Analyzing Real-World Data To Target Hard-To-Identify Patient Populations For Clinical Trials: A Case Study In Metastatic Breast Cancer

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INTRODUCTION

- Clinical research organizations (CROs) face challenges in patient recruitment arising from the increasing complexity of clinical trials. Delays caused by failing to achieve patient recruitment goals [**1-3**] and protocol amendments [**4**] contribute to CROs missing pre-launch expectations.
- These challenges are exacerbated in oncology and orphan diseases, where patient populations are historically difficult to identify and recruit for trials. Breast cancer (BrCa), in particular, poses additional hurdles to trial enrolment as investigators are increasingly targeting smaller niche patient segments.
- The objective of this study was to identify hospitals in the UK with late-stage BrCa patients in order to support patient recruitment.

METHODS

- IQVIA analyzed real-world data on drug prescriptions from the UK healthcare sector, captured in HPA (Hospital Pharmacy Audit), an IQVIA proprietary data source. HPA provides information on dispensing of drugs at UK hospitals.
- A drug basket to identify late-stage BrCa patients was first characterized and defined. The molecules used as tracer drugs for this analysis were eribulin, exemestane, fulvestrant, lapatinib, palbociclib, ribociclib, and trastuzumab emtansine.
- The dispensing volume of the drug basket by hospital medical oncology, radiotherapy, and all out-patient departments in the 12 months to February 2018, was obtained for each hospital in the HPA data. This was converted to the equivalent number of days of therapy based on the World Health Organization (WHO) Defined Daily Dose (DDD) **[5]**.
- The number of treated third-line BrCa patients was estimated for the UK. This was based on the prevalence of BrCa, IQVIA estimates of diagnosis and treatment rates, and IQVIA Oncology Dynamics (an IQVIA oncology-specific proprietary data source). Patient populations at each hospital were subsequently estimated based on the distribution of days of therapy at each hospital.
- Oncologists at consultant and specialist registrar level affiliated with the hospitals in the analysis were identified by cross-referencing hospitals against OneKey, a directory of healthcare professionals (HCPs) curated by IQVIA. Investigators known to IQVIA through participation in previous clinical trials were identified by cross-referencing against a second HCP directory, Clinical Trial Management System (CTMS).
- The BrCa patient population in the UK was further characterised by using biomarker testing data from Oncology Dynamics.

RESULTS

- 242 UK hospitals out of approximately 500 represented in HPA were identified as having a late-stage BrCa patient population (**Figure 1**) that had been treated with at least one of the drug basket molecules (eribulin, exemestane, fulvestrant, lapatinib, palbociclib, ribociclib, and trastuzumab emtansine) in the 12 months to February 2018.
- The top 10 hospitals in the UK that treated late-stage BrCa had 72 patients (estimated mean; **Figure 1**). These hospitals all treated third-line BC patients with palbociclib, ribociclib, and/or fulvestrant. This insight can help to identify preferential sites for complex trials of niche patient populations.
- Almost 2,050 oncologists were identified as specialists working at the UK hospitals identified in the analysis (**Figure 2**), of whom approximately 760 (37%) were investigators known to IQVIA.
- 41 hospitals had a high concentration of late-stage BrCa patients (together accounting for 50% of patients) with a mean estimated patient population of 40 (**Table 1**). These hospitals have a higher proportion of OneKey oncology specialists who are also in the CTMS HCP directory, compared to the medium and low concentration hospitals. This indicates that IQVIA's network of investigators are working in hospitals that have the highest patient concentration which could also expedite patient recruitment.
- The biomarker testing data demonstrated that HER2 and the hormone receptors (ER and PR) remain the most frequently tested biomarkers in BrCa treatment (**Figure 3**).

CONCLUSIONS

Identification of hospitals and physicians in the UK which treat late-stage breast cancer patients enables these sites and physicians to be contacted to engage them in clinical trial activity. This approach helps to expedite patient recruitment, engage with potential new investigators, and reduce the cost associated with clinical trial enrollment.

