The study explores seven specific clinical practice gaps in the patient diagnostic and treatment journey and quantifies the patient attrition at each step using de-identified Medicare claims and laboratory data from over 38,000 patients diagnosed with advanced non-small cell lung cancer (aNSCLC) in 2019. The practice gaps assessed in the study include those related to testing access and availability, sample processing, test performance, test interpretation, and utilization of results.

**Topline Findings:** Despite a lengthy history of biomarker testing in the care of patients with advanced aNSCLC, a study found that 64.4% of newly diagnosed aNSCLC patients (644 of every 1,000 newly diagnosed aNSCLC patients) were not initiated on targeted therapy, 49.7% are lost to factors associated with biomarker testing.

**Among patients who were potentially eligible for targeted therapy:** 4.0% of the studied cases (21 out of 524 patients) began treatment without consideration of biomarker results.

**Among patients who received test results:** 6.6% of cases studied (66 out of 1,000 patients) received conclusive testing results.

**Biomarker Test Ordering:** Appropriate biomarker testing was ordered for 50.2% of patients diagnosed with aNSCLC (251 out of 503 patients who tested positive for an actionable biomarker). 5.3% of patients (27 out of 524 patients) lost the opportunity to benefit from personalized medicine due to missing the opportunity to benefit from personalized medicine.

**Biospecimen Tumor Cell Content:** Among patients who were potentially eligible for biomarker testing (6.6% of cases studied), 14.5% of the studied cases (136 out of 934 successfully biopsied patients) lost the opportunity to benefit from personalized medicine due to tumors being overestimated, inhibiting biomarker testing.

**Biospecimen Collection:** Biospecimen tumor cell content was underestimated, inhibiting biomarker testing. 1.7% of the studied cases (17 out of 996 tested biopsied patients) lost the opportunity to benefit from personalized medicine due to tumors being underestimated, inhibiting biomarker testing.

**Biospecimen Evaluation/Pathology:** Important clinical practice gaps exist in the assessment of tumors for biomarker testing and its accuracy overestimated, inhibiting biomarker testing. 18.3% of cases studied (118 out of 642 patients who received the necessary testing) lost the opportunity to benefit from personalized medicine due to incorrect or delayed biomarker testing.

**Biospecimen Testing:** Important clinical practice gaps exist in the assessment of tumors for biomarker testing and its accuracy overestimated, inhibiting biomarker testing. 7.0% of cases studied (147 out of 2,092 patients who tested positive for an actionable biomarker) lost the opportunity to benefit from personalized medicine due to incorrect or delayed biomarker testing.

**Conclusion:** The insights from this study can inform efforts to optimize biomarker testing in clinical practice and thereby help drive the delivery of personalized medicine to all cancer patients. The data was normalized to a patient population of 1,000 to easily demonstrate the number of eligible patients that may be lost to receiving targeted therapies due to each clinical practice gap.

**Potential areas for focus and strategies for reducing clinical practice gaps and improving personalized medicine implementation include:**

- Developing best practices to ensure tumor sampling, handling and testing is efficient and accurate
- Improving practice integration and cross-stakeholder communication including laboratories as a key function
- Ensuring clear and timely reporting of test results
- Improving clinician awareness of testing and interpretation of results
- Improving practice integration and cross-stakeholder communication for tests and treatments underpinning personalized medicine

**Step by Step Findings:**

1. **Biopsy Referral:** Initial solid or blood specimen requested by a clinician for testing before testing was ordered (18.1% of cases studied, 118 out of 642 patients who tested positive for an actionable biomarker)

2. **Biospecimen Collection:** Biospecimen collection is challenging including imaging the best site for tissue sampling, ensuring tumor cell content is obtained and tumor cell content is obtained is challenged by technical factors (356 patients lost the opportunity to benefit from personalized medicine due to missing the opportunity to benefit from personalized medicine)

3. **Biospecimen Tumor Cell Content:** Among patients who were potentially eligible for biomarker testing (6.6% of cases studied), 14.5% of the studied cases (136 out of 934 successfully biopsied patients) lost the opportunity to benefit from personalized medicine due to tumors being overestimated, inhibiting biomarker testing.

4. **Biomarker Test Ordering:** Appropriate biomarker testing was ordered for 50.2% of patients diagnosed with aNSCLC (251 out of 503 patients who tested positive for an actionable biomarker). 5.3% of patients (27 out of 524 patients) lost the opportunity to benefit from personalized medicine due to missing the opportunity to benefit from personalized medicine.

5. **Biospecimen Evaluation/Pathology:** Important clinical practice gaps exist in the assessment of tumors for biomarker testing and its accuracy overestimated, inhibiting biomarker testing. 18.3% of cases studied (118 out of 642 patients who received the necessary testing) lost the opportunity to benefit from personalized medicine due to incorrect or delayed biomarker testing.

6. **Biospecimen Testing:** Important clinical practice gaps exist in the assessment of tumors for biomarker testing and its accuracy overestimated, inhibiting biomarker testing. 7.0% of cases studied (147 out of 2,092 patients who tested positive for an actionable biomarker) lost the opportunity to benefit from personalized medicine due to incorrect or delayed biomarker testing.

7. **Treated Decision:** Targeted treatment was not selected despite actionable test results. 28.4% of all patients (292 out of 1,000 patients who tested positive for an actionable biomarker) lost the opportunity to benefit from personalized medicine due to missing the opportunity to benefit from personalized medicine.