

Comparative Effectiveness Research of Treatments for Advanced Melanoma in Europe Using Existing Real-World Data Sources: A Feasibility Assessment

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Background

- With a wide range of immunotherapy and targeted agents now available for the treatment of advanced melanoma, clinicians and health authorities require data on the comparative effectiveness and safety of treatments in the routine clinical care setting.
- However, comparative effectiveness research (CER) is methodologically complex and requires appropriate real-world data (RWD) sources.

Rationale

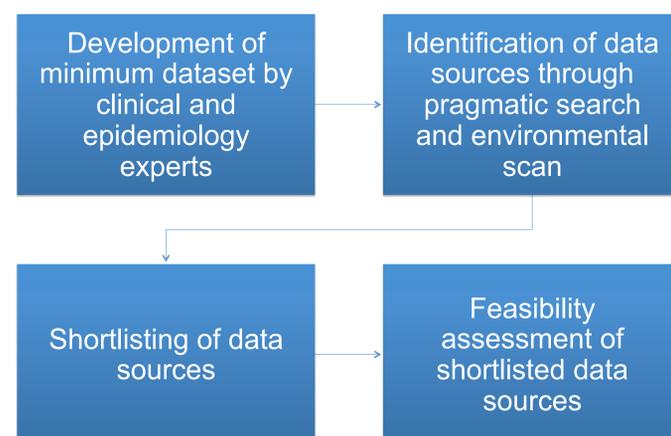
- To be useful for CER in advanced melanoma, a database should be fit-for-purpose i.e., provide the data elements required to address specific research questions and have the appropriate design. Finding fit-for-purpose databases is complex, considering the heterogeneity of databases in populations covered, endpoints, structure, and availability of data elements specific to advanced melanoma.
- Searchable databases of RWD sources tend to include healthcare databases that are not disease-specific, and that are not originally designed to meet the rigorous and robust needs of CER. In this context, it is necessary to evaluate the feasibility of conducting CER using an alternative approach.

Objectives

1. To define the minimum data requirements for robust CER in advanced melanoma;
2. To evaluate feasibility of CER within existing RWD sources in Europe.

Methods

Figure 1. Structured approach to the feasibility assessment of real-world data sources on advanced melanoma



Methods (continued)

Development of minimum dataset

Table 1. Minimum dataset required to conduct comparative effectiveness research in advanced melanoma

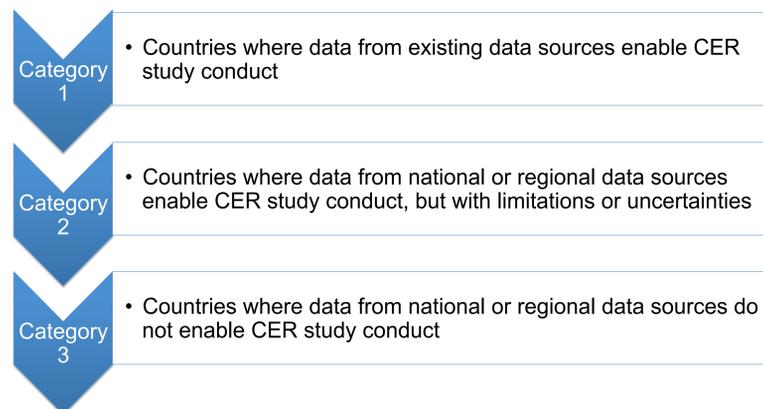
Variable	Eligibility Criteria	Comparator selection / Group definition	Effectiveness outcome	Safety outcome	Economics outcome
Melanoma diagnosis	X				
Melanoma stage	X	X			
TNM classification		X			
Age	X	X			
Gender		X			
ECOG or other performance score		X			
BRAF mutational status		X			
Brain metastasis status		X			
1 st or 2 nd line treatment		X			
Previous 1 st or 2 nd line treatment		X			
Calendar time of treatment initiation		X			
Survival status			X		
Time of death			X		
Database membership during study period			X		
Number of hospitalizations				X	
Number of medical procedures				X	
Number of primary care visits				X	
Treatment discontinuations				X	
Treatment discontinuations due to any cause				X	
Death due to treatment				X	
Hospitalizations during follow-up period					X
Number of medical procedures during follow-up period					X
Number of primary care visits during follow-up period					X

Identification of potential data sources in Europe

- **Pragmatic Internet search & High-level literature review**
- **Environmental scan of available data sources** through input from various stakeholders, including epidemiologists, registry specialists and clinical experts. Hospital EMRs were excluded.
- **Shortlisting** of data sources.
- **Follow-up questionnaires** sent to database custodians.

Feasibility assessment of data sources

Figure 2. Classification of countries according to data availability



Aspects considered when collecting data on potential data sources:

- Availability of longitudinal data;
- Database content: variables recorded, coverage, completeness of records, frequency of updates, reporting delays;
- Data linkage capabilities;
- Potential limitations (e.g., sample size, length of follow-up);
- Data access policy and governance.

Results

Figure 3. Process flow of identification of real-world data sources on advanced melanoma

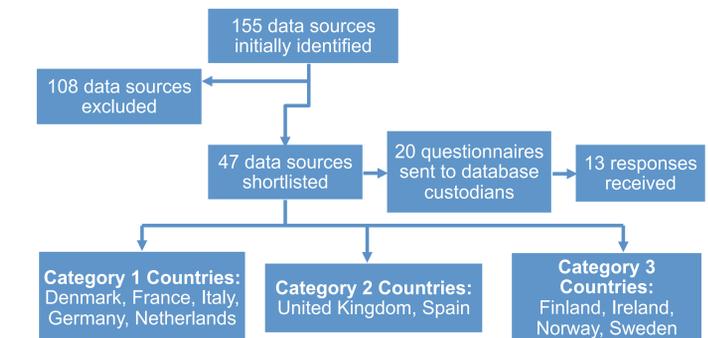


Table 3. Overview of retained data sources

	COUNTRY AND DATA SOURCES
CATEGORY 1	Denmark: National Melanoma Group Database; Oncology Database Italy: Clinical national melanoma registry France: MelBase Germany: ADOREG Netherlands: Dutch Melanoma Treatment Registry
CATEGORY 2	United Kingdom: National Cancer Intelligence Network (NCIN); Systemic Anti-Cancer Therapy (SACT) Spain: National Registry of Cutaneous Melanoma (NRCM)
CATEGORY 3	Finland: Finnish Cancer Registry, Register of Specialist Medical Care Ireland: National Cancer Register Norway: Norwegian Patient Register (NPR); National Quality Register for Melanoma Sweden: National Patient Register; Swedish Cancer Register; National Quality Register of Skin Melanoma

Data linkage capabilities:

- **All Nordic countries (Sweden, Norway, Denmark, Finland):** Possible in all databases due to a common national personal identification number
- **UK:** Data linkage is possible for all data sources, based on the National Health Service (NHS) number
- **Netherlands:** Possible with some databases, based on the Burger Service number

Key variables that were most frequently missing:

Details on systemic treatment, melanoma staging, brain metastases, ECOG Performance Status, mutational status.

Conclusion

- Before undertaking any CER, a given data source must be assessed at that time point, as some data sources are not mature enough with respect to sample size and length of follow-up.
- The majority of elements in the minimum dataset are routinely collected in clinical practice, yet are not included in most RWD sources identified. Adding these data elements to existing RWD sources would increase opportunities for reliable CER of advanced melanoma treatments in Europe.
- Completeness and consistency of data elements needed to support CER studies are variable, which confirms that the usefulness of a given data source must be assessed in relation to specific research questions. RWD sources that meet common study needs are limited.



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