MARKET ENTRANTS, MANUFACTURERS WITH NEW OR DEVELOPMENTAL DRUGS NEED TO HELP

Given the level of development in the NSCLC field, and the number of likely new market entrants, manufacturers with new or developmental drugs need to help establish an infrastructure for collecting NSCLC RWE in Europe. We reviewed published health technology assessment (HTA) and reimbursement agency site guidelines to determine data sources for or on RWE in France, Germany, Italy, the Netherlands, Spain, Sweden and the UK. In addition, we performed a pragmatic review of peer-reviewed literature to identify literature on RWE being published in Europe and collected information from RWE expert access specialists on RWE requirements among country representatives of a global pharmaceutical company.

RESULTS: Publicly-available guidance on NSCLC RWE data collection by HTA and reimbursement authorities is currently lacking. Likewise, data sources are highly limited in number and scope and there were no publications featuring feasible registries. Market access specialists highlighted five categories of RWE data types. All countries expressed a requirement for patient characteristics, treatment patterns and effectiveness. Resource use and quality of life were considered supportive but not essential. No current registries are able to meet these requirements.

CONCLUSIONS: Formal guidance on RWE requirements in NSCLC in Europe is lacking and there is a need for registries to capture the range of data types highlighted by market access specialists to obtain and maintain market access. Given the level of development in the NSCLC field, and the number of likely new market entrants, manufacturers with new or developmental drugs need to help establish an infrastructure for collecting NSCLC RWE in Europe.

PCN37
NEW DRUGS IN NON-SMALL CELL LUNG CANCER: DISPARITIES IN REQUIREMENTS FOR POST-LAUNCH REAL-WORLD EVIDENCE IN EUROPE

Floyd D, Langham J

OBJECTIVES: To determine country-specific requirements for real-world evidence (RWE) in Europe to support ongoing market access for new drugs to treat non-small cell lung cancer (NSCLC). Several new classes of drugs for NSCLC are coming to market and it is expected that market access for these drugs will be much more important in different countries. The aim is to describe the data sources that are currently required for RWE in Europe while highlighting the areas in which registries are lacking and there is a need for registries to capture the range of data types proposed by the manufacturer.

METHODS: We conducted a systematic literature review of published health technology assessment (HTA) and reimbursement agency guidelines to determine data sources for or on RWE in France, Germany, Italy, the Netherlands, Spain, Sweden and the UK. In addition, we performed a pragmatic review of peer-reviewed literature to identify literature on RWE being published in Europe and collected information from RWE expert access specialists on RWE requirements among country representatives of a global pharmaceutical company.

RESULTS: Publicly-available guidance on NSCLC RWE data collection by HTA and reimbursement authorities is currently lacking. Likewise, data sources are highly limited in number and scope and there were no publications featuring feasible registries. Market access specialists highlighted five categories of RWE data types. All countries expressed a requirement for patient characteristics, treatment patterns and effectiveness. Resource use and quality of life were considered supportive but not essential. No current registries are able to meet these requirements.

CONCLUSIONS: Formal guidance on RWE requirements in NSCLC in Europe is lacking and there is a need for registries to capture the range of data types highlighted by market access specialists to obtain and maintain market access. Given the level of development in the NSCLC field, and the number of likely new market entrants, manufacturers with new or developmental drugs need to help establish an infrastructure for collecting NSCLC RWE in Europe.
by crizotinib. **CONCLUSIONS:** In this NMA of treatments for patients with previously untreated 97% of NSCLC cases were associated with significantly reduced risks of death or progression, by 40-85%, and with higher ORR, compared with other active treatments. Comparisons of non-randomized treatment groups are limited by the potential for confounding due to unadjusted cross-study differences.

**PCN42**

**SURVIVAL AND COST AMONG PHOTOODYNAMIC THERAPY PATIENTS WITH NON-SMALL-CELL LUNG CANCER**

Jayadevappa R, Chattere S
University of Pennsylvania, Philadelphia, PA, USA

**OBJECTIVES:** In USA, there are 221,200 estimated new cases of lung cancer and 158,040 deaths due to lung cancer in 2015. Lung cancer accounts for about 27% of all cancer deaths and is the leading cause of cancer death. Non-small cell lung cancer (NSCLC) constitutes about 85-90% of all lung cancer cases. Objective of this study was to assess the incremental value of survival and cost to the network patients treated with photodynamic therapy (PDT), compared to radiation and ablation therapy.

**METHODS:** Retrospective analysis using SEER-Medicare linked data.

Patients with NSCLC diagnosed between 2000 and 2007 (n=221199) were identified from the SEER-Medicare database. Patients with NSCLC were matched 1:1 on age, sex, year of diagnosis, and year of death, between patients treated with PDT, radiation, and ablation in the same calendar year (n=442398). Total cost was analyzed as a follow-up period was modeled as exponential distribution (hazard rate equal to 0.01). Survival analyses revealed significant differences among the three groups: patients treated with ablation alone, radiation alone, and combined therapy. Therefore, the results of this study are not adjusted for age, sex, or stage of disease. The association of treatment with survival and cost was assessed using a Cox proportional hazards model. The Cox model was adjusted for age, sex, stage of disease, and comorbidities. The hazard ratio (HR) and 95% confidence interval (CI) were calculated for each group compared to the control group. The main outcome measures were overall survival (OS) and cost of care. The analysis was performed using R statistical software.

**RESULTS:** The survival rate was higher for patients treated with radiation alone (HR=0.73, 95% CI 0.67-0.80) compared to patients treated with combined therapy (HR=0.80, 95% CI 0.74-0.86). The cost of care was also lower for patients treated with radiation alone (HR=0.94, 95% CI 0.92-0.97). Therefore, radiation alone was the most cost-effective treatment for patients with NSCLC.

**CONCLUSIONS:** Radiation alone is the most cost-effective treatment for patients with NSCLC. Further studies are needed to confirm these findings and to evaluate the impact of treatment on quality of life and other outcomes.