Figure 1: Late-stage BrCa patient population distribution by hospital, UK, 12 months to Feb 2018

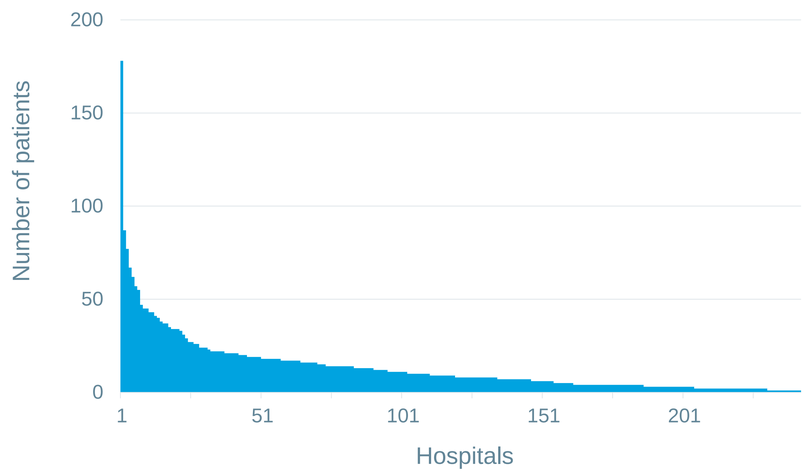


Figure 2: Map of late-stage BrCa patient population and oncologists per hospital, UK, 12 months to Feb 2018

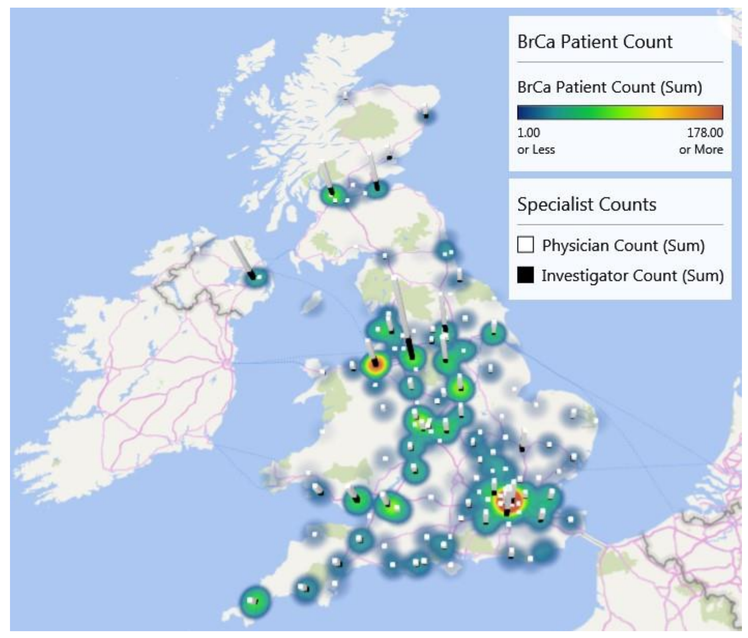
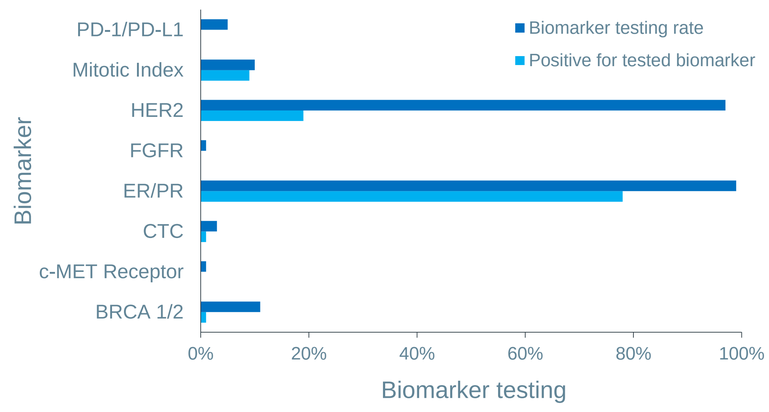


Table 1: Patient and physician counts by hospital category, UK, 12 months to Feb 2018

	Data Source	High concentration hospitals (50% of total patients)	Medium concentration hospitals (30% of total patients)	Low concentration hospitals (20% of total patients)
Number of hospitals	HPA	41	65	137
Mean number of patients per hospital	HPA	40	15	5
Mean number of specialists per hospital	OneKey	28	10	2
Mean number of investigators per hospital	CTMS	10	4	1

Figure 3: Biomarker testing in BrCa patients, UK, 12 months to Mar 2018



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