

# BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

**First published:** 01/02/2024

**Last updated:** 18/08/2025

**Data source**

**Human**

**Hospital discharge records**

**Pharmacy dispensing records**

**Primary care medical records**

## Administrative details

### Administrative details

#### **Data source ID**

21501

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#### **Data source acronym**

BIFAP

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#### **Data holder**

[Agencia Española de Medicamentos y Productos Sanitarios \(Spanish Agency for Medicines and Medical Devices, AEMPS\)](#)

**Data source type**

Hospital discharge records  
Pharmacy dispensing records  
Primary care medical records

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**Main financial support**

Funding by own institution

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**Care setting**

Hospital inpatient care  
Primary care – GP, community pharmacist level  
Primary care – specialist level (e.g. paediatricians)

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**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

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**Data source website**

[http://www.bifap.org/index\\_EN.html](http://www.bifap.org/index_EN.html)

## Contact details

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# Data source regions and languages

## **Data source countries**

Spain

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## **Data source languages**

Spanish

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## **Data source regions**

Aragón

Asturias, Principado de

Canarias

Cantabria

Castilla y León

Castilla-La Mancha

Extremadura

La Rioja

Madrid, Comunidad de

Murcia, Región de

Navarra, Comunidad Foral de

Valenciana, Comunidad

## Data source establishment

### **Data source established**

15/06/2001

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### **Data source time span**

**First collection:** 01/01/2002

The date when data started to be collected or extracted.

# Publications

## Data source publications

Updated list of Scientific Publications in peer reviewed journals describing the use of BIFAP for pharmacoepidemiology research linked to their respective DOIs.

Maciá-Martínez M-A, Gil M, Huerta C, et al. Base de Datos para la Investigación Farmacoepidemiológica en Atención Primaria (BIFAP): A data resource for pharmacoepidemiology in Spain. *Pharmacoepidemiol Drug Saf*. 2020;1-10.  
<https://doi.org/10.1002/pds.5006>

## Studies

List of studies that have been conducted using the data source

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

ADVANCE POC Study Protocol - Testing new approaches to monitoring benefit/risk with pertussis vaccines as test case. Coverage rates of acellular and whole-cell pertussis-containing vaccines in preschool children (ADVANCE Coverage POC)

Testing new approaches to monitoring benefit/risk with pertussis vaccines as test case: Incidence rates of pertussis and pertussis related outcomes of whole-cell pertussis and acellular pertussis vaccines in pre-school children (benefit study on pertussis vaccination)

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

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

NESTED CASE-CONTROL STUDY TO ASSESS THE ASSOCIATION BETWEEN THE USE OF METHYLPHENIDATE AND THE RISK OF VALVULAR HEART DISEASE AND PULMONARY HYPERTENSION

USE OF DRUGS ACTING ON RENIN-ANGIOTENSIN SYSTEM (RAS) AND RISK OF COVID-19: A CASE-POPULATION STUDY (SRAA-COVID19)

Real-world effectiveness of different COVID-19 vaccines in Spain: a cohort study based on public electronic health records (BIFAP) (effectiveness of COVID-19 vaccines in Spain)

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

Metamizole and risk of agranulocytosis

Risk of thromboembolic events and thrombocytopenia after vaccination against COVID-19 (Thrombosis risk COVID-19 vaccination)

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

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))

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)

Effectiveness of antiresorptives in preventing hip fractures in older women ( $\geq$  75 years) with osteoporosis: nested case-control study cohort (BiHip)

DARWIN EU® - Chondrosarcoma: patient demographics, treatments, and survival in the period 2010-2023

DARWIN EU® - Characterising interstitial lung disease in Europe

SAFETY-VAC: Network of Data Sources for Vaccine Safety Evaluation

ADEPT: The utilisation of antiseizure medications in pregnant women, other women of childbearing potential, and men: a multi-database study from 7 European countries

DARWIN EU® – Trends in utilisation of Attention-Deficit Hyperactivity Disorder (ADHD) Medications

SAFETY-VAC: Background incidence estimation of flares of pre-existing chronic diseases using pan-European electronic healthcare data sources.

Detection of therapeutic cascades associated with gabapentinoids and benzodiazepines in adults over 65 years old in Spain using BIFAP through prescription sequence symmetry analysis (GABALOOP)

ADEPT: feasibility of estimating the risk of adverse pregnancy, neonatal and child outcomes following either in utero ASM exposure through the mother, or peri-conceptional ASM exposure through the father

INCIDENCIA Y PREVALENCIA DE HIPOTIROIDISMO EN ESPAÑA, COMORBILIDAD, TRATAMIENTO Y ASOCIACION CON EFECTOS ADVERSOS DE SALUD (GRACHIPES)

SAFETY-VAC: Phenotype proposal and rates of immunocompromised populations in real-world data sources.

