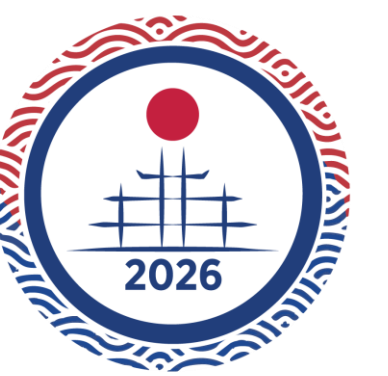




P3.048: Quality of Smoking Data Reporting in Clinical Trials Leading to FDA Approval of Lung Cancer Therapies

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INTRODUCTION

- Cigarette smoking significantly affects the outcomes of lung cancer from diagnosis to treatment.
- The dose, duration, and timing of tobacco exposure in relation to cancer diagnosis and treatment are critical determinants of histological aggressiveness, disease stage, and treatment-specific survival.
- Lung cancer trials should demand more than perfunctory smoking data collection and necessitate standardized, multidimensional reporting.
- We assessed the quality of smoking data reporting in pivotal clinical trials that led to FDA approval of lung cancer therapies.

METHODS

- We performed a cross-sectional review of all clinical trials supporting FDA drug approvals for lung cancer between 2015-2025
- Smoking data quality was assessed using a predefined 5-domain rubric developed based on 2016 NCI-AACR Cancer Patient Tobacco Use Assessment Task Force recommendation.
- Correlation between domains was variable, with generally low inter-domain correlations, supporting the conceptualization of the composite score as a multidimensional construct.
- Exploratory analyses were performed to assess associations between study characteristics and smoking data quality, using Fisher's exact and Kruskal-Wallis tests, followed by multivariable ordinal logistic regression (proportional odds model).
- To assess guideline impact, trials were dichotomized by a 2020 approval cutoff, allowing a 4-year lag for the 2016 NCI-AACR recommendations to influence trial design and completion.
- Generative artificial intelligence (ChatGPT, OpenAI) was used to assist with score structuring and R code development; all analyses and outputs were independently reviewed and validated by the authors.

DISCUSSION AND CONCLUSION

CONCLUSION

- While smoking status is nearly universally reported in registrational lung cancer trials, quantification of tobacco exposure (pack-years) remains a critical gap.
- smoking data quality has gradually improved over time, the 2016 AACR/NCI guidelines did not produce a measurable impact.

TAKE AWAY MESSAGE

- Standardized tobacco exposure reporting requirements should be mandated in registrational lung cancer trials to enable robust evaluation of smoking as a predictive and prognostic biomarker.

REFERENCES & ACKNOWLEDGEMENTS

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Artificial Intelligence (AI) Use Disclaimer

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RESULTS

A total of 75 trials were included. The median composite smoking data quality score was 5/9 (IQR: 4-7)

Trial phase ($p=0.02$), approval year ($p=0.02$), and sample size ($p=0.048$) were associated with higher quality. In multivariable ordinal regression, classification as a phase III trial was the only independent predictor of higher smoking data quality (OR 3.31, 95% CI 1.176-9.31, $p=0.023$).

There was a trend towards better quality with later approval years, non-US based trial headquarters and non-immunotherapy trials, but these trends were not statistically significant.

There was a significant association between pre/post 2020 trials approval and smoking reporting quality (Fisher's exact $p=0.031$). However, in ordinal logistic regression, the post-2020 era was not significantly associated with higher composite scores (OR 1.88, $p=0.18$), although a trend toward improved reporting was observed.

Smoking Data Quality Assessment Rubric

Predefined 5-domain rubric applied to pivotal trials supporting FDA lung cancer drug approvals, 2015-2025.

