

With the NIH projecting \$246 billion in total cancer costs by 2030, the United States (US) needs a more robust, integrated health information infrastructure. Eighty percent of medical data remain unstructured, and lung cancer (LC) biomarker risk prediction models currently lack validation in the US. This memo proposes a Biomarker Integration & Reporting Interface (BIRI) to help improve biomarker testing integration into the US lung cancer standard of care (SOC).

An approach to healthcare system integration is multi-faceted. Health information exchanges (HIE) facilitate interoperability across the country. For biomarker data, the infrastructure also facilitates findability, accessibility, and reusability. A pre-processed data and privacy standardization framework with access controls will enable efficiency and security. The proposed BIRI should be an add-on software tool available on HIEs in the US. BIRI is a clinical decision support system (CDSS) specific for precision oncology that offers analytics tools and biomarker test data to empower medical tumor boards (MTB) to make more informed decisions. LC biomarker data and other risk factors for LC can be leveraged to populate a narrative or summary that includes medical concepts. Additionally, the software should offer clinician-facing reminders to order biomarker testing. HIEs, BIRI, and MTB integration with multidisciplinary treatment teams can support scaling biomarker testing integration into SOC.

Updating LC treatment policy guidelines to address biomarker testing integration barriers for LC patients is recommended. The National Comprehensive Cancer Network treatment guidelines for Non-Small Cell Lung Cancer should be updated to recommend precision medicine for patients with LC. There is a lack of clarity on the care flow for biomarker testing, with recommendations only made before and after surgery. Consequently, it is difficult to advocate for adopting early biomarker testing for LC patients. Once the policy and treatment guidelines are updated and standardized nationwide, the update will positively affect adoption and present a case to payers, mandating increased coverage and access to personalized and targeted testing with biomarkers for patients with LC.

Stakeholder collaboration is critical to BIRI's acceptance. This will include clinicians, patients, payers, and pharmaceutical companies. Clinician education campaigns on the positive clinical outcomes associated with biomarker testing using case studies are recommended. A cost-benefit analysis report showing potential savings of up to \$23 billion for payers who cover early-stage biomarker testing can motivate insurance coverage and reduce projected \$30 billion total LC costs. Publishing evidence of better prognoses and 5-year survival rates from targeted therapy associated with biomarker testing will increase patient-driven demand. Pharmaceutical companies can sponsor studies and publish value-based findings on the efficacy of biomarker-based treatment. The coalition of these stakeholders will increase utilization and help establish biomarker testing as a standard in managing LC patients.

A key performance indicator (KPI) to measure success is the percentage of LC patients eligible for biomarker testing who receive it as part of their diagnostic workup. This KPI measures how effective stakeholder efforts are in improving adoption rates. The KPI can be computed over time and compared with the preceding initiatives.