COPD Biomarkers Qualification Consortium (CBQC)

Frequently Asked Questions (FAQs)

"Why are the biomarkers needed?"

COPD is the fourth leading cause of death in the United States. However, no new classes of drugs have been approved for use in the United States in more than twenty years, in part because of the tests that are used to measure treatment benefits. Qualified biomarkers will hopefully provide measures to facilitate the development of new treatments.

"Should patients be tested with the biomarkers for diagnosis or to guide treatment?"

No. The biomarkers are being evaluated to aid in the development of treatments. These markers may help guide the development process of drug by identifying select patients, or helping to quickly predict long term outcomes. An example of a biomarker is lung function, which can be assessed through a simple test known as spirometry.

"Why is a consortium needed?"

Many pharmaceutical companies, the National Heart Lung and Blood Institute and academic researchers have data from previous clinical studies evaluating various biomarkers. By pooling the existing data, sufficient information may be available to qualify biomarkers so that that Food and Drug Administration (FDA) and European Medicines Agency (EMA) can use them to evaluate new treatments. Without pooling existing data, this advance would not be possible.

"Is the Consortium discovering new biomarkers?"

No. The Consortium is pooling data elated to biomarkers from many clinical trials conducted by pharmaceutical companies, academia, and the NHLBI to create a sufficiently large data set to allow for evidence that supports qualification by the FDA and EMA.

"What is qualification and why is the Consortium pursuing it?"

Qualification is a new process by which the FDA and EMA can evaluate a biomarker and determine if it can be used in clinical trials that support regulatory submissions for the approval of new drugs. Qualified biomarkers may greatly accelerate the process of bringing new therapies to patients, as they may detect improvements in COPD sooner than traditional methods, and hence allow an evaluation of a new therapy in less time that would be possible using traditional methods.

"What biomarkers are the Consortium considering?"

The Consortium is evaluating a range of biomarkers including those that measure an individual's quality of life, those that measure exercise capacity, specific measures of lung function such as hyperinflation, and blood tests that report inflammation in COPD.

"What companies are involved?"

The Consortium is established with a legal agreement GlaxoSmithKline, Boehringer Ingelheim, AstraZeneca and Pfizer have signed. There are other interested parties as well.

"What data will be shared?"

"Member companies have agreed to share anonymized patient data from clinical studies and trials, enabling a large enough data set to conclusively establish the value of a biomarker."

"Will the data be made public?"

"The idea is to create a large data set to support biomarker qualification. The results of the biomarker qualification will be made public. The database will not be made public as the protection of patient data must be ensured, but will be made available to regulatory authorities."

"Will the biomarkers be made public?"

"Most of the biomarkers being considered are already in the public domain. While it is not the intent of the Consortium to discover biomarkers, if new biomarkers are found or related intellectual property created, they will be released into the public domain."

"How can academic scientists participate?"

"Academic and industrial scientists can participate in the various biomarker working groups with the assumption that they will actively contribute and agree to confidentiality."

"How can a company join?"

"To join as a Steering Committee member, a company must sign the Consortium Agreement, pay membership fees, share data and substantially support at least one working group."

"What do industry members contribute to the Consortium?"

"In addition to providing Clinical trial data and funding through membership fees, industry scientists will contribute regulatory clinical and statistical resources and know how to support submission of qualification packages".

"How will industry benefit from the Consortium?"

"By developing tools for patient stratification and assessment of efficacy the ultimate ambition of the consortium is that better therapies are faster developed for COPD. In addition to the obvious benefits ensuing to patients and healthcare systems this important initiative will open up more innovative and diverse avenues of research."