Assessing the ability of hospital sites from a European real-world network to support oncology evidence generation

RWD19

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INTRODUCTION

The oncology treatment landscape is dynamic and changing at a rapid pace. Insights from real-world (RW) clinical practice play a key role in showcasing the value of novel therapies (unmet medical need) and in demonstrating the value of existing therapies (RW effectiveness)

Clinically rich real-world data (RWD) (e.g., staging, biomarker results) required to generate such insights, are often not recorded in traditional large-scale RWD sources e.g., claims databases. RWD from hospital sites may capture the clinical depth required for such studies, and with the appropriate operational set up can contribute to efficient RW insight generation [1-4].

OBJECTIVE

Federated evidence networks allow faster, flexible and more cost-effective execution of RW studies through long-term partnerships with sites, registries and provider networks. Here we present the outputs from our first step in the setup of a federated network.

We conducted a series of data assessments with multiple sites across Europe to confirm RWD availability, accessibility and suitability for planned areas of real-world evidence (RWE) generation in endometrial, gastric, ovarian, and breast cancer and head and neck squamous cell carcinoma (HNSCC).

METHODS

- Hospital sites were selected from IQVIA's Oncology Evidence Network (OEN) based on expertise in the disease areas and RWE studies, and the strength of existing relationships.
- A feasibility questionnaire was shared with sites to ascertain in-depth information on patient counts, data availability, data quality and operational aspects of data access.
- The completeness and degree to which data was already available in a structured format were assessed by each hospital for the following variable types: clinical characteristics, treatments, clinical outcomes, biomarkers for each type of cancer.
- The exact approach taken varied by sites based on the available infrastructure and personnel – typically sites formulated search queries in their hospital data warehouses for structured data, and ad-hoc queries for unstructured data. Healthcare professionals (oncologists and/or pharmacists) qualified the results and compared them with current treatment practices at each site.

RESULTS

16 sites (~2/3 of sites contacted) had capacity to fill-in the feasibility questionnaire within the timelines across France, Germany, Israel, Italy, Portugal, Spain and the United Kingdom. >50% of sites provided answers consistently across all fields. Feasibility assessment was performed on data available from a total of 8,681 gastric, 7,283 ovarian, 13,895 endometrial, 71,905 breast and 4,412 head and neck cancer patients identified at these sites from 2018 (Figure 1).

Data on clinical characteristics (e.g., stage/TNM, ECOG, histology), treatment (e.g. drugs/regimens and start/end dates), and clinical outcomes (e.g. date and type of progression event) were captured consistently across sites. Differences in data completeness and format were observed across sites, with treatment-related variables having a higher degree of completeness and structured format (Figure 2).

Data on established biomarker testing results were also captured. For example, in breast cancer, PD-L1 testing was reported more widely among sites assessed in France while Ki-67 was less commonly reported at sites assessed in the UK (Figure 3).

Indication	Gastric/GEJ cancer	Ovarian cancer	Endometrial cancer	Breast cancer	Head & neck squamous cell carcinoma
Country (number of sites)	Patients diagnosed with oesophageal or gastro-esophageal cancer per year (number of sites)	Patients diagnosed with ovarian cancer per year (number of sites)	Patients diagnosed with endometrial cancer per year (number of sites)	Patients diagnosed with breast cancer per year (number of sites)	Patients diagnosed with locally advanced HNSCC per year (number of sites)
France (4)	789 (4)	350 (3)	476 (3)	3,183 (3)	91 (2)
Italy (4)	122 (2)	161 (3)	468 (3)	1,444 (2)	138 (2)
UK (4)	686 (4)	208 (3)	405 (3)	2,053 (4)	104 (3)
Germany (2)	41 (1)	43 (2)	36 (2)	N/A	N/A
Spain (1)	N/A	N/A	N/A	335 (1)	215 (1)
Israel (4)	325 (2)	616 (2)	976 (2)	9,555 (2)	78 (1)
Portugal (1)	586 (1)	66 (1)	184 (1)	1,155 (1)	N/A

Figure 1. Estimated patients counts can be produced by using searchable criteria. Patient populations can be identified to different levels of accuracy due to the difference in structure of data between sources, which also vary in terms of size. To produce this table, patient counts provided over a time period were extrapolated to a common unit (year). These counts are not intended for epidemiological purposes nor intend to be representative of a country-level. N/A: results not available at the time of the request. Head and Neck Squamous Cell Carcinoma (HNSCC): oropharynx, larynx, hypopharynx, or oral cavity.

Category	Variable of interest	Percentage of 10 assessed sites that captured each of the variable categories **with >70% of completeness**	Percentage of 10 assessed sites that captured each of the variable categories **in a structured format**
Clinical characteristics	*Date of diagnosis*	100	80
	Disease stage at diagnosis	90	30
	Disease stage at treatment initiation	70	20
	Tumor histology	*High degree of missingness across sites, with significant variability across disease areas.*	
	Presence of comorbidities	70	40
	ECOG and/or Karnofsky performance status at diagnosis	60	30
	ECOG and/or Karnofsky performance status changes during treatment	50	40
	TNM score at diagnosis	100	60
	TNM score at treatment initiation	60	20
	Metastatic disease (date of diagnosis)	80	0
	Metastatic disease (site of metastasis)	90	10
Treatment variables	*Drug name*	100	80
	Drug dose	100	70
	Start date and end date	100	70
	Details of surgery (date, procedure type)	100	80
	Details of radiotherapy (dates, radiation dose)	100	20
Clinical outcomes	*Date of death*	100	80
	Last follow up date	80	40
	Date and type of progression event (e.g., locoregional recurrence)	80	0
	Dates and results of real-world measures of response (e.g. radiographic assessments)	80	0

Figure 2. Indication-agnostic variables completion and format across sites

100% | 70-90% | 40-60% | <40%

Category	Variable of interest	FR			IT		UK				SP	IS		PT
		Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10	Site 11	Site 12	Site 13
Biomarker data – Breast Cancer	*ER, PgR and HER2 status and level/% of expression or other scoring system (e.g., Allred)*													
	BRCA1/2 mutation status													
	PD-L1													
	PI3KCA													
	Ki-67													
	Microsatellite Instability (MSI)													

Figure 3. Biomarker data availability in Breast Cancer across 13 sites with capacity to provide the information

Recorded as part of routine clinical care in >70% of cases
Recorded as part of routine clinical care in 40-70% of cases
Recorded as part of routine clinical care in <40% of cases / not collected
Information wasn't provided at the time of the request

CONCLUSIONS

Results of the assessment show that the RWD landscape is fragmented in terms of what data are available and can be accessed. Notably, differences in RWD capabilities and readiness for secondary data use can be observed across hospital sites.

Our analysis highlights the need for fit-for-purpose data assessments for RWE studies in oncology to inform study design and appropriate cohort/site selection based on evidence needs.

Continued efforts in improving data collection accuracy and structure, especially in biomarker testing results, are needed to achieve high quality secondary data use across multiple data sources and to provide more valid results.

Assessing the RWD landscape is a key first step towards generating accurate and scientifically valid RWE.

REFERENCES

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