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

First published: 27/05/2020

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35474

Study ID

37195

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Bulgaria
- Croatia

- Cyprus
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Liechtenstein
- Lithuania
- Luxembourg
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom
- United States

Study description

Registries can be used as data sources for conducting post authorisation safety studies (PASS) that aim to identify, characterise or quantify a safety hazard, aim to confirm the safety profile of a medicine or measure the effectiveness of risk-

management measures. In order to better understand the approach of registries towards the collection and reporting of adverse events related to medicines, the EMA will conduct a survey among registries registered within the ENCePP Resources database.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Valerie Strassmann

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/03/2020

Actual: 16/03/2020

Study start date
Planned: 01/04/2020

Actual: 17/04/2020

Data analysis start date
Planned: 29/06/2020

Date of final study report
Planned: 31/07/2020

Actual: 31/07/2020

Sources of funding

- EMA

Study protocol

Protocol - Survey on the collection of data on adverse events related to medicinal products through registries.pdf (139.01 KB)

Survey Protocol on collection and management of safety information in registries.pdf (136.84 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Survey on data collection on safety information by registries

Data collection methods:

Secondary use of data

Main study objective:

The objective of the survey is to gather information on the current practice and capability of registries registered in the ENCePP database to collect, manage and share data on adverse events related to medicines. The responses will provide to stakeholders of the regulatory network key information on the use of registry data as part of post authorisation safety studies.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey questionnaire

Population studied

Short description of the study population

N/A

Age groups

- 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)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

500.000

Study design details

Data analysis plan

The responses to the survey will be extracted from the EU Survey tool into excel and analysed using Excel tools

Documents

Study publications

Plueschke K, Jonker C, Strassmann V, Kurz X. Collection of Data on Adverse Even...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Advancing the Patient Experience in Chronic Obstructive Pulmonary Disease (COPD) Registry

UK Renal Registry

Advancing the Patient Experience in Chronic Obstructive Pulmonary Disease (COPD) Registry

REGISTRY: a study by the European Huntington’s Disease Network

Hepatitis Delta International Network (HDIN) - Patient Registry

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

PHARMACOVIGILANCE IN JUVENILE IDIOPATHIC ARTHRITIS PATIENTS (PHARMACHILD) TREATED WITH BIOLOGIC AGENTS AND/OR METHOTREXATE.

Advancing the Patient Experience in Chronic Obstructive Pulmonary Disease (COPD) Registry

UK Cystic Fibrosis Registry

ERN RARE-LIVER prospective research registry

German Atopic Dermatitis Registry TREATgermany

Danish registries (access/analysis)

European network of population-based registries for the epidemiological surveillance of congenital anomalies

EUROmediCAT central database

Deutsches Hämophilieregister

Portugal North Region Cancer Registry

FranceCoag
European registry and network for intoxication type metabolic diseases
EURAP International Registry of Antiepileptic Drugs and Pregnancy
Biologika in der Kinderrheumatologie
European Network and Registry for Homocystinurias and Methylation Defects - E-HOD
The European Clarkson’s syndrome registry
The PRES European Network of Registries for Autoinflammatory Diseases in Childhood
MS-Register of the National MS-Society of Germany (DMSG, Bundesverband e.V.)

Data source(s), other

Drugs and Pregnancy Finland, EUHASS - Blood disorders, EBMT, EUMDS - Myelodysplastic Syndrome, HUE-MAN Project - Alpha mannosidosis, SCETIDE - Primary Immune deficiencies, UK SMA Patient Registry, UK Duchenne and Becker, EurêClark registry-Systemic Capillary Leak Syndrom, ECFSPR - Cystic Fibrosis, ESPN/ERA-EDTA - Children Renal Replacement Therapy, ECARUCA - Chromosomal aberrations, EUROFEVER, ECMN - Mastocytosis, ChILD-EU - Children Interstitial lung diseases, COST-GnRH gonadotropin-releasing hormone deficienc, E-IMD, Euro WABB - rare genetic disorders, EURAP-Epilepsy and pregnancy, Icelandic National Registries, BIKER, Reuma.pt - Rheumatic diseases Portuguese Registry, E-HOD, EUHANET - Haemophilia, epidEMcat - Multiple sclerosis, ROR Centro - Oncology, RORENO - Oncology, ROR Sul - Oncology, German MS-Register, ICRS - Cartilage Damage, Sylvia Lawry Centre for MS Research Registry, PedNet, THAOS registry - Transthyretin Amyloidosis, HemoNED - Haemophilia, FranceCoag - Haemophilia, UKHCDO - Haemophilia, Hepather - Hepatitis B and C, Fabry registry - Fabry disease, DHR, ENCALS - Amyotrophic lateral sclerosis, INBC - Blood disorders, ALS Register -

Amyotrophic Lateral Sclerosis, FTLD Register - Frontotemporal lobar degeneration, NCRI - Oncology, ERCUSYN (European Register on Cushing's Syndrome), PARADIGHM registry - Chronic Hypoparathyroidism, APEX COPD Registry, UK CF Registry, World Bleeding Disorders Registry, ASTOR - Alport Syndrome, R-LIVER rare liver disease registry, TREATgermany-AD (Atopic Dermatitis) Registry, Norwegian Porphyria Registry, Danish Registries (access/analysis), EUROCAT, Drugs and Pregnancy Finland, EUROmediCAT, PROGNOSIS, EBMT, HAE, European Porphyria Registry (EPR), ESID Registry, EUHASS - Blood disorders, BSRBR - Rheumatic and Musculoskeletal conditions, Pharmachild - Juvenile idiopathic arthritis (JIA), EDMUS - Multiple Sclerosis, EHR - Blood disorder, EPCOT - Blood disorders, UK Renal Registry - Renal diseases, EUMDS - Myelodysplastic Syndrome, EUROPAC - Pancreatic diseases and cancer, EUROTRAPS - Autoinflammatory diseases, European registry of alveolar echinococcosis, X-ALD - X-linked adrenoleukodystrophy, EHDN - REGISTRY, European Prader-Willi syndrome database, HDIN - Hepatitis D

Data sources (types)

Disease registry

Drug registry

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No