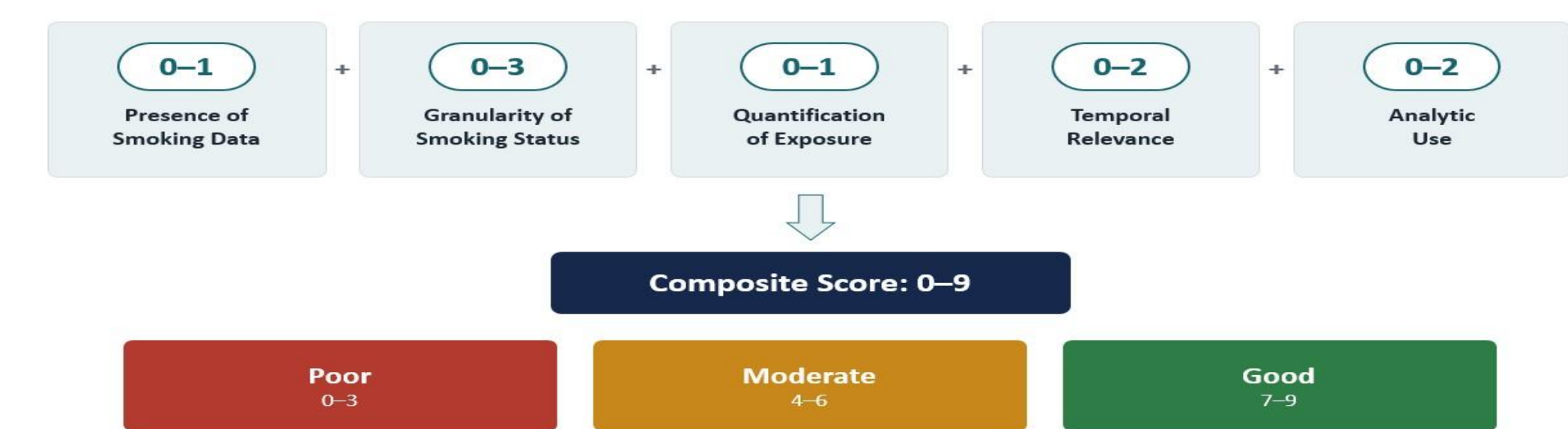


Figure 1: Smoking Data Quality Rubric

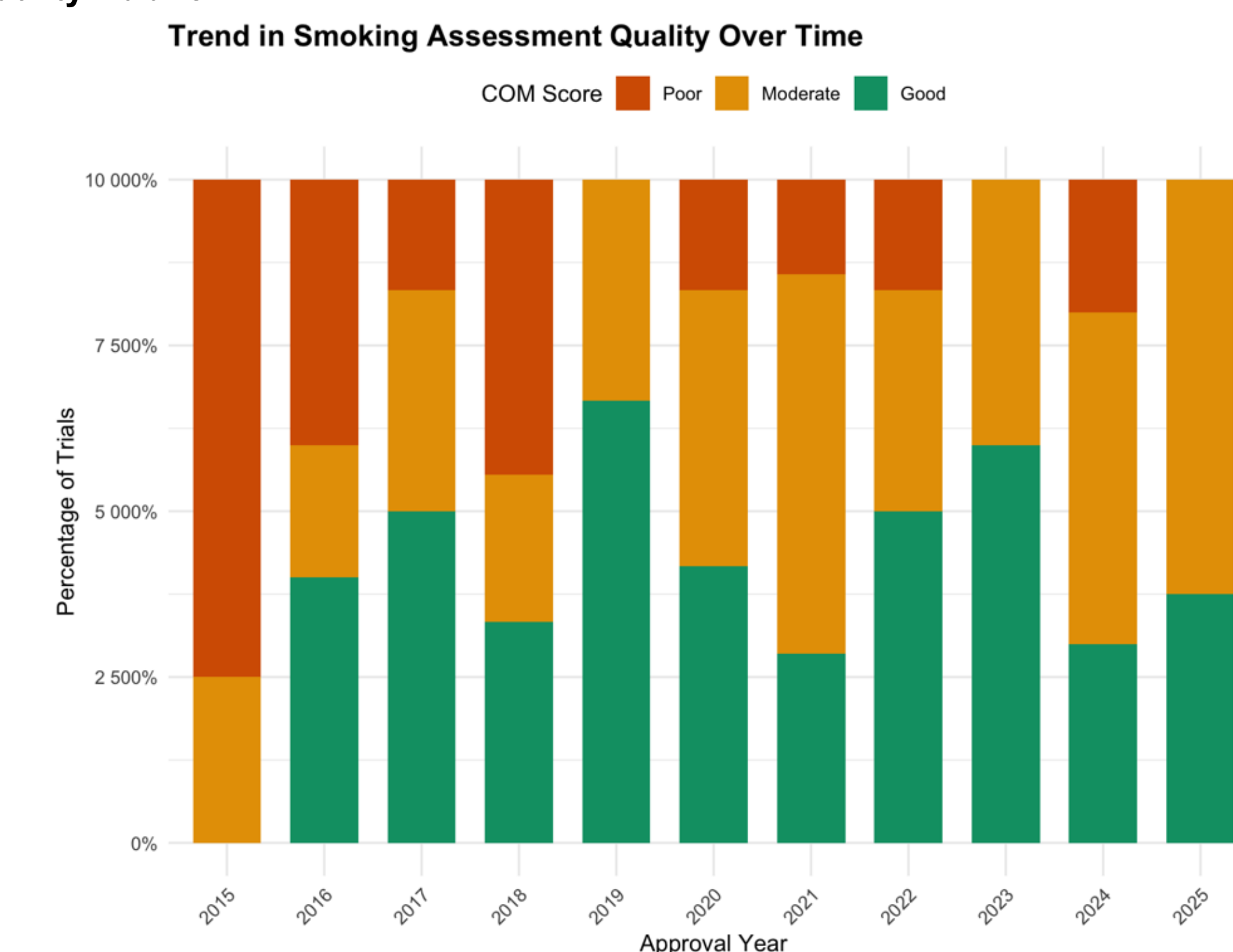


Figure 2: Trend in smoking assessment quality among approved trials by year, 2015-2025. Bars represent the percentage of trials in each approval year rated as Poor, Moderate, or Good based on completeness/quality of smoking status assessment (COM Score). Data reflect an increasing proportion of trials with Moderate-to-Good quality smoking assessments over the study period, with no trials rated Poor in 2025.