**Background:** Microsatellite instability (MSI) is a biomarker of active interest for targeted drug development for multiple cancers as patients with high MSI have been found to respond well to cancer therapy. Identifying MSI tested patients in electronic health records (EHR) is a difficult and complex process. In this era of precision medicine, it is important to understand and identify patients with biomarker data for epidemiologic and health outcomes research.

**Objectives:** To develop an optimal approach to identify MSI tested patients in the Veterans Affairs (VA) healthcare system.

**Methods:** A comprehensive list of 93 MSI-related 'search terms' and 47 CPT codes was generated by the study team that included oncologists, epidemiologists, bioinformatics and biomarker scientists. Structured and unstructured data (laboratory results, clinical and physician notes, etc.) in the VA healthcare database were searched using the CPT codes and search terms, respectively. From the identified records, a maximum of five randomly selected records for each search term or CPT code were manually reviewed to identify MSI tested cases. Frequently appearing MSI-related terms (e.g., MSI, microsatellite instability, etc.) found in the charts of MSI tested patients were used to further narrow down the search terms. A combination of CPT codes and search terms were explored for an optimal approach to identify MSI tested cases. Sensitivity (Sn), specificity(Sp), and positive predictive value (PPV) were calculated for all approaches.

**Results:** A total of 444 charts identified using 93 search terms were reviewed of which 129 (associated with 69 search terms) were found to be MSI tested cases. Another 198 charts identified using CPT codes were reviewed; 53 of which (associated with 26 CPT codes) were found to be MSI tested cases. In total, 642 unique patients were reviewed with 181 having MSI testing with at least one of the search terms or CPT codes. Search terms were narrowed down to 21 after reviewing all the frequently appearing MSI-related terms. Compared to 21 search terms ( Sn: 40%, Sp: 85%, PPV: 52%,) or 26 CPT codes (Sn: 62%, Sp: 75%, PPV: 49%) separately, a combination of 21 search terms and 20 CPT codes more efficiently (Sn: 45%, Sp: 98%, PPV: 89%) identified MSI tested patients.

**Conclusions:** Most of the cases (89%) identified by a combination of search terms and CPT codes were found to be truly MSI tested. This is an efficient approach to identify and study MSI tested patients for outcomes of clinical interest. Similar approaches could identify patients with other biomarker data in other EHR systems where patients are not readily identifiable.

## 4663 | Characteristics and study eligibility of British lung cancer patients for clinical trials evaluating targeted therapies (TTS) or immune checkpoint inhibitors (ICIS)

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**Background:** Inclusion and exclusion criteria used in clinical trials often lead to a homogeneous study-population. In this study we explored the characteristics of patients included in pivotal phase III clinical trials evaluating new drugs for patients with non-small cell lung cancer (NSCLC) with the characteristics of British patients diagnosed with lung cancer in daily practice.

**Objectives:** To study the characteristics and representativeness of British lung cancer patients compared to patients included in phase III clinical trials).

**Methods:** A retrospective study using the Clinical Practice Research Database (CPRD) GOLD was performed. All patients (N = 9239) with a first ever lung cancer registration (2014 - 2018) were included. Eligibility for inclusion was assessed for twelve clinical trials (evaluating osimertinib, alectinib, nivolumab, pembrolizumab, durvalumab, and atezolizumab) by applying all in- and exclusion criteria used in the clinical trials. Reasons for potential exclusion and the total number of unmet criteria were assessed for each study independently. Kaplan Meier analysis was used to compare overall survival between eligible and ineligible patients for each trial. In addition, Cox proportional hazards models were used to estimate hazard ratios and 95% confidence intervals (CI).

**Results:** The proportion of eligible patients based on for trials evaluating TTs was approximately 64.8%, while this was lower for studies evaluating ICIs (42.5%). Most patients would be eligible in the AURA3-study, for which 78.1% of the British patients population met inclusion criteria. While most patients would be excluded due to 1 or 2 criteria, the maximum number of unmet criteria was higher for studies evaluating ICIs. For all studies, the overall survival was longer for eligible patients compared to ineligible patients. Age and sex adjusted HRs ranged from 1.17 (95% CI = 1.14 - 1.20) to 1.24 (95% CI = 1.19 - 1.29).

**Conclusions:** A large proportion of British lung cancer patients would not have been eligible to be included in clinical trials evaluating drugs used in the treatment of NSCLC. A more lenient approach could be considered to increase the proportion of patients eligible for study participation and to better represent patients treated in daily practice.

## 4691 | Clinical value of oncology medicines in Europe: Is it different for conditionally approved medicines?

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**Background:** To allow early access to innovative medicines that address an unmet medical need, the European Medicines Agency