ARS Toscana

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Data source | Human | Administrative healthcare records (e.g., claims) | Birth registry | Death registry | Diagnostic tests or procedures reimbursement | Emergency care discharge records | Exemptions from co-payment | Hospital discharge records | Pharmacy dispensing records | Population registry

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24417

Data source ID

24417

Data source acronym

ARS

Data holder

Agenzia regionale di sanità della Toscana (ARS)

Data source type

Administrative healthcare records (e.g., claims)

Birth registry

Death registry

Diagnostic tests or procedures reimbursement

Emergency care discharge records

Exemptions from co-payment

Hospital discharge records

Pharmacy dispensing records

Population registry

Main financial support

National, regional, or municipal public funding

Other

Care setting

Hospital inpatient care

Hospital outpatient care

Other

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

http://www.ars.toscana.it/it/

Contact details

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Main

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Data source regions and languages

Data source countries

Italy

Data source languages

Italian

Data source regions

Toscana

Data source establishment

Data source established

15/06/2000

Data source time span

First collection: 15/06/1996

The date when data started to be collected or extracted.

Publications

Data source publications

Trifirò G, Isgrò V, Ingrasciotta Y, Ientile V, L'Abbate L, Foti SS, et al. Large-Scale Postmarketing Surveillance of Biological Drugs for Immune-Mediated Inflammatory Diseases Through an Italian Distributed Multi-Database Healthcare Network: The VALORE Project. BioDrugs. 2021 Oct 12

Willame C, Dodd C, Durán C, Elbers R, Gini R, Bartolini C, et al. Background rates of 41 Adverse Events of Special Interest for COVID-19 vaccines in 10 European healthcare databases - An ACCESS cohort study. Vaccine [Internet]. 2022 Nov 22 [cited 2022 Nov 25]

Spini A, Rosellini P, Bellan C, Furiesi F, Giorgi S, Donnini S, et al. Development and validation of a case-finding algorithm for the identification of non-small cell lung cancers in a region-wide Italian pathology registry. PLoS One. 2022;17(6):e0269232.

Bots SH, Riera-Arnau J, Belitser SV, Messina D, Aragón M, Alsina E, et al. Myocarditis and pericarditis associated with SARS-CoV-2 vaccines: A population-based descriptive cohort and a nested self-controlled risk interval study using electronic health care data from four European countries. Frontiers in Pharmacology [Internet]. 2022 [cited 2022 Nov 27];13.

Giometto S, Tillati S, Baglietto L, De Bortoli N, Mosca M, Conte M, et al. Use of Biological Drugs for Psoriasis: A Drug-Utilization Study Using Tuscan Administrative Databanks. Int J Environ Res Public Health. 2022 Jun 2;19(11):6799.

Studies

List of studies that have been conducted using the data source

Pattern of use of intravitreal drugs with antiangiogenic properties for age-related macular degeneration and other vascular retinopathies (Anti-VEGF drugs)

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)

Identification of type 2 diabetes cases in a set of databases participating to the EMIF project

ASPIrin use and colorectal CANcer risk (ASPICAN)

EMIF Use Case 17 - Investigating the relationship in paediatric population between dosing of antibiotics (prescribed, dispensed or administered) and patient’s weight. (EMIF UC17)

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

Pattern of use of incretin-based drugs in clinical practice

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

Time to treatment intensification in patients receiving metformin+incretin-based medicines versus metformin+other hypoglicemics (Time to treatment intensification with incretins)

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)

First-line anticancer drugs in patients with advanced, primary Non-Small Cell Lung Cancer: drug-utilization and effectiveness studies from Tuscany Region healthcare database

ExPloring efficAcy, safeTy, and adHerence oF dIsease-modifyiNg antirheumatic Drugs through trajEctoRy model: the PATHFINDER study

Impact of the COVID-19 pandemic in a cohort of anticoagulant users: a descriptive drug utilization study based on data from the Tuscany Healthcare administrative database

Utilization patterns, access to healthcare facilities and economic assessment of JAKi drugs used in rheumatoid arthritis patients in Tuscany: the LEONARDO study

Comparative Effectiveness and Safety of Drugs used in Rare Neuromuscular and Neurodegenerative Diseases (CAESAR)

Diagnostic delay, drug utilization and clinical effectiveness and safety outcomes in patients with Crohn’s disease: checKing and AssessIng Real wOrld data from healthcare adminiStrative databases in Tuscany, Italy. The KAIROS study (the KAIROS study)

Advanced treatment of ulcerative colitis using an Italian healthcare administrative database: drug utilization patterns, healthcare resource use and costs The MICHELANGELO study

