid Doses and Particle Size in Triple Inhalation Therapy for COPD: Real-Life Study

Real-World Use of Insulin Glargine U100 and U300 in Insulin-Naïve Patients with Type 2 Diabetes Mellitus: DosInGlar Study

Epidemiology, clinical profile, management, and two-year risk complications among patients with chronic kidney disease in Spain

Glucagon-Like Peptide 1 Receptor Agonists in Type 2 Diabetes Mellitus: Data from a Real-World Study in Spain

Economic impact of treatment-resistant depression: A retrospective observational study

Epidemiology and costs of depressive disorder in Spain: the EPICO study

Clinical Characteristics, Treatment Persistence, and Outcomes Among Patients With COPD Treated With Single- or Multiple-Inhaler Triple Therapy: A Retrospective Analysis in Spain

Treatment patterns and use of healthcare resources of patients with atherosclerotic cardiovascular disease and hypercholesterolemia and patients with familial hypercholesterolemia in Spain: Protocol of the Reality study

Incidence, prevalence, and treatment patterns in metastatic hormone-sensitive prostate cancer in Spain: ECHOS study

Achieving Lower LDL-C Levels After a Recent Myocardial Infarction Might Be Associated with Lower Healthcare Resource Use and Costs in Spain

Healthcare resource utilization and costs among patients with heart failure with preserved, mildly reduced, and reduced ejection fraction in Spain

Prevalence, Characteristics, Management and Outcomes of Patients with Heart Failure with Preserved, Mildly Reduced, and Reduced Ejection Fraction in Spain

Clinical characteristics, management, and one-year risk of complications among patients with heart failure with and without type 2 diabetes in Spain

Persistence, use of resources and costs in patients under migraine preventive treatment: the PERSEC study

Clinical and Economic Impact of Long-Term Inhaled Corticosteroid Withdrawal in Patients with Chronic Obstructive Pulmonary Disease Treated with Triple Therapy in Spain

<https://doi.org/10.1016/j.rec.2020.09.033>

Epidemiology and treatment of heart failure in Spain: the HF-PATHWAYS study

Healthcare resources and costs associated with nonvalvular atrial fibrillation in Spain: apixaban versus acenocoumarol

Economic Burden Associated with the Treatment with a Cardiovascular Polypill in Secondary Prevention in Spain: Cost-Effectiveness Results of the NEPTUNO Study

Burden of Illness beyond Mortality and Heart Failure Hospitalizations in Patients Newly Diagnosed with Heart Failure in Spain According to Ejection Fraction

Comprehensive Observational Study in a Large Cohort of Asthma Patients after Adding LAMA to ICS/LABA

Healthcare resource use and costs reduction with aripiprazole once-monthly in schizophrenia: AMBITION, a real-world study

Impact of COPD Exacerbations and Burden of Disease in Spain: AVOIDEX Study

Economic Consequences of the Overuse of Short-Acting β -Adrenergic Agonists in the Treatment of Asthma in Spain

Influence of the COVID-19 pandemic on patients receiving oral anticoagulants for the treatment of non-valvular atrial fibrillation

Prevalence, T2 Biomarkers, and Cost of Severe Asthma in the Era of Biologics: The BRAVO-1 Study

Post-event follow-up costs in patients with atherosclerotic cardiovascular disease in Spain

Prevalence of chronic rhinosinusitis without/with nasal polyps according to severity in Spain

Risk of severe cardiovascular events following COPD exacerbations: results from the EXACOS-CV study in Spain

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

ICD-9

ICD-9-CM

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?

Captured

Indication vocabulary

ICD-10

ICD-9

ICD-9-CM

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

ICD-10

ICD-9

ICD-9-CM

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.

Captured

Biomarker data vocabulary

BMO

FOBI

HPO

SMASH

Patient-reported outcomes

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

Yes

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

ICD-9

ICD-9-CM

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Dose

Package size

Route of administration

Strength

Medicinal product vocabulary

ATC

SNOMED

Quality of life measurements

Captured

Quality of life measurements vocabulary

Not coded (Free text)

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Sex

Quantitative descriptors

Population Qualitative Data

Population age groups

All

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

The database comprises approximately 25% of the total Spanish population

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)

Patients attending private care

Population

Population size

14500000

Active population size

12000000

Median observation time

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

10.00

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

9.00

Data flows and management

Access and validation

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

Using the longitudinal database of 2.3 million patients (Real Patient Database) obtained from anonymized electronic patient records that have been treated within the sanitary areas that are comprised in the database coverage. The sample of physicians is constant and nationally representative.

The electronic medical records are those that are introduced into the software of the doctor with whom he/she consults in the Health Centers, Hospitals and Specialty Centers. The information is transmitted in real time to the servers used to store the clinical information.

This information is anonymized by the source and it is impossible to reverse the process.

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

Practice registration

Start of treatment

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

Death

Emigration

Loss to follow up

Event triggering creation of a record in the data source

Every event that is related to a patient in terms of sanitary acknowledgment creates a new record (patient GP visit, new diagnose, hospitalization, hospital discharge, specialist encounter, dispensation of a medicinal product, recording of a congenital anomaly, laboratory test conduction, etc...).

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

Linkage description, pre-linked

The database uses a patient and doctor ID that is anonymized from the source (before Atrys has access to data). The fact the there are not other variables like center, or geographic area what so ever makes linkage impossible.

Linkage description, possible linkage

The database uses a patient and doctor ID that is anonymized from the source (before Atrys has access to data). The fact the there are not other variables like center, or geographic area what so ever makes linkage impossible.

Data management specifications that apply for the data source

Data source refresh

Monthly

Informed consent for use of data for research

Required for all 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?

Yes

Data source last refresh

30/06/2024

Common Data Model (CDM) mapping

CDM mapping

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

No