AIFA Monitoring Registries Platform

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Data source | Human | Other

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1111236

Data source ID

1111236

Data source acronym

wMRs

Data holder

Italian Medicines Agency (AIFA)

Data source type

Other

Data source type, other

Monitoring Register

Main financial support

National, regional, or municipal public funding

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

Data source website

https://www.aifa.gov.it/en/registri-farmaci-sottoposti-a-monitoraggio

Contact details

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Data source regions and languages

Data source countries

Italy

Data source languages

Italian

Data source establishment

Data source established

01/01/2013

Data source time span

First collection: 01/01/2013

The date when data started to be collected or extracted.

Publications

Data source publications

Impact of the COVID-19 pandemic on prescription of sacubitril/valsartan in Italy

Trabectedin use in soft-tissue sarcoma patients in a real-worldsetting: Data from an Italian national drug-access registry

Effectiveness and management of ponatinib as second-line treatment in chronic myeloid leukemia: an analysis from the monitoring registries of the Italian medicines agency (AIFA)

Management of chronic myeloid leukaemia patients treated with ponatinib in a real-life setting: A retrospective analysis from the monitoring registries of the Italian Medicines Agency (AIFA)

Mortality in SARS-CoV-2 Hospitalized Patients Treated with Remdesivir: A Nationwide, Registry-Based Study in Italy

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 (other)

The AIFA Monitoring Registries Platform is used to monitor the pharmaceutical treatment of specific diseases or clinical conditions. In this way, the wMRs collect data useful to qualify the appropriateness use of the pharmaceutical in the clinical practice (i.e: clinical paramenters in the diagnosis of the disease, including rare diseases; clinical setting; individual genetic data profile; presence/absence of a specific biomarker). However, these data are collected only in treated eligible population for the reimbursement by the Italian Healthcare Service, so the main aim of wMRs is not to monitor the overall disease in Italy (as in a disease registry), but only its treatment and outcome.

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)?

No

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Cause of death vocabulary

Other

Cause of death vocabulary, other

Specific for each registry and often common for registries in a certain therapeutic area.

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

Internal vocabulary

Dispensing of medicines

Captured

Dispensing vocabulary

other

Dispensing vocabulary, other

Internal vocabulary

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?

No

Indication for use

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

Captured

Indication vocabulary

Other

Indication vocabulary, other

SmPC therapeutic indication

Medical devices

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

No

Administration of vaccines

No

Procedures

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

Captured

Procedures vocabulary

Other

Procedures vocabulary, other

SmPC

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

It depends according to the medicinal product

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

It depends according to the medicinal product

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

Other

Diagnosis / medical event vocabulary, other

It depends according to the medicinal product

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dose

Formulation

Package size

Strength

Medicinal product vocabulary

AIC

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Gender

Type of residency

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

wMRs contains about 250 different drug/therapeutic indication pairs. Each registry is designed to include and adopt as much as possibile of the elegibility criteria reported in the pivotal clinical trial(s). Moreover, inclusion in the registry is mandatory for the monitored drug/therapeutic indication pair for the treatment to be reimbursed by the Italian National Health Service. Therefore, our estimates of capture, during the active period of the registry, is close (and in some cases up) to 100% of the treated population. 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)

AIFA wMRs are not patient registries. They are drug registries whose compilation is necessary for the access to the reimbursment by the Italian Health Service of some drugs in specific therapeutic indications. In these sense, AIFA wMRs Platform does not automatically link with other databases so there are not information other than those collected in each registry.

Population

Population size

4678462

Active population size

3408040

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	14416	12816
Term newborn infants (0 – 27 days)	99	72
Infants and toddlers (28 days – 23 months)	578	431
Children (2 to < 12 years)	6058	5527
Adolescents (12 to < 18 years)	7681	6786
Adults (18 to < 46 years)	223362	132546
Adults (46 to < 65 years)	1038272	648363
Elderly (≥ 65 years)	3402412	2614315
Adults (65 to < 75 years)	1244072	881290
Adults (75 to < 85 years)	1525007	1189557
Adults (85 years and over)	633333	543468

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?

Yes

Description of data collection

The AIFA monitoring registries Platform is a national network the use of which is mandatory for clinicians to prescribe a monitored medicinal product within a specific therapeutic indication and inside the Italian National Health Service reimbursement framework (SSN). Pharmacists access the wMRs as well and are responsible to insert all data regarding drug dispensation and managed entry agreements. Given the fact that most of medicinal products monitored throughout the wMRs are innovative and high cost, we are confident that the registries capture about 100% of the treated population.

From an administrative point of view, regional representatives can enable health centers and ward in their territory. Moreover, each region has the duty to perform an administrative control on the data quality.

Event triggering registration

Event triggering registration of a person in the data source

Other

Start of treatment

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

Eligibility to a given treatment

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

Other

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

De-registration occurs only in case of errors in patients registration for data quality management. A new registration is then required.

Event triggering creation of a record in the data source

Medical doctors fill in the demographic and eligibility forms for each patient before treatment start, this generates a record for the patient in the wMRs.

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

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?

Yes

Approval for publication

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

Yes

Common Data Model (CDM) mapping

CDM mapping

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

No