French Epidemiological Strategy and Medical Economics Metastatic Breast Cancer (ESME-MBC) Database

First published: 11/04/2025

Last updated: 11/04/2025

Data source | Human | Cancer registry

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000452

Data source ID

1000000452

Data source acronym

ESME MBC

Data holder

Unicancer

Data source type

Cancer registry

Main financial support

Funding from public-private partnership

Care setting

Hospital inpatient care

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

Description of the qualification

ISO certification for project management activities

Data source website

https://www.unicancer.fr/en/programs/esme/

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Data source regions and languages

Data source countries

France

Data source languages

English

French

Data source establishment

Data source established

23/01/2014

Data source time span

First collection: 23/01/2014

The date when data started to be collected or extracted.

Publications

Data source publications

Paclitaxel plus bevacizumab or paclitaxel as first-line treatment for HER2-negative metastatic breast cancer in a multicenter national observational studyDelaloge S, Perol D, Courtinard C, Brain E, Asselain B, Bachelot T, Debled M, Dieras V, Campone M, Levy C, Jacot W, Lorgis V, Veyret C, Dalenc F, Ferrero JM, Uwer L, Kerbrat P, Goncalves A, Mouret-Reynier MA, Petit T, Jouannaud C, Vanlemmens L, Chenuc G, Guesmia T, Robain M, Cailliot C.Ann Oncol. 2016 Sep;27(9):1725-32

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Real-word effectiveness of post-trastuzumab emtansine treatment for human epidermal growth factor. Receptor 2-positive metastatic breast cancer: a multicenter, maltcjhed cohort analysis from the Epidermology Strategy and Medical Economics database (2008-2018)Courtinard C, Barbet V, Schiappa R, Pilleul F, Michiels S, Dabakuyo S, Gourgou S, Jaffre A, Asselain B, Bosquet L, Dunton K, Rosenlund M, Liang Z, Cathcart J, Delaloge S.Real-World Data and Digital Oncology. 2024

Assessing the real-world effectiveness of 8 major metastatic breast cancer drugs using target trial emulationAntoine A, Pérol D, Robain M, Bachelot T, Choquet R, Jacot W, Yahia BBH, Grinda T, Delaloge S, Lasset C, Drouet YEur J Cancer. 2024

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

Breast cancer metastatic

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)?

No

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

international nonproprietary name (INN) for anti-cancer drugs only

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Dispensing of medicines

Captured

Dispensing vocabulary

other

Dispensing vocabulary, other

international non proprietary name (INN) for anti-cancer drugs only

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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)].

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?

Not Captured

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

Not coded (Free text)

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?

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.

Captured

Biomarker data vocabulary

Other

Biomarker vocabulary, other

Gene alteration (BRCA, PALB2, RAD51, PTEN, MSH6, MSH2, TP53, MLH1, CDH1, PMS2, EPCAM...) collected as pre-listed variables and HER2/RH status collected.

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

Not Captured

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Route of administration

Medicinal product vocabulary

Other

If 'other,' what vocabulary is used?

international nonproprietary name (INN)

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Gender

Other

Sex

Sociodemographic information other

Menopausal status, weight

Quantitative descriptors

Population age groups

Adult and elderly population (≥18 years)

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

38 000 patients included in the 2025 ESME-MBC database.
This database compiles data from existing data available from patient's electronic medical records (EMR) at 20 participating hospitals (French comprehensive cancer centers).

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)

Comprehensive inclusion of all patients treated for metastatic breast cancer in the 20 participating hospitals.

Population

Population size

38000

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).

ESME program_governance_2025.pdf

English (79.65 KB - PDF) View document

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

The database includes data related to patient demographics, tumor characteristics (age, primary diagnosis, histology, relapses, ECOG score, etc., treatments (dates, INN, route of administration, treatment protocols, reason for termination, etc.), and clinical events.
Data is collected at each participating site by technicians who are specifically trained for the project using an electronic data collection (eDC) tool.

Data imported into the final database are controlled, recoded, and harmonized before import according to the data management plan. All coding procedures are predefined by the data manager. There is no transmission of individual data; all data is centralized within each hospital using a shared anonymous format. All data is exclusively obtained retrospectively; no attempts are made to recover non available data from the patient's medical record by contacting healthcare providers or patients.

ESME MBC Database aims to be a clinical and therapeutic database centralizing existing and available data from different sources in French comprehensive cancer centers.

Data does not contain any personal data on patients. In compliance with the authorization delivered by the French Data Protection agency to Unicancer, only aggregated statistical reports and publication are released ouside Unicancer.

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
Breast cancer with first metastasis occurence

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

Event triggering de-registration of a person in the data source, other
patient opposition to data use

Event triggering creation of a record in the data source
patient demographics, tumor characteristics (diagnosis, histology, relapses, metastatic disease, etc.), treatments (dates, INN, route of administration, treatment protocols, reason for termination, etc.), and clinical events.

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

SNDS : Système National des données de santé (France) / will be available from second semester 2025.

Linkage description, possible linkage

probabilistic linkage

Data management specifications that apply for the data source

Data source refresh

Yearly

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

Data source preservation length (years)

20 years

Approval for publication

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

Yes

Data source last refresh

21/02/2025

Common Data Model (CDM) mapping

CDM mapping

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

No