DARWIN EU® – Paracetamol prescribing and paracetamol overdose in Europe: a descriptive analysis of trends and patient characteristics

Asymptomatic hyperuricemia: to treat or not to treat. A target trial emulation to assess major cardiorenal outcomes (HYPER-TTE-HARV)

DARWIN EU® - Suicidality incidence rates in adult male patients and in patients treated with finasteride and dutasteride

DARWIN EU® - Use of antiretroviral therapies in paediatric patients

Use of antipsychotics in children and adolescents in the Spanish National Health System: network project with real-world data from five Autonomous Communities to inform evidence-based health policies (Children and Adolescents Antipsychotic Research for Evidence-based Strategies – CARES Project)

DARWIN EU® - Antipsychotic prescribing in children in Europe: a descriptive analysis of trends and patient characteristics

DARWIN EU® - Eye disorders in women with breast cancer treated with anastrozole, letrozole or tamoxifen

DARWIN EU® - Coverage of meningococcal vaccines in the target population in Europe

DARWIN EU® – Trends in utilisation of Attention-Deficit Hyperactivity Disorder (ADHD) Medications

DARWIN EU® - Descriptive study of tetanus immunoglobulin use and tetanus-prone wounds in Europe

DARWIN EU® - RR Childhood hypertension and sartans prescribing in children

DARWIN EU® – Drug Utilisation Study of terbinafine-containing products

USO DE TRATAMIENTOS ANTIHIPERGLUCEMIANTES CON EFECTO PROTECTOR CARDIOVASCULAR, LOS INHIBIDORES DEL SGLT2 (ISGLT2) Y LOS AGONISTAS DEL RECEPTOR DEL GLP1 (ARGLP1) EN PERSONAS CON DIABETES TIPO 2, EVOLUCIÓN DE USO EN LOS ÚLTIMOS AÑOS EN ESPAÑA USANDO LA BASE DE DATOS BIFAP (FaProCaVa-SPAIN)

Estudio de utilización de medicamentos para el tratamiento de la insuficiencia cardíaca (IDIAP-IC-2025) / Drug utilization study of treatments for heart failure (IDIAP-IC-2025)

## 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

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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

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### **Pregnancy and/or neonates**

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

Yes

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### **Hospital admission and/or discharge**

Yes

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### **ICU admission**

Is information on intensive care unit admission available?

No

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### **Cause of death**

Captured

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### **Cause of death vocabulary**

ICD-10-CM

ICD-9-CM

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### **Prescriptions of medicines**

Captured

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### **Prescriptions vocabulary**

ATC

other

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### **Prescriptions vocabulary, other**

SNOMED

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## **Dispensing of medicines**

Captured

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## **Dispensing vocabulary**

ATC

other

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## **Dispensing vocabulary, other**

SNOMED

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## **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

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## **Contraception**

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

Yes

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## **Indication for use**

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

Captured

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## **Indication vocabulary**

SNOMED CT

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## **Medical devices**

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

Yes

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## **Administration of vaccines**

Yes

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## **Procedures**

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

Captured

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## **Procedures vocabulary**

ICD-10-CM

ICD-9-CM

SNOMED CT

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## **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

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## **Clinical measurements**

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

Yes

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## **Genetic data**

Are data related to genotyping, genome sequencing available?

Not Captured

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## **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

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## **Patient-reported outcomes**

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

No

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## **Patient-generated data**

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

No

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## **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

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## **Unique identifier for persons**

Are patients uniquely identified in the data source?

Yes

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## **Diagnostic codes**

Captured

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## **Diagnosis / medical event vocabulary**

ICD-10-CM

ICD-9-CM

Not coded (Free text)

SNOMED CT

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## **Medicinal product information**

Captured

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## **Medicinal product information collected**

Brand name

Dosage regime

Formulation

Package size

Strength

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## **Medicinal product vocabulary**

SNOMED

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## **Quality of life measurements**

Not Captured

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## **Lifestyle factors**

Captured

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## **Lifestyle factors**

Alcohol use

Other

Tobacco use

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## **Sociodemographic information**

Captured

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## **Sociodemographic information collected**

Age

Gender

Sex

## Quantitative descriptors

### Population Qualitative Data

#### **Population age groups**

All

Paediatric Population (< 18 years)

Neonate

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 65 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)

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

93% of population in twelve Spanish regions

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#### **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)**

People who are registered with a primary care physician within the Spanish NHS (=98,9% of the Spanish population) in the 12 out of the 17 Spanish regions contribute data. Regional Healthcare Services act as health service providers for all levels of care in their territories.