Cohort study to quantify the risk of glaucoma with intravitreal VEGF inhibitors (bevacizumab, ranibizumab, aflibercept)

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

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

Impact of diagnostic delay on drug utilization and use of healthcare facilities in patients with ulcerative colitis: observational study on real-world data taKen from the AdmInistRative healthcare database Of TuScany RegIon, Italy (The KAIROS-II study)

PATTERN OF USE AND SAFETY PROFILE OF BRANDED VS GENERIC ANTIEPILEPTIC DRUGS

Safety clinical outcomes associated with the use of Idarucizumab for severe bleeding/emergency surgery: an observational population based study (Idarucizumab use)

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)

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

ANALYSIS OF TREATMENT PATTERNS WITH DISEASE MODIFYING THERAPIES (DMTs) AMONG PATIENTS WITH MULTIPLE SCLEROSIS

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

Drug utilization of temozolomide with or without antiepileptic drugs in patients with malignant gliomas in the Tuscany region

Patterns of anti-CGRP mAbs use and triptan consumption before and after anti-CGRP treatment initiation: a descriptive drug utilization study in Tuscany region, Italy

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

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 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)

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)

Data characterization of population-based data sources: ConcePTION pipeline

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.

No

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

Captured

Cause of death vocabulary

ICD-10

ICD-9-CM

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)].

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

ICD-9

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-9

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Formulation

Package size

Route of administration

Medicinal product vocabulary

AIC

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Other

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Gender

Health area

Living in rural area

Pharmaceutical copayment

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

Approximately 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)

Inmates and those who are not legally resident in Tuscany

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

5000000

Active population size

3700000

Population by age group

Age group	Active population size
Paediatric Population (< 18 years)	532800
Infants and toddlers (28 days – 23 months)	42550
Children (2 to < 12 years)	287120
Adolescents (12 to < 18 years)	197580
Adults (18 to < 46 years)	1027490
Adults (46 to < 65 years)	1157360
Elderly (≥ 65 years)	982350
Adults (65 to < 75 years)	455840
Adults (75 to < 85 years)	357050
Adults (85 years and over)	173160

Median observation time

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

5.00

Data flows and management

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

Administrative data are recorded in any healthcare facility of the Regional Healthcare Service, or in agreement with (e.g. hospitals, pharmacies, diagnostic laboratories) that delivers healthcare services to any inhabitant that is officially resident in Tuscany. Data are collected in different databanks depending on the event that triggers the record. Information stored in the different databanks can be linked at person level using a region pseudonimized identifier.

Event triggering registration

Event triggering registration of a person in the data source

Other

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

Registration with the regional healthcare system due to birth or immigration

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

Hospital discharge; delivery in a hospital; dispensign of a medication in a community harmacy; dispensing in a hospital pharmacy for outpatient or domestic use (in some circumstances also for inpatient administration; registration or deregistration in the healthcare system; administration of a vaccine; ....

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

Linked data sources

Pre linked

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

Yes

Data source, other

ANAG

Linkage strategy

Deterministic

Linkage variable

Regional pseudonimized identification code

Linkage completeness

Linkage completeness is high for all data banks (i.e. above 95%)

Pre linked

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

Yes

Data source, other

CAP

Linkage strategy

Deterministic

Linkage variable

Regional pseudonimized identification code

Linkage completeness

Linkage completeness is high for all data banks (i.e. above 95%)

Pre linked

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

Yes

Data source, other

FED

Linkage strategy

Deterministic

Linkage variable

Regional pseudonimized identification code

Linkage completeness

Linkage completeness is high for all data banks (i.e. above 95%)

Pre linked

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

Yes

Data source, other

SDO

Linkage strategy

Deterministic

Linkage variable

Regional pseudonimized identification code

Linkage completeness

Linkage completeness is high for all data banks (i.e. above 95%)

Pre linked

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

Yes

Data source, other

SPA

Linkage strategy

Deterministic

Linkage variable

Regional pseudonimized identification code

Linkage completeness

Linkage completeness is high for all data banks (i.e. above 95%)

Pre linked

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

Yes

Data source, other

SPF

Linkage strategy

Deterministic

Linkage variable

Regional pseudonimized identification code

Linkage completeness

Linkage completeness is high for all data banks (i.e. above 95%)

Data management specifications that apply for the data source

Data source refresh

Quarterly

Informed consent for use of data for research

Not Required

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?

No

Approval for publication

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

No

Data source last refresh

15/03/2023

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 CDM version

2.2

Data source ETL status

Completed