Real World Evidence in Oncology: an Italian examples-based expert opinion on advancing clinical and regulatory decision-making

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000624

Study ID

1000000624

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Real World Evidence (RWE) is transforming oncology by integrating insights from randomized clinical trials (RCTs) with real-world data, enhancing personalized care, optimizing treatments, and informing clinical and regulatory decisions.

This expert opinion, based on a multidisciplinary Italian project, demonstrates RWE's ability to address gaps in RCTs, especially for complex or underrepresented populations, using case studies from the Fondazione Ricerca e Salute (ReS) healthcare database. While RWE shows transformative potential, challenges remain in data quality, accessibility, and regulatory integration. Experts emphasize standardizing data collection and harmonizing methodologies across healthcare systems to ensure actionable insights.

RWE is also crucial for pricing, reimbursement, and regulatory approvals, particularly in cases where large-scale trials are infeasible or raise ethical concerns. The integration of artificial intelligence tools is highlighted as essential for advancing data processing and analysis, enabling RWE to provide more nuanced insights. Collaboration among healthcare providers, researchers, and policymakers is critical to harness RWE's full potential.

By addressing these challenges, RWE can improve patient outcomes, streamline resource allocation, and enhance decision-making in oncology, driving progress toward more efficient and personalized cancer care.

This study highlights how real-world evidence complements clinical trials, advancing precision oncology and supporting regulatory and healthcare decision-making for improved patient outcomes.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

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Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Letizia Dondi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/02/2023

Study start date

Actual: 03/07/2023

Date of final study report

Actual: 01/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

unconditional contribution of: AstraZeneca S.p.A., Glaxosmithkline S.p.A., Pfizer S.r.l., Roche S.p.A

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Method development or testing

Data collection methods:

Secondary use of data

Study design:

Patients with tumor from 2014 to 2022 were identified and analysed as prevalent cases and/or incident cases. Epidemiology and demographics were described at baseline. According to the specific objective, drug utilisation and healthcare utilisation could also be assessed.

Main study objective:

The RWE Oncology Project aims to reach a consensus on the use of Real-World Data (RWD), in particular
administrative health data, to identify eligible patients (target populations) for new oncology drugs and analyze
them in their different peculiarities.
This report illustrates some examples of identification of populations affected by specific tumors and analyses
that can be conducted to generate Real World Evidence (RWE) in the oncology field, in order to suggest how
administrative health data can be used for different analytical purposes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Uterine cancer

Prostate cancer metastatic

Breast cancer

Lung cancer metastatic

Diffuse large B-cell lymphoma

Population studied

Short description of the study population

Italian inhabitants beneficiaries of the Italian National Health Service (SSN) included in the ReS database. All subjects who had received a diagnosis of cancer (according to the specific code of the ICD9-CM system, which allows a standardized classification of the different tumor sites) in the period between 2014 and 2022 were considered.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - 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)
- **Adult and elderly population (≥18 years)**
    - Adults (18 to < 65 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)

Study design details

Setting

Inhospital/local outpatient settings

Documents

RWE Oncology Project. The use of data for oncology care planning to support the...

Study publications

N Martini, M Altini, G Amunni, L Baldessin, O Brignoli, A Capuano, P Conte, R D...

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)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown