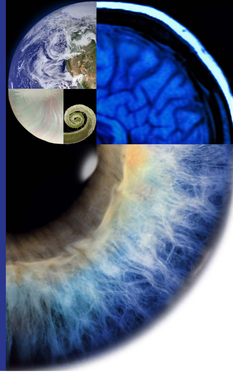
Identifying Real-World Data for Observational Studies: A Systematic Approach

PRM48



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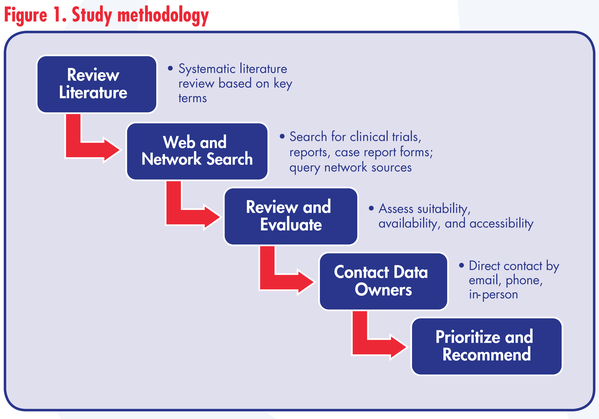
OBJECTIVE

- **Real-world evidence provides information about the effectiveness, safety, and value of healthcare interventions throughout the product lifecycle.**
- **A multitude of observational data sources exist but they vary by geographic location and in quality, data elements captured, and accessibility to external users.**
- **Our objective was to develop a systematic methodology to identify observational data sources for specific research questions and to test it in both common and rare conditions in a range of therapeutic areas.**

METHODS

- A 5-step process was developed and applied to identify and characterize potential data sources for use in 6 observational research programs spanning cardiology (2 programs, referred to as CV1 and CV2), stroke, diabetes, oncology, and respiratory medicine (**Figure 1**).

Figure 1. Study methodology



- **Step 1:** systematic literature searches were conducted in MEDLINE and Embase without language restrictions and limited to humans. Disease-specific search terms coupled with data source search terms were used to identify publications of observational studies.
- **Step 2:** internet searches were used to identify other sources of data, including those not captured in the literature search. Data sources included administrative claims and clinical practice databases, registries, cohorts, and surveys.
- **Step 3:** after screening the hits identified in Steps 1 and 2 for relevance and redundancy, data were captured from published and online materials. Inclusion criteria tailored to each project were applied and detailed information regarding the following was reported (**Table 1**):
  - availability of anonymized individual patient data
  - target geographies
  - type of data required including:
    - drugs (inpatient, outpatient, over the counter)
    - health resource utilization
    - laboratory and imaging results
    - clinical or biometric measures
    - patient-reported outcomes
    - clinical outcomes
  - length of follow-up
  - ability to link patient data across multiple data sources.
- **Step 4:** managers of data sources that met initial evaluation criteria were contacted to assess availability of data elements and accessibility to external researchers.
- **Step 5:** in-depth assessment to recommend data sources that best met observational research program objectives in terms of:
  - representation of target geography
  - availability of data elements
  - accessibility to external researchers (either directly or through a contractual or collaborative agreement).

RESULTS

- Across 6 separate studies, over 14,000 references or potential data sources (581–3530 per study) were screened to assess whether they reported information from a unique data source (**Figure 2**).
- Of the initial hits, 4.9% to 7.6% per study, comprising a combined total of 864 sources, were relevant and were reviewed further to see if they met study-specific inclusion criteria:
  - detailed information was reported for a total of 388 data sources across the 6 studies
  - for common diseases/multiple geographies, the number of reported data sources exceeded 50 per study
  - for the oncology research program (rare patient subset; inpatient/outpatient data; US sources) only 15 sources were reported.
- Detailed review and investigation of suitable sources generated a manageable number of recommended data sources (3–17 per study) that together could address specific research questions:
  - for prevalent conditions, such as cardiovascular disease, the data sources with the most comprehensive data collection and best linkage potential that were also accessible to external researchers were recommended
  - for rare conditions and complex data requirements, such as a narrow respiratory subpopulation requiring detailed clinical measures, patient-reported outcomes, and healthcare utilization, no data source met all necessary criteria. Thus, partnering with data managers was recommended to collect the full range of required data.
- Within 6 months of initiation of our assessments, the first studies planned using recommended data sources had begun and within 18 months were providing results.

