

Please find below comments from the ERG on the ACD for the Single Technology Appraisal (STA):
Ivabradine for the treatment of chronic heart failure (ID484)

1. In point 3.24 it is stated that "*the risk equations were adjusted for baseline heart rate to predict estimates for the population covered by the marketing authorisation with a heart rate of 75 bpm or more*" this is not strictly true as the regression equations for NYHA classification were not adjusted for heart rate.
2. Point 3.38 states that "*The treatment effect of ivabradine was not statistically significant for cardiovascular mortality and was borderline statistically significant for heart failure, unlike in the clinical trial in which they were significant.*" As pointed out by the manufacturer in the factual accuracy check, this is not strictly true as the regression equations used in the economic model are based on an analysis of the whole trial population, in which the treatment effect of ivabradine on CV mortality was not statistically significant. To clarify, it is probably best to reword this sentence to make it clear that "the treatment effect of ivabradine was not statistically significant for cardiovascular mortality...., unlike the clinical analysis of the licensed population in which they were significant."