



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 April 2017
EMA/264099/2018
Committee for Medicinal Products for Human Use (CHMP)

Submission of comments on 'Draft qualification opinion on plasma fibrinogen as a prognostic biomarker (drug development tool) for all-cause mortality and COPD exacerbations in COPD subjects' (EMA/474186/2016)

Comments from:

Name of organisation or individual

AstraZeneca

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).



1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
	<p>AstraZeneca supports the use of plasma fibrinogen as a stratification biomarker in clinical studies for patients with COPD. Fibrinogen is useful as a tool for patient stratification/selection in severe COPD event studies. High levels of plasma fibrinogen may potentially be predictive of mortality risk but also of severe exacerbations. Fibrinogen levels may also substantially differentiate COPD sub-populations, and increase severe exacerbation event rates in COPD studies. This could potentially result in smaller sample sizes and reduced costs for clinical studies.</p> <p>There is room for further evidence generation, exploring the biochemical/metabolic link between lung disease – systemic fibrinogen – all cause/specific cause mortality, as it would increase future value and usability of fibrinogen as biomarker in drug development. Additionally, as a continuous variable, plasma fibrinogen may bring difficulties into the interpretation of data and to the summary of product characteristics. Thresholds and standardized methodology for plasma fibrinogen need to be identified.</p>	<p>The European Medicines Agency is thankful for the comments provided by AstraZeneca supporting the use of plasma fibrinogen as a stratification/enrichment tool in COPD studies, and highlighting the importance to generate further data.</p>