Real-world response endpoints in patients with mNSCLC treated with chemotherapy across real-world datasets

Bratinyon Mckelvey1, Elizabeth Garrett-Mayer2, Andrew J. Belis3, Thomas D. Brown4, Jessica Dow5, Janet L. Espiritu6, Paul Kluzet7, Xinran Ma8, Andrea McCracken9, Pallavi Shrutisha Kalyani10, Yania Natanzon4, Danielle Potter6, Donna Rivera2, Hillary Stires4, Mark Stewart7, Jeff Allen1

1Friends of Cancer Research, 2American Society of Clinical Oncology, 3COTA Inc, 4Syapse, 5Tempus Labs, Inc, 6Ontario, 7Oncology, Center of Excellence, U.S. Food and Drug Administration, 8Pharmanet-Health, 9Guardian Research Networks, 10US Food and Drug Administration, 11ConcertRx, 12IQVIA

Background
• Response is an important outcome for measuring therapeutic benefit in oncology clinical trials. However, measurement of response in clinical trials differs from the real-world setting.
• Response Evaluation Criteria in Solid Tumors (RECIST)-based measures of response rely on imaging data at specific timepoints for uniform assessment.
• There is no consensus approach to measure real-world response (rW response) from routine clinical practice data.
• Friends of Cancer Research formed a multi-stakeholder partnership to evaluate access to available data elements for measuring rW-response across real-world data (RWD) sources to inform development of a consistent method for response assessment.

Methods
• A multi-stakeholder partnership of RWD EHR-focused partners, pharmaceutical companies, government officials, and academics developed the common protocol and statistical analysis plan to achieve the following objectives:
  - Evaluate the Consistency of a Measure of rW-Response Across Data Sources in an Aligned Population
  - Assess the Availability and Freqency of Core Data Components for Measuring rW-Response
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CONSORT Diagram

Results: Availability of Response Data Components

Conclusions
This unique partnership allowed us to assess the availability of data necessary to assess rW-response and evaluate the consistency of the measure across RWD sources.

Imaging reports and clinical assessments of response were available for most patients across cohorts, unlike images, with greatest consistency in the timing of assessments for the clinician assessment. The rW among patients with mNSCLC calculated using the clinician assessment was relatively consistent across all RWD sources, with consistent trends in time-to-event endpoints. The demonstrated feasibility of response endpoints based on clinician assessment suggests rW-response is clinically relevant and further exploration may inform drug effectiveness evaluation w/ RWD sources.

Aligning methodologies for aggregating and analyzing RWD will help ensure RWD is a reliable and consistent source of real-world evidence to support oncology drug development and regulatory decision-making.