Only a proportion of civil servants (around 4% of the Spanish population) opts out of the general public system and they are covered by the private sector.

There is a 13% of the Spanish population that contracts with private-for-profit health insurance companies, with an important regional variation.

However, in general private health schemes do not cover outpatient prescription medicines and these patients usually are also registered and attend NHS for healthcare and reimbursement.

This yields to only 1.1% of the Spanish population are not registered with a primary care physician within the Spanish NHS.

## Population

### **Population size**

30311044

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### **Active population size**

23897101

## Population by age group

<b>Age group</b>	<b>Population size</b>	<b>Active population size</b>
Paediatric Population (< 18 years)	4414233	3766056

Age group	Population size	Active population size
Neonate	155595	122956
Infants and toddlers (28 days – 23 months)	208755	168512
Children (2 to < 12 years)	2338560	1969994
Adolescents (12 to < 18 years)	1711323	1504594
Adults (18 to < 65 years)	18015636	14963634
Adults (18 to < 46 years)	9977804	7990443
Adults (46 to < 65 years)	8037832	6973191
Elderly ( $\geq$ 65 years)	7881175	5167411
Adults (65 to < 75 years)	3132462	2511340
Adults (75 to < 85 years)	2607677	1746715
Adults (85 years and over)	2141036	909356

## 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**

12.00

## 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).

[BIFAP Data Access Governance](#)

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## **Biospecimen access**

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

No

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## **Access to subject details**

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

No

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## **Description of data collection**

Please see Section 3.1 'Data Collection' in GOVERNANCE DOCUMENT in:

<http://www.bifap.org/data-governance?lang=en>

# Event triggering registration

## **Event triggering registration of a person in the data source**

Other

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## **Event triggering registration of a person in the data source, other**

Upon registration with a primary care physician within the Spanish NHS (=98,9% of the Spanish population) in the 9 out of the 17 Spanish regions that contribute data

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

Death

Emigration

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## **Event triggering creation of a record in the data source**

In every encounter with the general practitioner/paediatrician. Hospital admission and pharmacy dispensation will also trigger the creation of a record.

# 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

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## **Linkage description, pre-linked**

Within participant regional healthcare systems, the patient personal identification code—either regional or national (Código de Identificación Personal Autonómico, CIPA, or Código de Identificación Personal-SNS)—serves as the identifier for patients across various databanks, including primary care electronic health records, hospital discharge records, and dispensing pharmacies.

A pseudonymised code, based on CIPA, facilitates the linkage of relevant health care data from various databanks within BIFAP.

# Linked data sources

## **Pre linked**

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

No

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## **Data source, other**

BIFAP Diagnosis Tests of Covid-19

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## **Linkage strategy**

Deterministic

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## **Linkage variable**

The Personal Identification Code for the Autonomous Community (CIPA) is the variable used in the Autonomous Communities for the combination or linking of the different records for the same patient (primary care records, pharmacy dispensing records, hospital discharge diagnoses and Other Data banks). Subsequently a pseudonymisation procedure is carried out: the CIPA is eliminated by the computer technicians of the autonomous community, maintaining a pseudonymised identifier that distinguishes each patient from the Others in BIFAP. At the AEMPS, the Patient ID is finally generated from the first identifier.

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## **Linkage completeness**

Only patients included the Primary care medical records (PC-MR) and identified with a CIPA (the single linkage variable) are linked to the Other Data sources in BIFAP. Therefore, completeness is 100%. On the Other hand, any patients identified with a CIPA in Data sources (Data banks) but not having a PC-MR are not included in BIFAP.

## **Pre linked**

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

No

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## **Data source, other**

BIFAP EMRs from Primary Care

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## **Linkage strategy**

Deterministic

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## **Linkage variable**

The Personal Identification Code for the Autonomous Community (CIPA) is the variable used in the Autonomous Communities for the combination or linking of the different records for the same patient (primary care records, pharmacy dispensing records, hospital discharge diagnoses and Other Data banks). Subsequently a pseudonymisation procedure is carried out: the CIPA is eliminated by the computer technicians of the autonomous community, maintaining a pseudonymised identifier that distinguishes each patient from the Others in BIFAP. At the AEMPS, the Patient ID is finally generated from the first identifier.