CONCLUSIONS

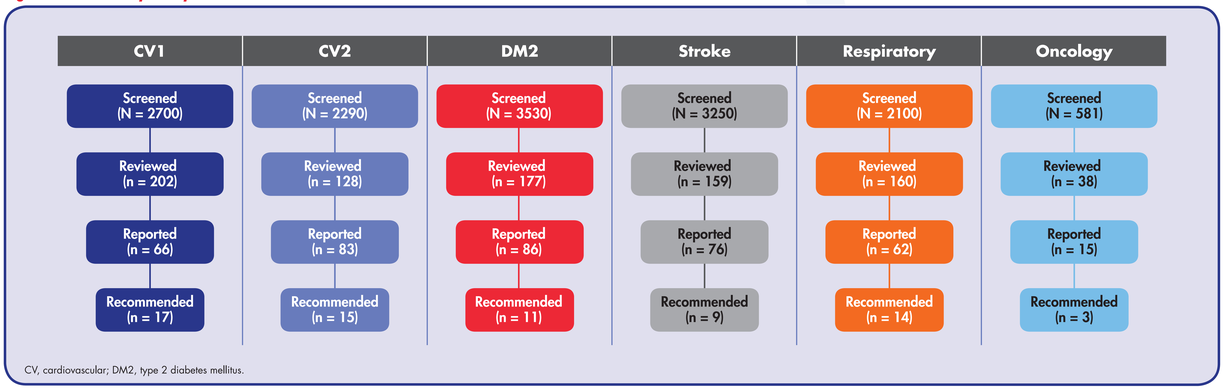
- **Our systematic approach to data-source assessment identified comprehensive, relevant, and accessible data sources for both rare and prevalent conditions.**
- **We recommended the most appropriate data sources in therapeutic areas with multiple options as well as identified data gaps for which additional data collection was needed to provide all pertinent information.**
- **A systematic understanding of real-world evidence has helped to guide observational research programs in diverse therapeutic areas with specialized data requirements.**

Table 1. Inclusion criteria by study

Data Type	CV1	CV2	DM2	Stroke	Respiratory	Oncology
Regions	Europe North America Asia-Pacific	Europe North America Asia	Europe North America Asia	Europe North America Asia	Europe Canada	United States
Drugs and date of receipt, prescription, or pharmacy fill	IP including oral OP/Rx OTC	IP including oral OP/Rx OTC	OP/Rx OTC	IP including oral OP/Rx OTC	IP and ER including oral OP/Rx	IP including oral, fluid restriction OP/Rx All chemotherapy (oral, injected)
HRU including diagnoses and procedures received	Date and place of service Cost	Date and place of service Cost	Date and place of service Cost	Date and place of service Cost	Date and place of service Cost	Date and place of service
Laboratory and imaging results	Preferred	Preferred	Required	Required	Required	Required
Clinical/biometric data	Preferred	Required	Required	Required	Required	Required
Patient-reported data	—	—	—	—	Required	—
Outcomes (event type and date)	Stroke MI CV death Any death	Stroke MI Revascularization CV death Any death	Stroke MI CV death Any death	Stroke MI CV death Any death	Hospitalization ER visit	30-Day readmission Any death
Length of follow-up	3+ Years	3+ Years	3+ Years	90 Days	1 Year	1 Year

CV, cardiovascular; DM2, type 2 diabetes mellitus; ER, emergency room; HRU, health resource utilization; IP, inpatient; MI, myocardial infarction; OP, outpatient; OTC, over the counter; Rx, prescription or pharmacy fill.

Figure 2. Results by study



CV, cardiovascular; DM2, type 2 diabetes mellitus.

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