Confronting the challenge of advancing new therapies using lung imaging outcome measures:

The urgent need for regulatory acceptance of innovative validated Drug Development Tools across Chronic Lung Diseases

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A collaborative public-private partnership, aiming to undertake regulatory qualification of biomarkers and clinical outcomes assessments (COAs) to facilitate the development and approval of novel treatments for CLDs

- **FDA Patient Listening Session October 8th, 2021**
  - Shared 8 patient stories focusing on unmet medical needs
  - Proposed “Concept of Interest” framework for Chronic Lung Disease
  - Discussed opportunities to efficiently advance important biomarkers and COAs

Followed by an advocacy event with legislators on October 12th
Biomarker name: Volume-adjusted lung density at the 15\textsuperscript{th} percentile of the CT histogram VALD\textsubscript{Perc 15}.

Biomarker Type: Radiologic

Context of Use Statement

We proposed the use of quantitative CT scanning, as measured by VALD\textsubscript{Perc15}, as a monitoring biomarker of emphysema severity for use in clinical trials.

Specifically, the difference from comparator in VALD\textsubscript{Perc15} on serial assessment will be used as an outcome to objectively measure disease progression in clinical trials aiming to assess the effect of active treatment in comparison to placebo (or Standard of Care) at a population level.

COA Development Across Chronic Lung Diseases

CBQC Recommendation
COA development grounded in a unified conceptual framework that identifies meaningful aspects of health impacted across chronic lung diseases