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## **Pre linked**

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

No

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## **Data source, other**

BIFAP Hospital Diagnosis at in patients discharge

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## **Linkage strategy**

Deterministic

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## **Pre linked**

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

No

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## **Data source, other**

BIFAP Medicines Dispensed at Community Pharmacies

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## **Linkage strategy**

Deterministic

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## **Linkage variable**

The Personal Identification Code for the Autonomous Community (CIPA) is the variable used in the Autonomous Communities for the combination or linking of the different records for the same patient (primary care records, pharmacy dispensing records, hospital discharge diagnoses and Other Data banks).

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## **Pre linked**

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

No

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## **Data source, other**

BIFAP Vaccines Covid-19 administered National Registry

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## **Linkage strategy**

Deterministic

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## **Linkage variable**

The Personal Identification Code for the Autonomous Community (CIPA) is the variable used in the Autonomous Communities for the combination or linking of the different records for the same patient (primary care records, pharmacy dispensing records, hospital discharge diagnoses and Other Data banks).

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## **Pre linked**

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

No

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## **Data source, other**

Causes of Death national registry

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## **Linkage strategy**

Deterministic

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## **Linkage variable**

The Personal Identification Code for the Autonomous Community (CIPA) is the variable used in the Autonomous Communities for the combination or linking of the different records for the same patient (primary care records, pharmacy dispensing records, hospital discharge diagnoses and Other Data banks).

Subsequently a pseudonymisation procedure is carried out: the CIPA is eliminated by the computer technicians of the autonomous community, maintaining a pseudonymised identifier that distinguishes each patient from the Others in BIFAP. At the AEMPS, the Patient ID is finally generated from the first identifier.

In the Causes of Death national registry persons personal identifiers are different from the CIPA. Therefore, an additional linkage process of the CIPA and the personal identifiers in the Causes of Death national registry (national identitiy number and Others) is performed by the autonomous regions.

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## **Linkage completeness**

Only patients included the Primary care medical records (PC-MR) and identified with a CIPA (the single linkage variable) are linked to the Other Data sources in

BIFAP. Therefore, completeness is 100%. On the Other hand, any patients with a record in the Cause of Death national registry but not having a PC-MR are not included in BIFAP.

### **Pre linked**

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

No

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### **Data source, other**

Hospital Pharmacies dispensing Data

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### **Linkage strategy**

Deterministic

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### **Linkage variable**

The Personal Identification Code for the Autonomous Community (CIPA) is the variable used in the Autonomous Communities for the combination or linking of the different records for the same patient (primary care records, pharmacy dispensing records, hospital discharge diagnoses and Other Data banks). Subsequently a pseudonymisation procedure is carried out: the CIPA is eliminated by the computer technicians of the autonomous community, maintaining a pseudonymised identifier that distinguishes each patient from the Others in BIFAP. At the AEMPS, the Patient ID is finally generated from the first identifier.

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identified with a CIPA in Data sources (Data banks) but not having a PC-MR are not included in BIFAP.

## Data management specifications that apply for the data source

### **Data source refresh**

Quarterly

Yearly

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### **Informed consent for use of data for research**

Not Required

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### **Possibility of data validation**

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

Yes

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### **Data source preservation**

Are records preserved in the data source indefinitely?

Yes

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### **Approval for publication**

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

No

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### **Data source last refresh**

31/12/2024

## 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**

BIFAP

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### **CDM website**

[http://www.bifap.org/docs/BIFAP\\_Data\\_Access\\_Governance\\_v2\\_2021\\_20211011\\_with%20.%20.pdf](http://www.bifap.org/docs/BIFAP_Data_Access_Governance_v2_2021_20211011_with%20.%20.pdf)

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### **CDM release frequency**

6 months

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### **Data source ETL CDM version**

1.0

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### **Data source ETL frequency**

4,00 months

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### **Data source ETL status**

Completed

### **CDM name**

ConcepTION CDM

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**CDM website**

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

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**CDM release frequency**

6 months

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**Data source ETL CDM version**

For ConcepTION each study implies one or more ETL and different versions of the CDM can be used in different moments.

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**Data source ETL frequency**

6,00 months

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**Data source ETL status**

Completed

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**CDM name**

OMOP

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**CDM website**

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

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**Data source ETL CDM version**

5.4

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**Data source ETL frequency**

4,00 months

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**Data source ETL status**

Completed