German Cystic fibrosis registry - Muko.web

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Data source

Human

Disease registry

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48774

Data source ID

48774

Data source acronym

German CF Registry

Data holder

Mukoviszidose Institut

Data source type

Disease registry

Main financial support

Funding by own institution

Care setting

Primary care – specialist level (e.g. paediatricians)

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

https://www.muko.info/was-wir-tun/register

Contact details

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Data source regions and languages

Data source countries

Germany

Data source languages

German

Data source establishment

Data source established

15/06/1995

Data source time span

First collection: 15/06/1995

The date when data started to be collected or extracted.

Publications

Data source publications

Epidemiological trends in nontuberculous mycobacterial infection among people with cystic fibrosis in Germany

Chronic inhaled antibiotic therapy in people with cystic fibrosis with Pseudomonas aeruginosa infection in Germany

Molecular Epidemiology of Mycobacterium abscessus Isolates Recovered from German Cystic Fibrosis Patients

Survival-Adjusted FEV1 and BMI Percentiles for Patients with Cystic Fibrosis before the Era of Triple CFTR Modulator Therapy in Germany

German Cystic Fibrosis Registry, Annual Data Report 2020

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

Cystic fibrosis

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?

No

Cause of death

Captured

Cause of death vocabulary

Other

Cause of death vocabulary, other

Muko.web dictionary

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)].

No

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

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)?

Not Captured

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.

No

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

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

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.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICPC

Not coded (Free text)

Other

Diagnosis / medical event vocabulary, other

As registered by the GP either coded or in free text fields

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dosage regime

Medicinal product vocabulary

ATC

Quality of life measurements

Captured

Quality of life measurements vocabulary

other

Quality of life measurements, other

CFQ-R

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Ethnicity

Gender

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

The data source collects data from more than 85% of all CF patients living in Germany. The age distribution is representative and is published in annual report. Exact values can be issued in the context of register requests.

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)

Nation-wide

Population

Population size

9500

Active population size

7500

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).

https://www.muko.info/was-wir-tun/register

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

Self-developed online register tool

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

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

Death

Loss to follow up

Event triggering creation of a record in the data source

Outpatient appointment

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

Linkage description, pre-linked

Under construction

Linkage description, possible linkage

The informed consent form allows the data source to be linked to other data sources. Currently in coordination/processing

Data management specifications that apply for the data source

Data source refresh

Monthly

Informed consent for use of data for research

Other

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

Informed consent, other

There is a committee to evaluate requests for data access

Data source last refresh

31/12/2022

Common Data Model (CDM) mapping

CDM mapping

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

No